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Executive Summary

The policy of the United States Government is to seek regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers.[1,2,3] These principles also apply to the update of the regulatory framework and systems that regulate the products of biotechnology put forward in this National Strategy for Modernizing the Regulatory Framework for such products. Federal agencies that regulate biotechnology products should strive continually to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements. It is critical that these improvements:

- maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
- establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and
- promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

While the current regulatory system for the products of biotechnology effectively protects health and the environment, in some cases, uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have imposed unnecessary costs and burdens on small and mid-sized companies and academics. In response, in July 2015, the Executive Office of the President (EOP) issued a memorandum[4] (July 2015 EOP memorandum) directing the primary agencies that regulate the products of biotechnology—the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—to accomplish three tasks:

- update the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) by clarifying current roles and responsibilities;
- develop a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, of the future products of biotechnology; and
- commission an expert analysis of the future landscape of biotechnology products to support this effort.

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[1] "Improving Regulation and Regulatory Review", Executive Order 13563, January 18, 2011.
[2] "Identifying and Reducing Regulatory Barriers", Executive Order 13610, May 10, 2012.
[3] "Principles for Regulation and Oversight of Emerging Technologies", Memorandum for the Heads of Departments and Agencies, March 11, 2011.
[4] Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture, "Modernizing the Regulatory System for Biotechnology Products", Executive Office of the President, July 2, 2015. The memorandum can be found at https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

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In directing the agencies to accomplish these three tasks, the Administration's goal is to ensure public confidence in the regulatory system and improve the transparency, predictability, coordination, and, ultimately, efficiency of the biotechnology regulatory system. This *National Strategy for Modernizing the Regulatory System for Biotechnology Products* was developed in order to satisfy the second of the three tasks identified in the July 2015 EOP memorandum and the accompanying proposed Update to the Coordinated Framework was developed to satisfy the first of the three tasks. EPA, FDA, and USDA have commissioned an independent study by the National Academy of Sciences (NAS) to satisfy the third of the three tasks.

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Background

The discovery of the three-dimensional structure of DNA in 1953 by Rosalind Franklin, James Watson, and Francis Crick laid the groundwork for an era of innovation in the life sciences. Twenty years later, Stanley Cohen and colleagues described recombinant-DNA techniques that could be used to cut gene sequences from the DNA of one organism and splice them into the DNA of another organism.[5]

In response to concerns as to whether the "regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for products obtained with the new techniques,"[6] such as recombinant DNA, the Coordinated Framework for the Regulation of Biotechnology was published in 1986. It outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products and described oversight responsibilities under existing statutes and among the relevant Federal agencies. While the Coordinated Framework addressed which agency(ies) have oversight authority for biotechnology products, it "did not address how that authority should be exercised in the frequent situations in which a statute leaves the implementing agency latitude for discretion."[7] Thus, in 1992, the Coordinated Framework was updated to describe the "proper basis for agencies' exercise of oversight authority within the scope of discretion afforded by statute."[7]

In part, the oversight system established by the Coordinated Framework led to decades of development and commercialization of biotechnology products with applications in medicine, agriculture, energy, biomanufacturing, and environmental protection, and to the growth of a large and competitive biotechnology sector in the United States and worldwide.

Advances in science and technology have, however, dramatically altered the biotechnology landscape since the issuance of the 1986 Coordinated Framework and associated 1992 update, enabling the development of products that were not envisioned when the 1986 and 1992 documents were published. Consequently, a further update of the Coordinated Framework was needed to facilitate the appropriate Federal oversight by the regulatory system and increase transparency, while continuing to provide a framework for advancing innovation.

In July 2015, the Administration released a memorandum[4] (July 2015 EOP memorandum) noting that while "the current regulatory system for the products of biotechnology effectively protects health and the environment, in some cases, unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have arisen. These costs and burdens have limited the ability of small and mid-sized

[5] Cohen, S.N., A.C.Y. Chang, H, Boyer, and R.B Helling. 1973. Construction of biologically functional bacterial plasmids in vitro. Proceedings of the National Academy of Sciences of the United States of America 70:3240–3244.
[6] https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf
[7] https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf

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companies to navigate the regulatory process and of the public to understand easily how the safety of these products is assured."

That memorandum reiterated that the Federal regulatory system must protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers. It also initiated a process to modernize the Federal regulatory system for biotechnology products[8] and to establish mechanisms for periodic updates of that system.[4]

The objectives of the tasks described in the July 2015 EOP memorandum are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, predictability, and efficiency of the regulation of biotechnology products and the coordination among regulatory agencies, while continuing to protect health and the environment.

This *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (*Strategy*) sets forth a vision for ensuring that the Federal regulatory system is prepared to efficiently assess the risks, if any, of the future products of biotechnology. The *Strategy* and the accompanying proposed Update to the Coordinated Framework, which *inter alia* clarifies agency jurisdiction for biotechnology products, were developed by the Biotechnology WG. The Biotechnology WG was established by the July 2015 EOP memorandum under the Emerging Technologies Interagency Policy Coordination (ETIPC) Committee.

To inform the development of these documents and other activities described in the July 2015 EOP memorandum, the National Science and Technology Council (NSTC) published a notice of request for information (RFI) in the *Federal Register* to seek relevant data and information from stakeholders. In addition, the White House Office of Science and Technology Policy (OSTP), EPA, FDA, and USDA jointly held three public meetings, under the auspices of the NSTC, in different regions of the country to inform the public about their activities and seek public comments.[9,10,11] Transcripts of the public meetings, including oral comments received at the meetings, were placed in the public docket.[12] The third public meeting also included breakout listening sessions, and a summary of individual input received during those sessions is available in the public docket.[12] The Biotechnology WG reviewed all written comments submitted in response to the RFI, oral comments made at the three public meetings, and input from the breakout listening sessions, in preparing this *Strategy*. A general summary of the issues raised in

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[8] "Biotechnology products" refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations. Products such as human drugs and medical devices are not the focus of the activities described in the memorandum (July 2015 EOP memorandum).

[9] http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm463783.htm

[10] https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/modernizing-regulatory-system-biotechnology-products

[11] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/stakeholder-meetings/cf_meeting/

[12] http://www.regulations.gov/docket?D=FDA-2015-N-3403

public responses and a review of these responses is provided in Appendix 1 of the proposed Update to the Coordinated Framework. EPA, FDA, and USDA will continue to consider relevant public responses as part of future work related to the implementation of this *Strategy*.

In addition, as these agencies continue their work in pursuit of the objectives in the July 2015 EOP memorandum, consideration will be given to additional actions to clarify further their regulatory processes and procedures, as appropriate. In this regard, agencies will consider the results of the forthcoming National Academy of Sciences report on the *Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System*.

Goals and Objectives

The goal of this *Strategy* is to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens. EPA, FDA, and USDA intend to fulfill this goal, including by addressing the following priorities identified in the July 2015 EOP memorandum.

Increasing Transparency

- Establish a timetable and mechanisms to work with stakeholders to identify impediments to innovation, focusing on building new, and augmenting existing, stakeholder collaborations to inform efforts, increase transparency, streamline processes, reduce costs and response times, and ensure the protection of health and the environment
- Coordinate the development of tools and mechanisms for assisting small businesses developing biotechnology products to navigate the regulatory system
- Develop a modernized, user-friendly set of tools for presenting to the public the regulatory agencies' authorities, practices, and bases for decision making for the regulation of biotechnology products, including digital services, to improve the interactions among FDA, EPA, USDA, the general public, and product developers, as well as updating these tools and practices regularly to ensure optimal transparency
- Engage with the public to discuss how the Federal Government uses a risk-based, scientifically sound approach to regulating the products of biotechnology, and clearly communicating to the public which types of products are regulated, which types of products are not regulated, and why

Increasing Predictability and Efficiency

- Develop a plan for periodic, formal horizon-scanning assessments of new biotechnology products to ensure that regulatory agencies are prepared for future products well before they reach the regulatory system

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- Ensure product evaluations are risk-based and grounded in the best science available, including regularly adjusting regulatory activities based on experience with specific products and the environments into which those products have been introduced
- Identify changes to authorities, regulations, and policies that could improve agencies' abilities to assess expeditiously the potential impacts and risks arising from future products of biotechnology and to ensure the transparency, predictability, and efficiency of regulatory oversight for such products

Supporting the Science that Underpins the Regulatory System

- Develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities with regard to the assessment of biotechnology products, and to reflect these priorities in agency budget submissions

Increasing Transparency

EPA, FDA, and USDA have developed processes to communicate with the public and stakeholders, including consumers and small businesses. For example, all three of these agencies have mechanisms for soliciting and utilizing public input related to regulatory decisions. Examples include advisory committees of experts in key disciplines relevant to specific products or product areas;[13] opportunities for public input on regulations and guidance documents, through petitions on certain environmental assessments and impact statements, and through public meetings; webinars and workshops on the regulatory framework for interested stakeholders, including industry and consumers; and information on regulatory activities and updates for consumers posted on agency websites. The agencies' websites provide information to the public on agencies' activities, including guidance for developers of products subject to regulatory oversight, and consumer and public-oriented brochures and factsheets, many of which are available several different languages.

The proposed Update to the Coordinated Framework that accompanies this *Strategy* contains a table that summarizes the current responsibilities and the relevant coordination across EPA, FDA, and USDA for the regulatory oversight of biotechnology products, based on the scope of each agency's current authorities. Product developers who are uncertain regarding the relevant regulatory requirements, particularly small businesses, are encouraged to contact the agencies early in the product development process to obtain information from the agencies on potential safety and regulatory requirements that may be associated with their intended products.

[13] For example, EPA regularly holds meetings of its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) to solicit technical advice from recognized experts in their respective scientific disciplines on specific topics relevant to EPA's regulation of pesticides. These meetings generally are open to the public, and pertinent materials are made available to the public through EPA's website for the SAP (https://www.epa.gov/sap). The public also is given an opportunity to comment on the questions being posed to the SAP at each meeting.

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Discussions with regulatory officials can provide information on the regulatory process most relevant to their product and how best to navigate the regulatory system.

Examples of existing mechanisms and activities are listed below

- **EPA, FDA, USDA, and OSTP hosted three public meetings to clarify current roles and responsibilities in different regions of the country at which, in total, over 800 people participated in person or by webcast.** The first meeting was held on October 30, 2015, at the FDA's White Oak Campus in Silver Spring, Maryland to inform the public about the activities described in the July 2015 EOP memorandum, invite oral comments from interested parties, and provide information about where and how to submit written comments, data, or other information. The second public meeting was held on March 9, 2016 at EPA's Region 6 Office in Dallas, Texas. The primary purpose of this meeting was to illustrate current Federal roles and responsibilities regarding biotechnology products by reviewing case studies of hypothetical products. The third public meeting was held on March 30, 2016, at the University of California's Davis Conference Center in Davis, California. At this public meeting, representatives from the EPA, FDA, and USDA illustrated the current roles and responsibilities of the EPA, FDA, and USDA regarding biotechnology products by discussing case studies of hypothetical products. In addition, breakout listening sessions were conducted that focused on three general thematic areas relevant to the tasks assigned to the EPA, FDA, and USDA in the July 2015 EOP memorandum – Governance; Education, Communication, and Outreach; and Improving Regulatory Certainty. Additional materials for all of these meetings, including agendas and presentations, are available on the meeting websites and in the corresponding docket on regulations.gov.
- **EPA, FDA, and USDA periodically host workshops to help small businesses developing biotechnology products navigate the regulatory system.** For example, in 2011 EPA, FDA, and USDA hosted a workshop during which case studies were presented by product developers and each of the three regulatory agencies described how they would engage with the developer as the product went through each of the three regulatory systems. USDA provides enhanced education, coordination, and outreach through its Specialty Regulatory Crop Assistance program and provides a detailed User's Guide to assist companies in preparing petitions for nonregulated status. FDA holds workshops on topics of emerging relevance to FDA to engage all stakeholders and obtain expert input into future directions and policy development. EPA, FDA, and USDA will continue to organize such workshops and to announce these through their respective stakeholder announcements, web portals, and *Federal Register* notices as appropriate.
- **EPA, FDA, and USDA provide information to developers and to the general public via their websites and through email systems**. These websites and email systems allow developers to pose specific questions related to those agencies' programs, including USDA's BiotechQuery, EPA's BPPDQuestions, and FDA's links for industry and consumer inquiries.

FDA also issues Constituent Updates to inform stakeholders of regulatory activities, such as public meetings or the availability of regulatory documents for public comment; as well as Consumer Updates and other information for consumers on a variety of topics. EPA provides guidance on its website regarding reduced Pesticide Registration Improvement Act (PRIA) fees for small businesses, and fee waivers for IR-4 submissions and Federal and state governments. EPA also keeps the public informed about biotechnology issues via its webpages and updates distributed to interested parties via email and the Federal Register. For example, EPA involves the public in regulatory decisions for significant new biotechnology pesticide products and for biotechnology microorganism products.

- **EPA, FDA, and USDA will continue to provide leadership in international fora to promote scientific competency, understanding of the U.S. regulatory approach, and regulatory compatibility worldwide for biotechnology products.** The U.S. agencies actively work to strengthen engagement between countries through coordinated and collaborative international initiatives. Through these efforts the United States shares technical and scientific expertise and supports the adoption of transparent, risk-based regulatory approaches grounded in the best science available, including with respect to the application of the most recent technical and scientific advances to the biotechnology products. These initiatives support attainment of shared global health and environmental protection goals while supporting greater regulatory predictability and reducing impediments to U.S. innovation and products worldwide. For example, experts from two U.S. regulatory agencies currently chair, and all three agencies actively contribute to, working groups in the Organization for Economic Cooperation and Development (OECD) on scientific and technical issues underpinning regulatory approaches for the products of agricultural and industrial biotechnology.
- **EPA Office of Pollution Prevention and Toxics (OPPT) is currently updating the *Points to Consider in the Preparation of Toxic Substances Control Act (TSCA) Biotechnology Submissions for Microorganisms (Points to Consider)* document.** This document identifies a broad range of risk assessment topics relevant to TSCA biotechnology submissions and provides technical support to assist those who must prepare microorganism pre-manufacturing notifications to EPA under TSCA. The *Points to Consider* do not currently provide specific support for product developers using the emerging technologies of algae production and advanced biotechnology. To keep its risk assessment process for biotechnology algae open and transparent, EPA intends to develop a separate document on the scientific and technological issues it currently understands to be key and unique for evaluating risks, if any, from the production and use of biotechnology algae. EPA will develop its *Algae Guidance for the Preparation of TSCA Biotechnology Submissions* document in parallel with updating the *Points to Consider* document. EPA held a public meeting on this effort on September 30, 2015. There will be a follow up meeting on October 27, 2016. See here for more information.

- **FDA has instituted a number of activities aimed at providing assistance to regulated small businesses.** These include small business assistance programs, which provide technical assistance to small companies; meetings to hear the views and perspectives of small businesses; educational workshops; informational materials; and an accessible, efficient channel through which small businesses can acquire information from the FDA. FDA publishes the Small Business Guide to FDA to help make small businesses' contacts with FDA as efficient and productive as possible. This guide is presented as a blueprint that small firms can follow to achieve their business aims consistent with FDA's mission on public health. FDA created openFDA in June 2014, to make FDA's public information more accessible and useful to developers. FDA has made a continuous effort to better understand the needs of the developer community and build on existing resources.
- **USDA organizes workshops with specialty crops groups to discuss the regulatory system and how best to navigate it.** FDA and EPA participate with USDA in these workshops, such as those hosted periodically by Specialty Regulatory Crop Assistance program and at periodic USDA annual Stakeholder Meetings, so that attendees understand how to navigate the regulatory system at all three agencies. In September, 2016, the agencies are hosting a workshop to provide regulatory assistance for public sector scientists and public and private sector crop developers on putting together a regulatory dossier for genetically engineered specialty crops.

Future activities

- **EPA, FDA, and USDA are exploring new opportunities to conduct sessions with industry, consumers, and other stakeholders, including at scientific conferences and at agency-hosted workshops, much like the annual USDA Biotechnology Regulatory Service stakeholder meeting.**
- **EPA, FDA, and USDA will review existing communication tools and, as appropriate, may revise existing or develop new user-friendly sources of regulatory information for product developers and the general public.** For example, FDA has information for consumers on its website about food from genetically engineered plants and about FDA's consultation process for developers of such foods. See "Consumer Info About Food from Genetically Engineered Plants," "How FDA Regulates Food from Genetically Engineered Plants," and "Questions & Answers on Food From Genetically Engineered Plants". FDA also regularly updates its Genetically Engineered Animals web page, including a current listing of all animals with related FDA-approved applications. In addition, FDA has developed a Strategic Plan for Risk Communication, which describes FDA's strategy for improving how the agency communicates with patients and consumers about regulated products. USDA maintains a variety of information on its website about how it protects plant health including a video overview of its biotechnology regulatory program. EPA and USDA

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also regularly update their web page listings for registered and deregulated biotech products, respectively.

In addition, the agencies are reviewing the feedback received during the three public meetings and the fall 2015 Request for Information to better understand the specific areas of interest to the public regarding the regulation of biotechnology products and preferred mechanisms for conveying regulatory information. For example, the agencies are examining the feasibility of providing a single source for regulatory information so that developers can easily determine the appropriate regulatory pathway for their product. In addition, the agencies are examining the feasibility of expanding various types of training programs where product developers, particularly small companies, and the public would have opportunity to learn about the roles of the three regulatory agencies.

- **EPA Office of Pesticide Programs (OPP) will hold a "Plant-Incorporated Protectant (PIP) Data Requirements Symposium" on September 29, 2016 to describe for stakeholders and the public its thoughts on the types of data appropriate for evaluating a PIP product in the registration process.** This symposium is intended to be an opportunity for EPA scientists to describe the various types of information and data they would normally review when evaluating various types of PIPs, and to clarify expectations by describing procedures, new efficiency initiatives, and the regulatory approach that underpins EPA OPP's approach to PIPs. This meeting is also intended to help small businesses better understand EPA's requirements and thus to better navigate the regulatory system. USDA and FDA will also be participating in the Symposium to provide information on their respective regulatory systems. Learn more here.

Increasing Predictability and Efficiency

Consistent with the 1986 Coordinated Framework, the 1992 Update to the Coordinated Framework, Executive Order 13563, Executive Order 13610, the 2011 "Principles for Regulation and Oversight of Emerging Technologies" memorandum (2011 memorandum), and the July 2015 EOP memorandum, EPA, FDA, and USDA strive to develop and implement regulatory approaches to protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers. The 1992 Update to the Coordinated Framework describes a risk-based, science-based regulatory approach "to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment."[7] The United States Government reiterated that this risk- and science-based approach to regulation applied to oversight of products of emerging technologies, such as synthetic biology and genetic engineering, in the 2011 memorandum.[3] This National Strategy reaffirms the centrality of this approach in the United States Government.

EPA, FDA, and USDA rely on horizon scanning techniques to detect early signs of important developments in biotechnology. The three regulatory agencies maintain staffs of experts, trained

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in a variety of scientific disciplines, who keep up with knowledge in the various sciences important to understanding and evaluating biotechnology products. These agencies learn about new technologies and new products in development through a combination of activities, including participation in scientific and trade forums and discussions with national and international counterparts; monitoring scientific and trade literature; participating on technical advisory panels; maintaining membership in interagency, national, and international scientific organizations dedicated to state-of-the-art science and technology; and convening scientific advisory committees and public meetings. On occasion, EPA, FDA, and USDA have also sought advice on cutting-edge issues from groups of independent technical experts including, for example, the National Academies of Science, Engineering and Medicine.

Examples of existing mechanisms and activities are listed below

- **EPA, FDA, and USDA have commissioned an independent study by the National Academy of Sciences (NAS)** "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System." The study will identify (1) major advances and potential new types of biotechnology products over the next five to ten years, (2) potential future products that might pose a different type of risk relative to existing products and organisms, (3) areas in which the risks or lack of risk relating to biotechnology are well understood, and (4) the scientific capabilities, tools, and expertise that may be useful to the regulatory agencies as they oversee potential future products of biotechnology. NAS initiated the study in early 2016. Consistent with the July 2015 EOP memorandum, products such as human drugs and medical devices are not a focus of the study. The NAS committee held three public meetings in the spring and summer of 2016 to gather information for the study. The findings by NAS will be considered by the agencies in order to inform ongoing and future agency activities, including the implementation of the *Strategy*. EPA, FDA, and USDA will use the report to (1) gain a better understanding of future products and how they fit within the U.S. regulatory system; (2) consider any necessary updates to scientific assessments; (3) consider any necessary updates to regulatory processes or procedures; and (4) help enhance communication with stakeholders. The July 2015 EOP memorandum also notes that, due to the rapid pace of change in this arena, such independent external analysis should be completed at least every five years.
- **EPA, FDA, and USDA's frequent interactions with product developers.** All three agencies encourage product developers to begin discussions with the regulatory agencies early in the development process, as advance notice and information about products being contemplated enable the agencies to provide input to developers about the safety and regulatory issues relevant to their product. Staff from each of the three agencies routinely have discussions with their counterparts at the other agencies to share information (as appropriate) about products on the horizon or in the regulatory pipeline.
- **EPA, FDA, and USDA strive to use the best available science to address the protection**

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goals established by their respective statutes. For example, USDA's authority under the Plant Protection Act identifies the aspects of plant health that need to be protected from harm (what to protect, where, over what period).[14] These aspects of plant health drive the collection of relevant information for a plant health risk assessment. USDA's environmental risk assessment is an iterative process that uses a scientific approach in which specific hypotheses are formulated and then either proven or refuted through the use of appropriate testing methods.

- **EPA OPP is modifying its approach to PIPs in breeding line intermediates (BLIs).** A BLI is used in plant breeding to bring together or "stack" several individual PIPs into seed. EPA's current approach requires a unique registration for each combination of two or more PIPs combined in BLIs. As companies combine multiple PIPs together, the number of BLI registrations needed to develop one combination PIP product increases. In light of this, EPA is proposing to modify its approach so that a unique registration for each combination of PIPs in BLIs would no longer be required. Rather, EPA will regulate PIPs in BLIs through conditions placed on the registrations of the individual PIPs to be combined in BLIs. This will result in a reduction in the number of registrations needed to produce a combination PIP product. Learn more here.
- **FDA's continuous efforts to expand regulatory science and the use of "smart regulation."** FDA's Strategic Priorities, 2014-2018, identified several cross-cutting strategic priorities and FDA's core mission goals and objectives, which are relevant to ensuring science- and risk-based product evaluations. For example, regulatory science and "smart regulation" are among the focus of FDA's programs. In addition, FDA's core mission goals and objectives include: (1) increasing the use of regulatory science to inform standards development, analysis, and decision-making; (2) increasing regulatory science capacity to effectively evaluate products; and (3) reducing risks in the manufacturing, production, and distribution of FDA-regulated products. For example, with respect to the safety of foods derived from genetically engineered plants, FDA's voluntary consultation process focuses on the characteristics of the plant species and the introduced trait. This process is consistent with international standards established by *Codex Alimentarius*.
- **USDA's encouragement of product development through its *Am I Regulated* process and its permit and notification system.** USDA developed the *Am I Regulated* process by which developers, including small private- and public-sector entities, will ask whether a proposed product would be subject to USDA regulations prior to requesting an authorization for a regulated activity. This allows USDA to have some early notification of products that may be about to enter the regulatory system and provides an additional window into emerging technologies. Also, through the USDA authorization system, which provides permits and notifications for regulated import, interstate movement, and field testing of

[14] Plant Protection Act of 2000; (PPA, 7 U.S.C. 7701 et seq.).

biotech products, the agency is able to learn about potential commercial products three or more years before they are commercialized.

- **USDA's efforts underway to revise its regulations at 7 CFR part 340.** On February 5, 2016, USDA published a notice in the *Federal Register* announcing that it is developing a draft programmatic environmental impact statement (EIS), required under the National Environmental Policy Act, that will evaluate a range of risk-based approaches to regulation that the Agency can take as it works to update its biotechnology regulations. The notice also invites the public to comment on the range of alternatives that USDA will study in the draft EIS, along with definitions that USDA plans to use in the draft EIS. Learn more here.
- **USDA developed an international product horizon scanning assessment.** Recognizing that future biotechnology products are currently being developed in other countries, USDA has developed, and shares with EPA and FDA, annual Vulnerability Assessments that scan information about plant, animal, and microorganism biotechnology research and development activities in other countries for biotechnology products that are in development pipelines and could be imported into the United States. These assessments identify products already in commercial production in other countries, but not yet authorized in the United States.

Future activities

During development of the proposed Update to the Coordinated Framework, the agencies identified a number of actions intended to improve predictability and efficiency. To this end, EPA, FDA, and USDA are committing to the following:

- **EPA, FDA, and USDA commit to interagency communication that helps with timely decisions on regulatory jurisdiction for biotechnology products, in order to help clarify for developers which of the regulatory agency(ies) might have oversight responsibility for a novel biotechnology product for a specific application.**
- **EPA, FDA, and USDA will continue to explore ways to enhance collaborations for the oversight of biotechnology products in an effort to optimize the review and use of scientific data or regulatory assessments**. Greater collaborations between agencies have the potential to reduce the cost, complexity, and time needed to bring safe, new products to market, which is especially important to small and mid-sized companies and academics. Enhanced collaboration and, where feasible, coordination, can also benefit developers and the public by ensuring that the best possible science, standards, and practice drive the regulatory process.
- **EPA, FDA and USDA will continue to examine their regulatory structures with the goal of clarifying how the U.S. Federal Government will regulate genetically engineered insects in an integrated and coordinated fashion to cover the full range of potential products.** The agencies are working to better align their responsibilities over genetically

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engineered insects with their traditional oversight roles, for example, considering mechanisms that would enable EPA to regulate genetically engineered mosquitos under FIFRA when the developer claims they are intended to control population levels, and FDA to regulate them under FD&C Act when the developer makes a disease claim. USDA will continue to exercise its authorities for control of certain plant or animal pest insects.

- **EPA OPP is undertaking a reorganization of the EPA staff assigned to the regulation of biopesticides, including genetically engineered microorganisms and plant-incorporated protectants**. The reorganization is to facilitate interaction among the various experts needed to address novel products of modern biotechnology, and, thus, to facilitate EPA's ability to more efficiently address such products. The reorganization will also create efficiencies by centralizing review and regulation of plant-incorporated protectants (PIPs) into one group.
- **EPA OPP is modifying its approach to transformation event in product identification.** The "transformation event" is generally part of the identity of a PIP. EPA has historically assumed that a different transformation event means a different PIP even if the same vector is used in the engineering. Advances in techniques for the sequencing of genetic information now give EPA the ability to determine whether PIPs associated with different transformation events might be properly considered as "identical or substantially similar". Such a consideration could, for example, affect how the PIP is registered. The modified approach to transformation event would apply to PIPs in seed propagated and in clonally propagated plants, but would likely be most useful for companies developing PIPs in clonally propagated plants. More details will be made available to interested stakeholders at EPA OPP's September 29, 2016 "Plant-Incorporated Protectant (PIP) Data Requirements Symposium."
- **EPA OPP intends to clarify its approach to pesticidal products derived from genome editing techniques.** This clarification will be consistent with the principles for the regulation of biotechnology products articulated in the Coordinated Framework and the goals and objectives of the July 2015 EOP memorandum.
- **FDA intends to clarify its policy for the regulation of products derived from genome editing techniques, including, as appropriate, identifying and/or updating relevant existing guidance documents.** For example, FDA intends to update its Guidance for Industry 187, *Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs,* to clarify how developers of animals produced using emerging technologies (e.g., genome editing) may meet applicable statutory and regulatory requirements. This update will be consistent with the principles for the regulation of biotechnology products articulated in the proposed Update to the Coordinated Framework and the goals and objectives of the July 2015 EOP memorandum.
- **FDA intends to explore updating guidance regarding the consultation procedures for food derived from new plant varieties.** An update to these procedures, which date back to 1996, will help developers have a clearer understanding of what FDA expects during a

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consultation. Any update to these procedures will be consistent with the principles for the regulation of biotechnology products articulated in the proposed Update to the Coordinated Framework and the goals and objectives of the July 2015 EOP memorandum.

- **FDA's Emerging Sciences Working Group will be used to identify science and technology trends of relevance to FDA's regulatory responsibilities, including those for biotechnology products.** For FDA to achieve its mission of protecting and promoting public health, it must be prepared for emerging issues and scientific advances that will affect regulated products, and it must be so prepared well in advance of formal FDA regulatory submissions. To help it realize this goal, FDA formed the Emerging Sciences Working Group. The group will provide an FDA-wide science-based forum to identify and communicate scientific regulatory approaches to anticipated high-impact emerging science and technology.

Supporting the Science that Underpins the Regulatory System

One of the key principles of the U.S. Federal regulatory system for biotechnology products is that regulatory reviews and decisions should be based on the best available science. EPA, FDA, and USDA/APHIS support such science through collaborations with Federal research agencies and through intramural and extramural research portfolios, when appropriate.

Examples of existing mechanisms and activities are listed below

- **FDA leverages its intramural and extramural research portfolios to support regulatory science.** Regulatory science, for FDA, is the science of developing new tools, standards, and approaches to assess the safety, effectiveness, quality, toxicity, public health impact, or performance of FDA-regulated products. FDA identified regulatory science as a cross-cutting strategic priority in its most recent Strategic Priorities document, issued in 2014. In addition, FDA developed a Strategic Plan for Regulatory Science that identified plans to close critical gaps in scientific knowledge required to support regulatory decision-making. As discussed in this plan, a science priority area is to ensure FDA readiness to evaluate innovative emerging technologies, including by coordinating regulatory science for emerging technology product areas. In addition, the Global Coalition of Regulatory Science Research, for example, is building a foundation of collaborative research, scientific exchange, and training as a basis for regulatory decision-making. As needed, FDA also engages in various extramural and intramural research activities to address scientific gaps and develop new methods, models, and approaches required to inform regulatory policy development and decision-making. For example, FDA has relationships with several academic institutions through its Centers of Excellence in Regulatory Science and Innovation (CERSI) as well as through several subject-specific Centers of Excellence. FDA regulatory science activities seek to employ or develop tools that are relevant to biotechnology products (e.g., with respect to food safety, research to

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improve the understanding of allergens to help inform the assessment of the potential allergenicity of proteins; and research related to whole genome sequencing).

- **USDA leverages expertise and resources from USDA's research agencies, the Agricultural Research Service (ARS) and the National Institute of Food and Agriculture**. In cases where there is mutual interest, USDA funds can be directed towards research to inform regulatory activities. One mechanism for such coordination is the Biotechnology Risk Assessment Grants (BRAG) program, which supports the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the effects of introducing biotechnology products into the environment. Investigations of effects on both managed and natural environments are relevant. Also, APHIS discusses research needs with ARS which, when mutual interests arise, uses intramural funds for projects that inform regulatory activities.

Future activities

- **EPA, FDA, and USDA will continue to explore mechanisms to enhance coordination with Federal research agencies to help support agencies' regulatory science needs.**

Implementation of the Strategy

As instructed in the July 2015 EOP memorandum, for at least five years, starting one year after the release of the S*trategy*, EPA, FDA, and USDA are expected to produce an annual report on the specific steps the agencies are taking to implement this *Strategy*. In their first annual report, the agencies may, if appropriate, provide a concrete list of regulatory and other activities and expected timeframes. The agencies will also include in that report any additional actions taken by the agencies to improve the transparency, predictability, and efficiency of biotechnology regulation and the coordination among the regulatory agencies. This report will be made available to the public by the Executive Office of the President.

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Building on 30 Years of Experience to Prepare for the Future of Biotechnology

By ROBBIE BARBERO, TED BOLING, JULIA DOHERTY, MELISSA GOLDSTEIN, JAMES KIM

SUMMARY: EPA, FDA, and USDA unveil two documents as part of the Administration's continuing effort to modernize the Federal regulatory system for biotechnology products.

Today, the Federal government has taken an important step to ensure public confidence in the regulatory system for biotechnology products and to improve the transparency, predictability, coordination, and, ultimately, efficiency of that system.

In 1986, the White House Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology, which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The Framework was updated in 1992. The oversight system established by the Coordinated Framework led, in part, to decades of development and commercialization of biotechnology products with applications in medicine, agriculture, energy, biomanufacturing, and environmental protection. It also contributed to the growth of a large and competitive biotechnology sector in the United States and worldwide.

Advances in science and technology have dramatically altered the biotechnology landscape since 1992. The complexity of the array of regulations and guidance documents developed by the three primary Federal agencies with jurisdiction over biotechnology products—the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—can make it difficult for the public to understand how the safety of biotechnology products is evaluated. Navigating the regulatory process for these products can be challenging, especially for small companies.

For these reasons, last year the Administration initiated an effort to modernize the regulatory system for biotechnology products by asking the EPA, FDA, and USDA, to accomplish three tasks:

- clarify the current roles and responsibilities of the EPA, FDA, and USDA in the regulatory process;
- develop a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, of the future products of biotechnology; and
- commission an expert analysis of the future landscape of biotechnology products.

To accomplish these tasks, EPA, FDA, and USDA spent the last 14 months performing a detailed analysis of the Federal system for regulation of biotechnology products, including by reviewing more than 900 comments that were submitted in response to a Request for Information that was posted last fall, and interacting with members of the public at three public meetings that were held in different regions of the country.

DRAFT

Clarifying current roles and responsibilities

Today's proposed Update to the Coordinated Framework represents the first time in 30 years that the Federal government has produced a comprehensive summary of the roles and responsibilities of the three principal regulatory agencies with respect to the regulation of biotechnology products. The proposed update offers the public a complete picture of a robust and flexible regulatory structure that provides appropriate oversight for all products of modern biotechnology. Within that regulatory structure the Federal agencies maintain high standards that, based on the best available science, protect health and the environment, while also establishing transparent, coordinated, predictable and efficient regulatory practices.

In order to help product developers and the public understand what the regulatory pathway for products might look like, this proposed Update to the Coordinated Framework presents information about agency roles and responsibilities in several forms, including:

- graphics that illustrate agency-specific overviews of regulatory roles;
- case studies that demonstrate how a product developer might navigate the regulatory framework, and;
- a comprehensive table that summarizes the current responsibilities and the relevant coordination across EPA, FDA, and USDA for the regulatory oversight of an array of biotechnology product areas.

This comprehensive set of information should also give the public the confidence that products that are making it to market have been appropriately reviewed for safety.

The Administration is seeking public comment on this proposed Update to the Coordinated Framework, and will finalize it taking into account comments received. Once the notice of request for public comment has posted in the Federal Register, the public will have [40] days from the date of publication to comment. To submit comments, follow the instructions in the notice.

Preparing for the future

The *National Strategy for Modernizing the Regulatory System for Biotechnology Products* sets forth a vision for ensuring that the Federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, maintaining public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens. In the *Strategy*, the Federal agencies demonstrate their sustained commitment to ensure the safety of future products of biotechnology, increase public confidence in the regulatory system, and prevent unnecessary barriers to future innovation and competitiveness.

The *Strategy* highlights many existing and new activities at EPA, FDA, and USDA, including the following key commitments:

- EPA, FDA, and USDA will review existing communication tools and, as appropriate, may revise existing or develop new user-friendly sources of regulatory information for product developers and the general public.

- EPA, FDA, and USDA are emphasizing their commitments to interagency communication and collaboration in order to make timely decisions on regulatory jurisdiction for biotechnology products and to optimize the review and use of scientific data for regulatory assessments.

- EPA and FDA intend to clarify their respective approaches for oversight of products developed using genome editing techniques, including, for example, pesticidal products at EPA and genetically engineered animals at FDA.

- EPA, FDA and USDA will continue to examine their regulatory structures with the goal of clarifying how the U.S. Federal Government will regulate genetically engineered insects in an integrated and coordinated fashion to cover the full range of potential products.

- EPA, FDA, and USDA commit to reporting annually, for at least the next five years, on specific steps that they are taking to implement the *Strategy*, as well as any additional actions being taken to improve the transparency, predictability, and efficiency of biotechnology regulation and the coordination among the regulatory agencies.

- EPA, FDA, and USDA will continue to provide leadership in international fora to promote scientific competency, understanding of the U.S. regulatory approach, and regulatory compatibility worldwide for biotechnology products.

- EPA, FDA, and USDA commissioned a study by the National Academy of Sciences, entitled "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System." A report is forthcoming, which will be used by the EPA, FDA, and USDA to inform ongoing and future agency activities.

We want to hear from you

The documents released today represent major steps forward for the Federal government's effort to modernize the regulatory system for biotechnology products.

But, there is more to be done. In the *Strategy*, the agencies have identified areas where additional work is needed, including the key commitments highlighted above. These ongoing and future activities, along with the commitment from the agencies to report annually on implementation progress, provide direction for the federal regulatory system for biotechnology products to keep pace with advances in science and technology.

DRAFT

We also need continued engagement from key stakeholders, including public and private organizations such as companies, universities and research institutes, trade associations, scientific societies, foundations, consumer organizations, non-profits, and individual citizens.

The Administration looks forward to receiving feedback on the proposed Update to the Coordinated Framework.

Robbie Barbero is Assistant Director for Biological Innovation at the White House Office of Science and Technology Policy.

Ted Boling, Associate Director for the National Environmental Policy Act at the White House Council on Environmental Quality

Julia Doherty is the Senior Director, Agricultural and SPS Affairs in the Office of the U.S. Trade Representative.

Melissa Goldstein is Assistant Director for Bioethics and Privacy at the White House Office of Science and Technology Policy.

James Kim is a toxicologist in the Office of Information and Regulatory Affairs at the Office of Management and Budget.

DRAFT

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/15/2016 1:29:51 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Bogdanoff, Alec (Markey) [Alec_Bogdanoff@markey.senate.gov]
Subject: RE: Sen. Markey PCB questions (set 2) corrected

We'll push it - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, September 15, 2016 9:26 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: Re: Sen. Markey PCB questions (set 2) corrected

We are editing full report drafts right now and I'd really like to get everything by early next week at latest - would that workk?
Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, September 15, 2016 8:55 AM
To: Freedhoff, Michal (Markey)
Cc: Bogdanoff, Alec (Markey)
Subject: RE: Sen. Markey PCB questions (set 2) corrected

Michal – I'm checking on the PCB definitional questions.

Also, R10 says they have reports for the summary chart. We need time to review and get them in the form of the other submissions. What's your deadline on the report? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, September 14, 2016 5:26 PM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: RE: Sen. Markey PCB questions (set 2) corrected

Another option could be what is below – if this works better, can you send me what "XXX" needs to be?

> (5) POLYCHLORINATED BIPHENYL-CONTAINING MATERIAL. – The term "PCB-containing material" means liquid-PCB-filled electrical equipment (as defined in XXX), manufactured building materials containing non-liquid PCBs at concentrations of greater than 50 parts per million, or any material that has been contaminated by a spill or release of PCBs in concentrations greater than 50 parts per million.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Freedhoff, Michal (Markey)
Sent: Wednesday, September 14, 2016 5:07 PM
To: 'Kaiser, Sven-Erik'
Cc: Bogdanoff, Alec (Markey)
Subject: RE: Sen. Markey PCB questions (set 2) corrected

Sven:

Does this definition of PCB-containing material work?

> (5) POLYCHLORINATED BIPHENYL-CONTAINING MATERIAL. – The term "PCB-containing material" means a fluorescent light ballast that contains a liquid-PCB-filled capacitor, manufactured building materials containing non-liquid PCBs at concentrations of greater than 50 parts per million, or any material that has been contaminated by a spill or release of PCBs in concentrations greater than 50 parts per million.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, September 09, 2016 3:09 PM
To: Freedhoff, Michal (Markey)

Cc: Bogdanoff, Alec (Markey)
Subject: RE: Sen. Markey PCB questions (set 2) corrected

Michal – please use this corrected version instead. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Friday, September 09, 2016 2:33 PM
To: 'Freedhoff, Michal (Markey)' <Michal_Freedhoff@markey.senate.gov>
Cc: Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: Sen. Markey PCB questions (set 2)

Michal,
Attached are responses to questions 2, 8, and 12. The remaining questions (4, 9, and 10) are being worked on. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, July 19, 2016 5:59 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: PCB questions

Sven

Here are a bunch of questions for your team – thanks. It would be great to get your sense of how long these will take to respond to. It is fine with me if you respond to them as you get each one answered - no need to wait til they are all done if you think some will take longer than others. I've attached our MASK Act, which I know you've looked at before, for your reference.

Thanks
michal

1. Do contractors that are remediating PCB-containing building materials like those that might be found in schools require special accreditation the way asbestos-workers do? if not, should they, or is the removal of such materials less complicated to do? what about inspectors? Title II of TSCA goes on at some length about the types of courses and certifications that are required by asbestos contractors and inspectors – is something like this needed (or is it already in the 6e rules) for PCBS?

2. Title II of TSCA defines ASBESTOS-CONTAINING MATERIAL.—The term "asbestos- containing material" means any material which contains more than 1 percent asbestos by weight. I know you are in the midst of re-

drafting your PCB rules. Would a definition of PCB-CONTAINING MATERIAL which I drew from your 1998 PCB regulation make sense, or are there different/more items I should be considering?

"The term polychlorinated biphenyl-containing material means 1) a fluorescent light ballast that contains more than 50 parts per million in the insulating material which fills the space between the functioning parts of the ballast and its outer metal covering, 2) a nonliquid material containing polychlorinated biphenyls at concentrations of more than 50 parts per million but less than 500 parts per million [QUESTION – WOULD THIS CAPTURE CAULK AND PAINT, AND WHY THE 500 PPM MAX?] AND 3) DO I NEED TO WORRY ABOUT PCB-CONTAINING ELECTRICAL EQUIPMENT IN SCHOOLS OR OTHER THINGS BESIDES WHAT IS LISTED IN THIS DRAFT DEFINITION?,

3. Title II of TSCA contains the following definition: (12) RESPONSE ACTION.—The term ''response action'' means methods that protect human health and the environment from asbestos-containing material material. Such methods include methods described in chapters 3 and 5 of the Environmental Protection Agency's ''Guidance for Controlling Asbestos-Containing Materials in Buildings.'' Are these the analogous PCB documents listed below? If so, can you pls send the right URLs (all the links are broken), and if not, can you pls send the right materials?

EPA and Federal Partners

- Fact Sheets for Schools and Teachers about PCB-Contaminated Caulk from EPA provides information about PCBs in caulk used in some buildings, including schools, in the 1950s through the 1970s and offers suggestions on what to say to children about PCBs to encourage proper precautions. The website includes:
  - Fact Sheet for Schools: PCBs in Caulk School Checklist (PDF) (1pp, 106KB)
- PCB-Containing Fluorescent Light Ballasts in School Buildings: A Guide for School Administrators and Maintenance Personnelfrom EPA provides information on the risks posed by PCBs in light ballasts, how to properly handle and dispose of these items and how to properly retrofit school lighting fixtures to remove potential PCB hazards.
- PCBs in Caulk in Older Buildings on the EPA website offers background information, steps to minimize exposure, testing methods and a schools information kit.

4. Title II of TSCA refers to "least burdensome" in several places . Would it be better to delete these references?

5. Title II of TSCA tells EPA to prescribe transportation and disposal regulations for asbestos-containing waste. I am assuming that your 6(e) regs (and any revisions thereto) would cover this for PCBs, right?

6. Title II of TSCA requires warning labels to be placed in maintenance areas when inspections discover asbestos-containing materials. It is not clear to me that a similar label should be required for PCB-containing materials in schools given the different nature of these materials. Does EPA have a technical view?

7. Title II of TSCA says you can only update the asbestos removal guidance through rulemaking. Is it typical to require guidance updates to be done by rule, and if not, would it make sense to delete that requirement in this case?

8. Title II of TSCA describes an inspection standard and methodology that must be met for asbestos: Either a scanning electron microscope or a transmission electron microscope shall be used to determine the ambient interior concentration. In the absence of reliable measurements, the ambient exterior concentration shall be deemed to be—

   (A) less than 0.003 fibers per cubic centimeter if a scanning electron microscope is used, and

   (B) less than 0.005 fibers per cubic centimeter if a transmission electron microscope is used.

Does EPA still believe that this is the right methodology and standard? If not, what is?
Is there an analogous standard and methodology for PCBs and if so what is it?

9. As I gather from other TA, the Asbestos Trust Fund won't really exist anymore soon:
"The asbestos loan program is a direct loan program managed under the Credit Reform Act of 1990 (CRA). The issuance of new asbestos loans under the program officially ended in 1993. Subsequently, all remaining loan activity since 1993 has occurred for managing loan repayment/collection activities in accordance with the CRA and Debt Collection Act requirements. The Credit Reform Act of 1990 precludes Agencies from repurposing funds for other needs. All asbestos loan related funds under the loan program are managed in accordance with the CRA, which specifically identifies how to manage collections received. Because FY 2016 serves as the final subsidy closing re-estimate year for the asbestos direct loan program, all of the remaining balances related to the Act requirements (including the $32,189.20 amount) are expected to be zeroed out prior to September 30, 2016 in close-out transactions at the end FY 2016. Although the funds may look available, they are not. The funds are tied to the Asbestos loan program, which is managed under the Credit Reform Act of 1990. The CRA identifies the process for final closing re-estimates. The final Asbestos loan closing re-estimate is in process and will sweep all of the account balances to Treasury prior to September 30, 2016."

But the statutory text does not talk about loans. It talks about grants. I'm confused about your TA as well as what we might need to do legislatively to reverse the outcome you've described above, or specify that the program is managed under the credit reform act of 1990. Can you please help me understand the statutory basis for your TA above as well as what a statutory remedy might be?

> For purposes of this sub- section, a ''violation'' means a failure to comply with respect to a single school building. The court shall order that any civil penalty collected under this subsection be used by the local educational agency for purposes of complying with this title. Any portion of a civil penalty remaining unspent after compliance by a local edu- cational agency is completed shall be deposited into the Asbestos Trust Fund established by section 5 of the Asbestos Hazard Emer- gency Response Act of 1986.

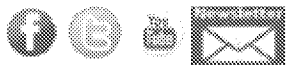
10. The MASK Act authorizes $10 mill/year for enforcement of asbestos requirements. If the bill was drafted to expand to PCBs as well, would EPA need more resources, and if so, how much?

11. Does the asbestos ombudsman still exist at EPA, and does the role work as envisioned? Should it be expanded to include PCBS?

12. Title II of TSCA required EPA to do a one-time study of where asbestos is in public bldgs.. The MASK Act requires these to be redone every 10 years. Would there be a benefit to a similar PCB study?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/13/2016 5:46:38 PM
To: jordan_baugh@gillibrand.senate.gov; alyson_northrup@gillibrand.senate.gov
Subject: Sen. Gillibrand Letter on PFOA and TSCA
Attachments: Gillibrand letter on PFOA and TSCA prioritization.pdf; EPA Response.PFOA and TSCA prioritiation.pdf

Jordan and Alyson,
I'm sending along EPA's response to Sen. Gillibrand's letter of June 23, 2016, on the prioritization of PFOA under TSCA. Although the response letter was signed several weeks ago, it is unclear that it was received in your office. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 26 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

The Honorable Kirsten Gillibrand
United States Senate
Washington, DC 20510-3206

Dear Senator Gillibrand:

Thank you for your letter of June 23, 2016 to the U.S. Environmental Protection Agency (EPA) urging EPA to prioritize the assessment of perfluorooctanoic acid, commonly known as PFOA, under the Toxic Substances Control Act (TSCA) so that EPA can make a determination as to whether the use of this chemical should be restricted or banned at the federal level. The Administrator referred your letter to my office for response.

EPA has taken a number of actions to reduce exposure to PFOA. The agency has worked with individual companies to phase out many of these chemicals, and in 2000, 2002, 2006, and 2015, published regulations under TSCA restricting the return of any of these phased-out chemicals to the U.S. market without EPA review. In January 2006, EPA initiated the 2010/2015 PFOA Stewardship Program, and obtained commitments from the leading global companies to reduce PFOA and related chemical emissions and product content by 95% by 2010, and to eliminate them by 2015.

As you note in your letter, the Frank R. Lautenberg Chemical Safety for the 21st Century Act establishes new requirements under section 6 of TSCA for prioritizing existing chemicals for evaluation and taking action where risks are identified. Consistent with the amended TSCA, EPA will evaluate whether the remaining ongoing uses of PFOA are a high priority for assessment. If EPA's assessment of remaining PFOA uses indicates risk, EPA will take regulatory action to address the risk.

Also, EPA has recently established health advisory levels for PFOA and perfluorooctane sulfonate (PFOS) to provide Americans, including the most sensitive populations, with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water. If residents of the Village of Hoosick Falls, or other locations, are exposed to PFOA due to past manufacture or uses of the chemical that are not subject to TSCA, EPA will work through other statutory authorities and approaches in order to reduce the risks.

Again, thank you for your letter. If you have additional questions, please contact me or your staff may contact Sven-Erik Kaiser in EPA's Office of Congressional and Intergovernmental Relations at 202-566-2753.

Sincerely,

James J. Jones
Assistant Administrator

KIRSTEN GILLIBRAND
NEW YORK
SENATOR

RUSSELL SENATE OFFICE BUILDING
SUITE 478
WASHINGTON, DC 20510-3205
202-224-4451

COMMITTEES:
ARMED SERVICES
ENVIRONMENT AND PUBLIC WORKS
AGRICULTURE
SPECIAL COMMITTEE ON AGING

United States Senate

WASHINGTON, DC 20510-3205

June 23, 2016

The Honorable Gina McCarthy
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator McCarthy,

The residents of the Village of Hoosick Falls, Town of Petersburgh, and Town of Hoosick, New York, were recently informed of exposure to the chemical compound perfluorooctanoic acid, commonly known as PFOA, through their drinking water. The results of blood testing showed that there are residents of Hoosick Falls with levels of PFOA in their bloodstream as much as 50 or 100 times above the national number. All age groups have been affected, from infants to senior citizens.

There are very serious concerns that PFOA is potentially linked to tragic health effects, including various types of cancer. The presence of PFOA in the drinking water of Hoosick Falls is likely the result of pollution from a nearby plastics manufacturing plant. However, this is not an isolated incident; PFOA contamination has been found in other states as well, and threatens to become a major public health crisis across the Northeast and anywhere this chemical has been used in manufacturing. Although my immediate concern is for the residents of Hoosick Falls and their families, the issue of PFOA contamination is a national concern that must be addressed by the Environmental Protection Agency immediately.

Given the concerns about the effects of PFOA on public health, I urge you to prioritize this chemical for assessment under the Toxic Substances Control Act (TSCA) as soon as possible so that EPA can make a determination as to whether the use of this chemical should be restricted or banned at the federal level. A TSCA analysis will help to improve upon the science so that my constituents have a better understanding of the long-term effects of PFOA exposure, and ensure our communities are better protected against this chemical.

Thank you for your attention to this urgent request.

Sincerely,

Kirsten Gillibrand

Kirsten Gillibrand
United States Senator

PRINTED ON RECYCLED PAPER

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/21/2016 12:14:37 AM
To: 'Adam_Zipkin@booker.senate.gov' [Adam_Zipkin@booker.senate.gov]
Subject: Administration Views Letter on TSCA Reform Bills
Attachments: TSCA Reform Views.Boxer.pdf

Adam,
Please see attached and let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/9/2016 7:08:55 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Bogdanoff, Alec (Markey) [Alec_Bogdanoff@markey.senate.gov]
Subject: RE: Sen. Markey PCB questions (set 2) corrected
Attachments: Markey.PCB.Set 2.1.docx

Michal – please use this corrected version instead. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Friday, September 09, 2016 2:33 PM
To: 'Freedhoff, Michal (Markey)' <Michal_Freedhoff@markey.senate.gov>
Cc: Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: Sen. Markey PCB questions (set 2)

Michal,
Attached are responses to questions 2, 8, and 12. The remaining questions (4, 9, and 10) are being worked on. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, July 19, 2016 5:59 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: PCB questions

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But the statutory text does not talk about loans. It talks about grants. I'm confused about your TA as well as what we might need to do legislatively to reverse the outcome you've described above, or specify that the program is managed under the credit reform act of 1990. Can you please help me understand the statutory basis for your TA above as well as what a statutory remedy might be?

> For purposes of this sub- section, a ''violation'' means a failure to comply with respect to a single school building. The court shall order that any civil penalty collected under this subsection be used by the local educational agency for purposes of complying with this title. Any portion of a civil penalty remaining unspent after compliance by a local edu- cational agency is completed shall be deposited into the Asbestos Trust Fund established by section 5 of the Asbestos Hazard Emer- gency Response Act of 1986.

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Washington, DC 20510
202-224-2742

Connect with Senator Markey

Answers to Questions (2, 8 & 12)

2. Title II of TSCA defines ASBESTOS-CONTAINING MATERIAL.—The term "asbestos- containing material" means any material which contains more than 1 percent asbestos by weight. I know you are in the midst of re-drafting your PCB rules. Would a definition of PCB-CONTAINING MATERIAL which I drew from your 1998 PCB regulation make sense, or are there different/more items I should be considering?

"The term polychlorinated biphenyl-containing material means 1) a fluorescent light ballast that contains more than 50 parts per million in the insulating material which fills the space between the functioning parts of the ballast and its outer metal covering, 2) a non-liquid material containing polychlorinated biphenyls at concentrations of more than 50 parts per million but less than 500 parts per million [QUESTION – WOULD THIS CAPTURE CAULK AND PAINT, AND WHY THE 500 PPM MAX?] AND 3) DO I NEED TO WORRY ABOUT PCB-CONTAINING ELECTRICAL EQUIPMENT IN SCHOOLS OR OTHER THINGS BESIDES WHAT IS LISTED IN THIS DRAFT DEFINITION?

Answer: The proposed definition is problematic.

1) The primary PCB concern with fluorescent light ballasts (FLBs) is a liquid-filled PCB small capacitor contained within the FLB; the contamination of the insulating tar (potting material) is of secondary importance, as the PCB concentrations involved typically are much lower. Additionally, PCB FLBs are currently regulated differently from non-liquid PCB-containing building materials, as PCB FLBs are regulated as authorized uses of the liquid-filled PCB small capacitors contained within. (The question of contaminated potting material cannot be determined without destructive sampling of individual ballasts; therefore, the Agency does not require the testing of potting material for those units in use and the concentration of PCBs in potting material primarily affects disposal requirements for FLBs).

2) The second part of the proposed definition draws upon the existing definition of "PCB-Contaminated" at 40 CFR 761.3, which is used to defind a PCB concentration range of $\geq$50 ppm but <500ppm (or >10ug to <100ug for wipe test results), rather than a category of products such as PCB-containing building materials. This is not useful in defining all PCB-containing building materials, as these materials can be found at concentrations above 500 ppm.

3) Regarding electrical equipment, liquid PCBs at concentrations $\geq$50 ppm may be present in school buildings, in old (pre-July 2, 1979) electrical equipment such as fluorescent light ballasts (in the small capacitor inside the FLB), other small capacitors, such as found in high-intensity discharge light fixtures, air conditioner units or elevator machinery, and transformers. The use of PCB Transformers ($\geq$500 ppm PCBs) and PCB Large Capacitors (containing over 3 lbs of PCB liquid) is severely restricted and they are unlikely to be found in school buildings. Liquid-filled PCB electrical equipment is already defined and addressed by use authorizations in the regulations, and creating a new definition for PCB-containing

building materials that includes liquid-filled PCB electrical equipment, could result in confusion.

In its guidance, EPA uses the term "PCB-containing building materials" to refer to manufactured building materials containing non-liquid PCBs at concentrations of ≥50 ppm, or an any concentration in a substrate or adjacent building material if contaminated by spills or releases from sources ≥50 ppm, including products such as caulk, grout, sealants, paint, coatings, adhesives, plastic, Galbestos, insulation, gaskets, brick, mortar, masonry, concrete, fluorescent light ballast potting material, ceiling tiles, wallboard and other building materials.

8. Title II of TSCA describes an inspection standard and methodology that must be met for asbestos: Either a scanning electron microscope or a transmission electron microscope shall be used to determine the ambient interior concentration. In the absence of reliable measurements, the ambient exterior concentration shall be deemed to be—

(A) less than 0.003 fibers per cubic centimeter if a scanning electron microscope is used, and
(B) less than 0.005 fibers per cubic centimeter if a transmission electron microscope is used.

Does EPA still believe that this is the right methodology and standard? If not, what is? Is there an analogous standard and methodology for PCBs and if so what is it?

Answer: The referenced provision of TSCA §204 was only provided by Congress in case EPA failed to act to promulgate standards. In fact, EPA promulgated standards for testing air for asbestos, which are in effect, thus §204 was not needed. Analysis of asbestos present in air following the completion of a response action pursuant to 40 CFR section 763.90(i) must be conducted using Transmission Electron Microscopy (TEM). The TEM method is provided at Appendix A to 40 CFR part 763. (Another method, phase contrast microscopy (PCM) may be used to confirm completion of a response action that is greater than small-scale short duration activity and involves less than or equal to 160 square feet or 260 linear feet of asbestos-containing building material.) EPA did not specify a default outside air concentration to be used in calculations; rather, in response actions analyzed using TEM, EPA's regulation requires that outside sampling be performed or that the average concentration of asbestos does not exceed the filter background level. Therefore the default values in TSCA §204 are not in EPA's regulations.

There is no analogous PCB standard for air testing. Asbestos consists of mineral fibers and these must be visually identified and counted under a microscope, whereas PCBs are organic chlorinated hydrocarbons which are chemically analyzed to determine their presence and concentration. As guidance (not promulgated standards), EPA has developed Exposure Levels for Evaluating PCBs in indoor school air (ELEs), but EPA cautions that the ELEs should not be interpreted or applied as "bright-line" or "not-to-exceed" criteria. These can be found in Part IV of the EPA guide: **PCBs in Building Materials – Questions & Answers (July 28, 2015)**. See questions 27-31 for a full discussion of the factors and limitations of these ELE levels. The link is here: https://www.epa.gov/sites/production/files/2016-03/documents/pcbs_in_building_materials_questions_and_answers.pdf

A number of standard EPA and ASTM testing and sampling methods are used for measuring PCBs, depending on the material being tested and the specific data sought. Where necessary, EPA specifies methods to be used in the regulations or guidance and updates these references periodically as needed.

12. Title II of TSCA required EPA to do a one-time study of where asbestos is in public bldgs. The MASK Act requires these to be redone every 10 years. Would there be a benefit to a similar PCB study?

Answer: If a PCB study were conducted, a one-time study would likely be sufficient. The 1979 ban on PCBs applied to the installation of new building materials containing PCBs; therefore one study, if properly conducted, should identify the remaining inventory of PCB-containing building materials, as no additional such materials would be installed in the future.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
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Attachments: Markey.PCB.Set 2.docx

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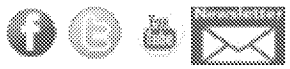

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/9/2015 1:22:56 PM
To: 'Elizabeth_Olsen@epw.senate.gov' [Elizabeth_Olsen@epw.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]
Subject: SEPW TSCA Hearing QFRs
Attachments: SEPW.3.18.15.Final QFRs.Inhofe.pdf; SEPW.3.18.15.Final QFRs.Boxer.pdf

Attached please find EPA responses to the questions for the record following the March 18, 2015 hearing on TSCA reform. Hard copy to follow through the mail. Please let me know if any questions. Thanks,
Sven

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN - 8 2015

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Barbara Boxer
Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Senator Boxer:

Thank you for the opportunity to respond to the questions for the record following the March 18, 2015, hearing on the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S.697). Enclosed are the Environmental Protection Agency's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser at kaiser.sven-erik@epa.gov or 202-566-2753.

Sincerely,

Laura Vaught
Associate Administrator

Enclosure

Senate Committee on Environment and Public Works
Hearing on "Frank R. Lautenberg Chemical Safety for the 21st Century Act (S.697)
March 18, 2015
Questions for the Record

The responses are based on the March 10, 2015, version of S.697 that was the subject of the hearing. Any changes made in subsequent versions of S.697 are not reflected in the responses.

Senator Inhofe

Inhofe 1. During the March 18 hearing, you stated that EPA would interpret the "likely to meet" standard for low priority chemicals as requiring the Agency be very confident of that determination. Please provide additional information on how the Agency would expect to be confident of that determination. In particular, please contrast current law with the approach required under S.697.

Response: In identifying low-priority substances under the March 10, 2015, version of S.697, the EPA would be required to conclude information is sufficient to establish that the chemical substance is likely to meet the safety standard, as opposed to conducting a full-blown risk assessment and making a determination that the chemical substance does meet the safety standard. Given this, the EPA would want to make the finding based on clear indications of low risk which could be readily determined by reviewing the available data on hazard and exposure, without conducting extensive quantitative assessment; for example, if it were clear that hazard and/or exposure were very low. There is no prioritization process for identifying low priority chemicals under TSCA that is analogous to that in S.697.

Inhofe 2. Several times during the hearing on March 18, you stated that EPA had "no duty" to regulate chemicals under TSCA today. Yet under Section 5, EPA clearly has a duty to review and possibly regulate new chemicals, and under Section 6 EPA clearly has a duty to regulate chemicals that pose an unreasonable risk to health or the environment. Please clarify your statement that "EPA has no duty to regulate chemicals under TSCA today"?

Response: The EPA's testimony was regarding existing chemicals. TSCA section 6(a) states:

> "If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements."

So under the circumstance where the EPA makes a finding regarding an existing chemical, it would then have a duty to mitigate those risks by rule. However, there is no mandate under

current law for the EPA to establish a program to prioritize and assess existing chemicals. Without such a mandate, the EPA has found it difficult to maintain action over a sustained period of time.

Inhofe 3. In response to a question posed at the March 18 hearing, you stated there was "ambiguity" with respect to the preemption of State clean air and clean water regulations.

3a. Does TSCA today preempt state actions under the Clean Air Act or any other federal law?

Response: TSCA does not preempt state action adopted under the authority of federal law, including the Clean Air Act.

3b. Is TSCA today "ambiguous" on the preemptive effect of a TSCA action on state clean air and water regulations?

Response: There is some ambiguity about what state requirements would be covered under the heading of requirements "adopted under the authority of federal law." This is because certain state environmental programs acknowledged under federal law, and apparently intended to be protected from exemption when TSCA was drafted, (e.g., state implementation plans subject to approval under the Clean Air Act) are not literally "adopted under the authority of" federal law. See H.R. Rep. No. 1341, 94th Cong., 2nd Sess. 54 (1976).

3c. Under TSCA today, if a state regulates a chemical substance under a state clean water standard that EPA finds does not pose an unreasonable risk, and that EPA therefore finds does not warrant regulation under Sections 5 or 6, would EPA's decision preempt the state action?

Response: No.

Inhofe 4. You testified in November 2014, that EPA should have clear authority to assess chemicals against a risk-based standard and to take action on chemicals that do not meet the standard.

4a. Does S.697 mandate that EPA base its chemical safety decisions solely on considerations of risk to public health and the environment?

Response: The safety standard, which is the standard used in making a safety determination, as defined in the March 10, 2015, version of S.697, specifically excludes taking into consideration cost and other non-risk factors.

4b. Is S.697 clear that costs and benefits may not factor into a chemical safety evaluation?

Response: The March 10, 2015, version of S.697 is clear that cost and other non-risk factors cannot factor into a chemical safety evaluation.

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4c. Does S.697 require that all chemicals in commerce, including those "grandfathered" under existing TSCA, be reviewed?

Response: The prioritization throughput requirements in the March 10, 2015, version of the bill would ultimately result in all chemicals actively in commerce being reviewed.

Inhofe 5. You testified in November 2014 that EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on risk and exposure considerations.

5a. Does S.697 require EPA to establish a risk-based prioritization screening process within a year of enactment?

Response: Yes, section 4A(a)(1) of the March 10, 2015, version of the bill requires that, "not later than 1 year after enactment of this section, the Administrator shall establish, by rule, a risk-based screening process" for prioritizing.

5b. How does EPA's process under the Work Plan Chemical program compare to the requirements of S. 697 for the prioritization, assessment and possible regulation of priority substances?

Response: The March 10, 2015, version of S.697 would require the EPA to develop policies and procedures for carrying out the various requirements in the bill, so the precise details of these processes are not fully specified. That said, the hazard and exposure criteria specified in the bill for the prioritization screening process are similar to what was done to create the EPA's current Work Plan.

Senator Vitter

Vitter 1. Can you please explain the impact on an existing state law once a chemical is designated a high priority? The intention is that any and all existing state laws and regulations remain in place after a chemical is designated as a high priority, is that your clear interpretation of the language in the bill?

Response: Yes, it is the EPA's interpretation that regarding the March 10, 2015, version of the bill, the designation of a chemical substance as high priority does not affect the status of existing state laws and regulations.

Vitter 2. EPA adopted Compliance Monitoring Guidance for TSCA in 2011. Does that guidance anticipate a role for state governments in implementing or enforcing EPA's new and existing chemicals program?

Response: The TSCA new and existing chemicals programs are exclusively federal programs.

Vitter 3. Under TSCA's existing preemption provision States can adopt requirements that are "identical" to EPA's decisions without running afoul of TSCA's preemption provision. If a State

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adopts a requirement identical to TSCA, the State would have a responsibility to enforce its own law, not federal law, correct? In fact, there is no "co-enforcement" of federal law by the States under TSCA today, or under S. 697, correct?

Response: "Co-enforcement" is not a term that the EPA typically uses. It is correct that, under both TSCA and the March 10, 2015, version of S.697, states do not enforce federal law.

Vitter 4. In your response to a question posed at the March 18, 2015 hearing on co-enforcement, you said you were not aware that co-enforcement by States that has created any problems. Your response appeared to indicate a view that State co-enforcement required the States to adopt the exact same standard or regulation as EPA.

4a. EPA has issued hundreds of Significant New Use Rules over the years. Under TSCA today, those actions preempt state action. How many state actions to restrict or prohibit chemicals has EPA determined are preempted by SNURs?

Response: As the EPA interprets TSCA section 18, significant new use rules do not preempt state law.

4b. How many state actions regarding testing requirements has EPA determined are preempted by test rules or consent agreements under Section 4?

Response: TSCA does not call for the EPA to determine whether state laws are preempted; rather, that determination would typically be made by a court. The EPA is not aware of a case where the agency has been asked about a state testing requirement.

4c. Does EPA regularly assess state restrictions or prohibitions on chemical substances to determine if they adopt the "exact" standard or regulation as EPA?

Response: No.

4d. What criteria does EPA apply to determine if a state action on a chemical substance is identical to the EPA action?

Response: As stated above, TSCA does not call for the EPA to make determinations on whether state laws are preempted. To the best of our knowledge, the EPA has not received any requests to determine whether state actions are identical to the EPA action.

4e. Does EPA believe that state enforcement and penalty provisions associated with a state action on a chemical substance must also be identical to federal law or regulation?

Response: As stated above, TSCA does not call for the EPA to make determinations on these kinds of issues.

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4f. Is it possible that State law might be enforced differently from Federal law, and that significant state-to-state differences in enforcement could result in an inconsistent patchwork of state regulation?

Response: It is possible that a state may take a different approach to enforcement of a state requirement than the EPA does to an identical federal requirement.

Senator Markey

Markey 1. New York's Attorney General recently sent a letter describing the ways State authority to set strong chemical safety standards and enforce existing laws is preempted in the Udall-Vitter bill. Do you agree that all of the erosions of State authority described in this letter are enabled by the bill text?

Response: In large measure, the letter matches the EPA's analysis of how the March 10, 2015, version of S.697 would preempt state law. However, the EPA does not necessarily agree with all of the analysis in the letter. For example, the EPA believes the bill could be read to provide that preemption under section 18(b) would end as soon as the EPA makes a determination that a chemical substance does not meet the safety standard. The EPA notes that 18(b) preemption only applies to a "chemical substance that is a high-priority substance designated under section 4A." (page 141, lines 24-25), and the bill commands the EPA to "remove the chemical substance from the list of high-priority substances" as soon as a safety determination is complete (section 4A(a)(3)(A)(iii)(I); page 35 line 25 to page 36 lines 1-3).

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Response: In large measure, the letter matches the EPA's analysis of how the March 10, 2015, version of S.697 would preempt state law. However, the EPA does not necessarily agree with all of the analysis in the letter. For example, the EPA believes the bill could be read to provide that preemption under section 18(b) would end as soon as the EPA makes a negative safety determination. The EPA notes that 18(b) preemption only applies to a "chemical substance that is a high-priority substance designated under section 4A." (page 141, lines 24-25), and the bill commands the EPA to "remove the chemical substance from the list of high-priority substances" as soon as a safety determination is complete (section 4A(a)(3)(A)(iii)(I); page 35 line 25 to page 36 lines 1-3).

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Response: The March 10, 2015, version of the bill creates two types of preemption and two corresponding types of waivers. For the EPA to waive preemption caused by an EPA determination that a chemical meets the safety standard or EPA regulation of a chemical, the EPA must find that the state requirement is warranted by compelling state or local conditions. For the EPA to waive preemption caused by commencement of an EPA safety assessment, the EPA must find that the state requirement is warranted by a compelling local interest. These provisions – especially the first one, which requires a showing of state or local conditions rather than just a local interest – could be interpreted as requiring a showing of a risk concern that is specific to the state.

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Response: The March 10, 2015, version of the bill allows the EPA to identify "additional priorities" for safety assessment and determination pursuant to the request of a manufacturer and processor, subject to payment of fees. These chemicals would not be "high priority" substances under the bill, and the "additional priority" designation would not itself trigger preemption (section 4A(c)(5)).

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Response: Under the March 10, 2015 version of the bill, the criteria for designating a chemical substance as high or low priority are the same whether the EPA evaluates the substance on its own initiative or pursuant to the bill's state notification process. In addition, the bill does not impose a time limit for the EPA to complete prioritization reviews for the chemicals subject to this process (or for any other chemicals under prioritization review). Thus, it is unclear whether that process would make it more likely that the EPA would act to preempt state regulation.

Markey 7. In 1989, EPA tried to ban asbestos under its TSCA authority, but industry successfully overturned the ban in court. The term in the Udall-Vitter bill that is used to define what is meant by "safe" contains the "unreasonable risk" language that was in part the subject of that litigation. Do you believe that the use of this same language that has already been the subject of litigation would increase the likelihood that EPA would be sued using some of the same arguments industry used to overturn the asbestos ban?

Response: The safety standard as defined in the March 10, 2015, version of the bill includes language that alters the meaning of "unreasonable risk" from current TSCA. That being said, it is still possible that the EPA might be sued using similar arguments as in prior cases.

Markey 8. In 2014, a chemical safety case decided in the DC Circuit of the US Court of Appeals reiterated an earlier finding that "This court has acknowledged the difficulties of applying the substantial evidence test "to regulations which are essentially legislative and rooted in inferences from complex scientific and factual data, and which often necessarily involve highly speculative projections of technological development in areas wholly lacking in scientific and economic certainty." The Udall-Vitter bill includes this same "substantial evidence" standard, even though it can be a much harder standard to meet than the one used in other environmental laws. This standard was also part of industry's successful arguments to overturn EPA's asbestos ban. Do you agree that the so-called "substantial evidence" standard is not yet settled law, and that its use in this bill would increase the likelihood that EPA would be sued using some of the same arguments industry used to overturn the asbestos ban?

Response: The EPA may be sued using some of the same arguments used in the asbestos case, in view of the retention of the "substantial evidence" standard. We note, though, that the D.C. Circuit, in the case the question refers to, remarked on "an 'emerging consensus' of the Courts of Appeals, that the difference between the two standards [substantial evidence standard and arbitrary and capricious standard] should not be 'exaggerate[d].'" We also note that whatever benefit might accrue to litigants under the standard would accrue both to industry and environmental litigants challenging the EPA action.

Markey 9. In 1989, EPA tried to ban asbestos under its TSCA authority, but industry successfully overturned the ban in court. Asbestos is already banned in 54 countries, and exposure to it kills 10,000 Americans each year. Would the Udall-Vitter bill allow EPA to immediately propose a ban or restriction on asbestos, or would it have to complete a safety assessment first?

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Response: Under the March 10, 2015, version of the bill, the EPA would have the discretion to prioritize asbestos immediately. The safety assessment and determination processes described in the bill would need to be followed before any potential risk management could be promulgated.

Markey 10. Persistent, bio-accumulative and toxic chemicals like mercury and PCBs are known to persist in the environment and accumulate in the body, and can include dangerous chemicals that pass from pregnant women to developing fetuses. Would the Udall-Vitter bill allow EPA to immediately propose a ban or restriction on these known dangers?

Response: PCBs are already banned by TSCA section 6(e). With respect to other PBT chemicals, under the March 10, 2015, version of the bill, the EPA would have the discretion to prioritize these types of chemicals immediately, but would not be required to. The safety assessment and determination processes described in the bill would need to be followed before any potential risk management could be promulgated.

Markey 11. Flame retardant chemicals are used in everything from couches to clothes. If EPA finds that flame-retardant chemicals are unsafe, is it true that under the Udall-Vitter bill, EPA would have to do a separate analysis for EACH type of consumer product that includes them? It is true that under the bill, EPA might even have to study each type of chair or couch and each type of garment as a condition for regulating each one?

Response: It is true that the March 10, 2015, version of the bill requires the EPA, if it intends to regulate an article, to have evidence of significant exposure 'from such article", and it is possible that the language in the bill could include multiple analyses along the lines described in the question.

Markey 12. Do you agree that if EPA wishes to ban or restrict the use of a chemical in, for example, plastic, that EPA should be able to analyze exposure from that chemical in ALL plastic products that contain that chemical, instead of having to separately analyze each product that uses that type of plastic?

Response: The EPA agrees that a requirement to separately analyze each product to be regulated could impose significant burden.

Markey 13. Recently, news reports indicated that floorboards that were imported from China contained high levels of formaldehyde, a known carcinogen. Do you agree that the Udall-Vitter bill makes it harder for EPA to intercept products containing dangerous chemicals that are being imported from countries like China?

Response: Yes, the March 10, 2015, version of the bill establishes limitations on EPA's ability to impose requirements on articles and to require import certification for chemical substances in imported articles.

Markey 14. When EPA designates a chemical as "low priority" that essentially means that EPA thinks it is safe. Do you agree that the Udall-Vitter bill contains no way for a member of the public to challenge the scientific validity of that determination in court?

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Response: The only provision in the March 10, 2015, version of the bill that expressly provides for challenging prioritization designations allows for judicial review by a state that had recommended a low-priority designation for a chemical substance. This provision could well imply that Congress did not intend for judicial review of prioritization decisions to be otherwise available.

Markey 15. When EPA designates a chemical as "low priority," that essentially means that EPA thinks it is safe. The Udall-Vitter bill includes a limited way for some States to challenge the scientific validity of that determination in court even though it would not be possible for an individual or other organization to do so. If a State did successfully make such a challenge and cause EPA to re-classify the chemical as "high priority" instead, wouldn't that also result in the preemption of the State from doing anything to protect against that chemical itself?

Response: Regarding the March 10, 2015, version of the bill, it is unclear to the EPA exactly how this judicial review provision is intended to operate. Under one plausible interpretation, the scenario described above would be precluded. The judicial review provision appears to only apply to a state that has submitted "a recommendation . . . to designate a chemical substance as a low priority." If so, then this provision would only allow such states to challenge high priority designations (a state would have nothing to challenge if it requested a low priority designation and the EPA followed the state's recommendation).

Senator Boxer

Boxer 1. Assistant Administrator Jones, in 1989, EPA tried to ban asbestos under its TSCA authority, but industry successfully overturned the ban in court. The term in the Vitter-Udall bill that is used to define what is meant by "safe" contains the same core language that was the subject of that litigation. Do you believe that the use of this same "unreasonable risk" language that has already been the subject of litigation would increase the likelihood that EPA would be sued using some of the same arguments industry used to overturn the asbestos ban?

Response: The safety standard as defined in the March 10, 2015, version of S.697 includes language that alters the meaning of "unreasonable risk" from current TSCA. That being said, litigants may make similar arguments to those used in prior cases.

Boxer 2. Mr. Jones, flame retardant chemicals are used in everything from couches to clothes. If EPA finds that flame-retardant chemicals are unsafe, is it true that under the Vitter-Udall bill, EPA would have to do a separate analysis for EACH type of consumer product that includes them? Isn't it true that under the bill, EPA might even have to study each type of chair or couch and each type of garment as a condition for regulating each one?

Response: It is true that the March 10, 2015, version of the bill requires the EPA, if it intends to regulate an article, to have evidence of significant exposure 'from such article", and it is possible that the language in the bill could include multiple analyses along the lines described in the question.

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Boxer 3. Mr. Jones, recent news reports indicated that floorboards that were imported from China contained high levels of formaldehyde, a known carcinogen. Do you agree that the Vitter-Udall bill makes it harder for EPA to intercept products containing dangerous chemicals that are being imported from countries like China?

Response: Yes, the March 10, 2015, version of the bill establishes limitations on EPA's ability to impose requirements on articles and to require import certification for chemical substances in imported articles.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN - 8 2015

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable James M. Inhofe
Chairman
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Thank you for the opportunity to respond to the questions for the record following the March 18, 2015, hearing on the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S.697). Enclosed are the Environmental Protection Agency's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser at kaiser.sven-erik@epa.gov or 202-566-2753.

Sincerely,

Laura Vaught
Associate Administrator

Enclosure

Senate Committee on Environment and Public Works
Hearing on "Frank R. Lautenberg Chemical Safety for the 21st Century Act (S.697)
March 18, 2015
Questions for the Record

The responses are based on the March 10, 2015, version of S.697 that was the subject of the hearing. Any changes made in subsequent versions of S.697 are not reflected in the responses.

Senator Inhofe

Inhofe 1. During the March 18 hearing, you stated that EPA would interpret the "likely to meet" standard for low priority chemicals as requiring the Agency be very confident of that determination. Please provide additional information on how the Agency would expect to be confident of that determination. In particular, please contrast current law with the approach required under S.697.

Response: In identifying low-priority substances under the March 10, 2015, version of S.697, the EPA would be required to conclude information is sufficient to establish that the chemical substance is likely to meet the safety standard, as opposed to conducting a full-blown risk assessment and making a determination that the chemical substance does meet the safety standard. Given this, the EPA would want to make the finding based on clear indications of low risk which could be readily determined by reviewing the available data on hazard and exposure, without conducting extensive quantitative assessment; for example, if it were clear that hazard and/or exposure were very low. There is no prioritization process for identifying low priority chemicals under TSCA that is analogous to that in S.697.

Inhofe 2. Several times during the hearing on March 18, you stated that EPA had "no duty" to regulate chemicals under TSCA today. Yet under Section 5, EPA clearly has a duty to review and possibly regulate new chemicals, and under Section 6 EPA clearly has a duty to regulate chemicals that pose an unreasonable risk to health or the environment. Please clarify your statement that "EPA has no duty to regulate chemicals under TSCA today"?

Response: The EPA's testimony was regarding existing chemicals. TSCA section 6(a) states:

> "If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements."

So under the circumstance where the EPA makes a finding regarding an existing chemical, it would then have a duty to mitigate those risks by rule. However, there is no mandate under

current law for the EPA to establish a program to prioritize and assess existing chemicals. Without such a mandate, the EPA has found it difficult to maintain action over a sustained period of time.

Inhofe 3. In response to a question posed at the March 18 hearing, you stated there was "ambiguity" with respect to the preemption of State clean air and clean water regulations.

3a. Does TSCA today preempt state actions under the Clean Air Act or any other federal law?

Response: TSCA does not preempt state action adopted under the authority of federal law, including the Clean Air Act.

3b. Is TSCA today "ambiguous" on the preemptive effect of a TSCA action on state clean air and water regulations?

Response: There is some ambiguity about what state requirements would be covered under the heading of requirements "adopted under the authority of federal law." This is because certain state environmental programs acknowledged under federal law, and apparently intended to be protected from exemption when TSCA was drafted, (e.g., state implementation plans subject to approval under the Clean Air Act) are not literally "adopted under the authority of" federal law. See H.R. Rep. No. 1341, 94th Cong., 2nd Sess. 54 (1976).

3c. Under TSCA today, if a state regulates a chemical substance under a state clean water standard that EPA finds does not pose an unreasonable risk, and that EPA therefore finds does not warrant regulation under Sections 5 or 6, would EPA's decision preempt the state action?

Response: No.

Inhofe 4. You testified in November 2014, that EPA should have clear authority to assess chemicals against a risk-based standard and to take action on chemicals that do not meet the standard.

4a. Does S.697 mandate that EPA base its chemical safety decisions solely on considerations of risk to public health and the environment?

Response: The safety standard, which is the standard used in making a safety determination, as defined in the March 10, 2015, version of S.697, specifically excludes taking into consideration cost and other non-risk factors.

4b. Is S.697 clear that costs and benefits may not factor into a chemical safety evaluation?

Response: The March 10, 2015, version of S.697 is clear that cost and other non-risk factors cannot factor into a chemical safety evaluation.

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4c. Does S.697 require that all chemicals in commerce, including those "grandfathered" under existing TSCA, be reviewed?

Response: The prioritization throughput requirements in the March 10, 2015, version of the bill would ultimately result in all chemicals actively in commerce being reviewed.

Inhofe 5. You testified in November 2014 that EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on risk and exposure considerations.

5a. Does S.697 require EPA to establish a risk-based prioritization screening process within a year of enactment?

Response: Yes, section 4A(a)(1) of the March 10, 2015, version of the bill requires that, "not later than 1 year after enactment of this section, the Administrator shall establish, by rule, a risk-based screening process" for prioritizing.

5b. How does EPA's process under the Work Plan Chemical program compare to the requirements of S. 697 for the prioritization, assessment and possible regulation of priority substances?

Response: The March 10, 2015, version of S.697 would require the EPA to develop policies and procedures for carrying out the various requirements in the bill, so the precise details of these processes are not fully specified. That said, the hazard and exposure criteria specified in the bill for the prioritization screening process are similar to what was done to create the EPA's current Work Plan.

Senator Vitter

Vitter 1. Can you please explain the impact on an existing state law once a chemical is designated a high priority? The intention is that any and all existing state laws and regulations remain in place after a chemical is designated as a high priority, is that your clear interpretation of the language in the bill?

Response: Yes, it is the EPA's interpretation that regarding the March 10, 2015, version of the bill, the designation of a chemical substance as high priority does not affect the status of existing state laws and regulations.

Vitter 2. EPA adopted Compliance Monitoring Guidance for TSCA in 2011. Does that guidance anticipate a role for state governments in implementing or enforcing EPA's new and existing chemicals program?

Response: The TSCA new and existing chemicals programs are exclusively federal programs.

Vitter 3. Under TSCA's existing preemption provision States can adopt requirements that are "identical" to EPA's decisions without running afoul of TSCA's preemption provision. If a State

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adopts a requirement identical to TSCA, the State would have a responsibility to enforce its own law, not federal law, correct? In fact, there is no "co-enforcement" of federal law by the States under TSCA today, or under S. 697, correct?

Response: "Co-enforcement" is not a term that the EPA typically uses. It is correct that, under both TSCA and the March 10, 2015, version of S.697, states do not enforce federal law.

Vitter 4. In your response to a question posed at the March 18, 2015 hearing on co-enforcement, you said you were not aware that co-enforcement by States that has created any problems. Your response appeared to indicate a view that State co-enforcement required the States to adopt the exact same standard or regulation as EPA.

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Response: Under the March 10, 2015 version of the bill, the criteria for designating a chemical substance as high or low priority are the same whether the EPA evaluates the substance on its own initiative or pursuant to the bill's state notification process. In addition, the bill does not impose a time limit for the EPA to complete prioritization reviews for the chemicals subject to this process (or for any other chemicals under prioritization review). Thus, it is unclear whether that process would make it more likely that the EPA would act to preempt state regulation.

Markey 7. In 1989, EPA tried to ban asbestos under its TSCA authority, but industry successfully overturned the ban in court. The term in the Udall-Vitter bill that is used to define what is meant by "safe" contains the "unreasonable risk" language that was in part the subject of that litigation. Do you believe that the use of this same language that has already been the subject of litigation would increase the likelihood that EPA would be sued using some of the same arguments industry used to overturn the asbestos ban?

Response: The safety standard as defined in the March 10, 2015, version of the bill includes language that alters the meaning of "unreasonable risk" from current TSCA. That being said, it is still possible that the EPA might be sued using similar arguments as in prior cases.

Markey 8. In 2014, a chemical safety case decided in the DC Circuit of the US Court of Appeals reiterated an earlier finding that "This court has acknowledged the difficulties of applying the substantial evidence test "to regulations which are essentially legislative and rooted in inferences from complex scientific and factual data, and which often necessarily involve highly speculative projections of technological development in areas wholly lacking in scientific and economic certainty." The Udall-Vitter bill includes this same "substantial evidence" standard, even though it can be a much harder standard to meet than the one used in other environmental laws. This standard was also part of industry's successful arguments to overturn EPA's asbestos ban. Do you agree that the so-called "substantial evidence" standard is not yet settled law, and that its use in this bill would increase the likelihood that EPA would be sued using some of the same arguments industry used to overturn the asbestos ban?

Response: The EPA may be sued using some of the same arguments used in the asbestos case, in view of the retention of the "substantial evidence" standard. We note, though, that the D.C. Circuit, in the case the question refers to, remarked on "an 'emerging consensus' of the Courts of Appeals, that the difference between the two standards [substantial evidence standard and arbitrary and capricious standard] should not be 'exaggerate[d].'" We also note that whatever benefit might accrue to litigants under the standard would accrue both to industry and environmental litigants challenging the EPA action.

Markey 9. In 1989, EPA tried to ban asbestos under its TSCA authority, but industry successfully overturned the ban in court. Asbestos is already banned in 54 countries, and exposure to it kills 10,000 Americans each year. Would the Udall-Vitter bill allow EPA to immediately propose a ban or restriction on asbestos, or would it have to complete a safety assessment first?

ED_002117_00009826-00008

Response: Under the March 10, 2015, version of the bill, the EPA would have the discretion to prioritize asbestos immediately. The safety assessment and determination processes described in the bill would need to be followed before any potential risk management could be promulgated.

Markey 10. Persistent, bio-accumulative and toxic chemicals like mercury and PCBs are known to persist in the environment and accumulate in the body, and can include dangerous chemicals that pass from pregnant women to developing fetuses. Would the Udall-Vitter bill allow EPA to immediately propose a ban or restriction on these known dangers?

Response: PCBs are already banned by TSCA section 6(e). With respect to other PBT chemicals, under the March 10, 2015, version of the bill, the EPA would have the discretion to prioritize these types of chemicals immediately, but would not be required to. The safety assessment and determination processes described in the bill would need to be followed before any potential risk management could be promulgated.

Markey 11. Flame retardant chemicals are used in everything from couches to clothes. If EPA finds that flame-retardant chemicals are unsafe, is it true that under the Udall-Vitter bill, EPA would have to do a separate analysis for EACH type of consumer product that includes them? It is true that under the bill, EPA might even have to study each type of chair or couch and each type of garment as a condition for regulating each one?

Response: It is true that the March 10, 2015, version of the bill requires the EPA, if it intends to regulate an article, to have evidence of significant exposure 'from such article", and it is possible that the language in the bill could include multiple analyses along the lines described in the question.

Markey 12. Do you agree that if EPA wishes to ban or restrict the use of a chemical in, for example, plastic, that EPA should be able to analyze exposure from that chemical in ALL plastic products that contain that chemical, instead of having to separately analyze each product that uses that type of plastic?

Response: The EPA agrees that a requirement to separately analyze each product to be regulated could impose significant burden.

Markey 13. Recently, news reports indicated that floorboards that were imported from China contained high levels of formaldehyde, a known carcinogen. Do you agree that the Udall-Vitter bill makes it harder for EPA to intercept products containing dangerous chemicals that are being imported from countries like China?

Response: Yes, the March 10, 2015, version of the bill establishes limitations on EPA's ability to impose requirements on articles and to require import certification for chemical substances in imported articles.

Markey 14. When EPA designates a chemical as "low priority" that essentially means that EPA thinks it is safe. Do you agree that the Udall-Vitter bill contains no way for a member of the public to challenge the scientific validity of that determination in court?

ED_002117_00009826-00009

Response: The only provision in the March 10, 2015, version of the bill that expressly provides for challenging prioritization designations allows for judicial review by a state that had recommended a low-priority designation for a chemical substance. This provision could well imply that Congress did not intend for judicial review of prioritization decisions to be otherwise available.

Markey 15. When EPA designates a chemical as "low priority," that essentially means that EPA thinks it is safe. The Udall-Vitter bill includes a limited way for some States to challenge the scientific validity of that determination in court even though it would not be possible for an individual or other organization to do so. If a State did successfully make such a challenge and cause EPA to re-classify the chemical as "high priority" instead, wouldn't that also result in the preemption of the State from doing anything to protect against that chemical itself?

Response: Regarding the March 10, 2015, version of the bill, it is unclear to the EPA exactly how this judicial review provision is intended to operate. Under one plausible interpretation, the scenario described above would be precluded. The judicial review provision appears to only apply to a state that has submitted "a recommendation . . . to designate a chemical substance as a low priority." If so, then this provision would only allow such states to challenge high priority designations (a state would have nothing to challenge if it requested a low priority designation and the EPA followed the state's recommendation).

Senator Boxer

Boxer 1. Assistant Administrator Jones, in 1989, EPA tried to ban asbestos under its TSCA authority, but industry successfully overturned the ban in court. The term in the Vitter-Udall bill that is used to define what is meant by "safe" contains the same core language that was the subject of that litigation. Do you believe that the use of this same "unreasonable risk" language that has already been the subject of litigation would increase the likelihood that EPA would be sued using some of the same arguments industry used to overturn the asbestos ban?

Response: The safety standard as defined in the March 10, 2015, version of S.697 includes language that alters the meaning of "unreasonable risk" from current TSCA. That being said, litigants may make similar arguments to those used in prior cases.

Boxer 2. Mr. Jones, flame retardant chemicals are used in everything from couches to clothes. If EPA finds that flame-retardant chemicals are unsafe, is it true that under the Vitter-Udall bill, EPA would have to do a separate analysis for EACH type of consumer product that includes them? Isn't it true that under the bill, EPA might even have to study each type of chair or couch and each type of garment as a condition for regulating each one?

Response: It is true that the March 10, 2015, version of the bill requires the EPA, if it intends to regulate an article, to have evidence of significant exposure 'from such article", and it is possible that the language in the bill could include multiple analyses along the lines described in the question.

ED_002117_00009826-00010

Boxer 3. Mr. Jones, recent news reports indicated that floorboards that were imported from China contained high levels of formaldehyde, a known carcinogen. Do you agree that the Vitter-Udall bill makes it harder for EPA to intercept products containing dangerous chemicals that are being imported from countries like China?

Response: Yes, the March 10, 2015, version of the bill establishes limitations on EPA's ability to impose requirements on articles and to require import certification for chemical substances in imported articles.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/23/2015 3:52:38 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
Subject: TSCA Reform TA
Attachments: TSCA Reform.TA.Preemption 18c.docx

Dimitri,
Following up, please find attached a revision to 18(c)(3) that would implement your intent as we understand it. There are two ideas here:

1. For legacy actions that developed under pre-CSIA TSCA, evaluate preemption using pre-CSIA TSCA Section 18.
2. For chemical substances and mixtures that EPA already regulated in some fashion under pre-CSIA section 6 (PCBs, most notably) keep on evaluating preemption using pre-CSIA TSCA Section 18, even in connection with post-CSIA updates and additions to those rules and orders.
    a. The exception would be if EPA puts the chemical on the high priority list. Then EPA would apply the new preemption provisions, as with any other substance.
    b. But if just updating a PCB regulation, using stand alone authority to continue managing PCB issues under TSCA 6(e), EPA would keep on operating in terms of pre-CSIA preemption.

The language is provided by EPA as technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, draft language and comments.

"(c)(3) APPLICABILITY OF SECTION 2617 OF THIS TITLE (AS IN EFFECT IMMEDIATELY BEFORE [INSERT DATE OF ENACTMENT OF CSIA]) TO CERTAIN RULES AND ORDERS— Notwithstanding section 18(d),

(i) nothing in this section shall be construed as modifying the effect under this section, as in effect immediately prior to [insert the effective date of the Chemical Safety Improvement Act], of any rule or order promulgated or issued under this Act prior to [insert the effective date of the Chemical Safety Improvement Act];

and

(ii) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to [insert the effective date of the Chemical Safety Improvement Act], this section as enacted prior to [insert the effective date of the Chemical Safety Improvement Act] shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after [insert the effective date of the Chemical Safety Improvement Act], unless such rule or order is with respect to a chemical substance and follows a designation of that chemical substance as a high-priority substance under Section 4A.

Commented [A1]: This is no longer just a "rule of construction" if you are intending to apply pre-CSIA preemption to future, post-CSIA, rules and orders.

Commented [A2]: This is a necessary clarification because (c)(3)(ii) directs the reader to an earlier version of TSCA preemption that is capable of preempting pre-1/1/2015 state law, even though 18(d) says that nothing in this section (including (c)(3)(ii)) will result in a preemption of pre- 1/1/2015 state law.

If there were no clarification here, it would be ambiguous whether (c)(3)(ii) would be operative in the event that application of pre-CSIA preemption would result in preemption of pre-1/1/2015 state law.

This paragraph would say "Yes," but subsection 18(d) would say "No." The "notwithstanding" language makes clear that this paragraph prevails in the event that such a conflict arises.

Commented [A3]: Under current TSCA 18, preemption is triggered by a federal rule or order respecting a "chemical substance or mixture" hence that is the relevant trigger here.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/20/2015 2:49:01 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: SEPW TSCA Reform TA on preemption and PCBs

Dimitri,
What about 2 pm today for a call? Can use Personal Phone / Ex. 6 code Personal Phone / Ex. 6 Let me know if that works for you and the industry folks. Thanks,
Sven

On Jan 16, 2015, at 7:10 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

It will be Meg Hunt and Jim Roewer from EEI and their counsel Doug Green.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, January 16, 2015 07:08 PM
To: Karakitsos, Dimitri (EPW)
Subject: Re: SEPW TSCA Reform TA on preemption and PCBs

Dimitri,
Thanks for the message. I'll let folks know and get something set up. Can you tell me who would be joining the call. Best,
Sven

On Jan 16, 2015, at 6:43 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven – looks like we hit another snag in this. I would really appreciate if we could get your folks back on the phone maybe this time with the utilities themselves? I have included below a response to my email to them on the substance for staff's background. Please let me know if there might be some good times for a call next week.

Thanks and have a nice long weekend.

Dimitri

while it is an improvement, it is limited to rules or order issued *prior* to the effective date of the CSIA. The problem is that It would not extend preemption language to the upcoming PCB rule and, unless we are missing something, under the CSIA we have no practical way to obtain preemption protection for PCBs under a subsequent rulemaking (this is because PCBs are highly unlikely to be a high priority chemical substance and therefore would not be subject to a safety determination or an "additional restriction" rulemaking under new section 6). This would lead to the anomalous result and a confusing regulatory regime of having the *existing* PCB rules continuing to have preemption protection, but any subsequent PCB rules not having the same protection.

We think the way to correct this is through the following edit:

In Section 18

Nothing in this section shall be construed as modifying the effect under this section as enacted prior to the effective date of the Chemical Safety Improvement Act ~~of any rule or order~~ with respect to

a chemical substance, mixture or article for which any rule or order has been promulgated or issued under this Act prior to the effective date of the Chemical Safety Improvement Act.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, January 15, 2015 9:10 AM
To: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA Reform TA on preemption and PCBs

Dimitri,
Thanks for talking with us yesterday about the requested technical assistance. We do not see any problems with the suggested language, except a suggestion to change "Act" to "Chapter" where indicated below. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill. Please let me know if any additional questions. Best,
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Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

In the bill but not amending actual TSCA

Nothing in this Act shall be construed as requiring the Administrator to modify or withdraw any rule or order promulgated or issued under this Act prior to the effective date of the Chemical Safety Improvement Act.

In the bill amending actual TSCA (perhaps Section 26?)

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Sent: 1/17/2015 12:13:42 AM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: SEPW TSCA Reform TA on preemption and PCBs

Ok thanks

On Jan 16, 2015, at 7:10 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/16/2015 4:23:30 PM
To: Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: FW: House E&C Inquiry on Florida TSCA conference
Attachments: JJ Chems Mgmt CSPA 12-8-14- final.pptx

Jacqueline,
It was the Consumer Specialty Products Association Annual Meeting in December. Jim Jones participated in a panel discussion for the Government Affairs Advisory Committee titled "Bringing Together Federal and State Leaders: Priorities and Perspectives on Chemical Management Policy." The other panelists included:

- Dave McCarthy, Chief Counsel for the Majority, U.S. House Energy & Commerce Committee
- Alexandra Dunn, Executive Director, ECOS
- Ben Dunham, Counsel, McKenna Long & Aldridge

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

United States Environmental Protection Agency

EPA's Chemicals Management Program

Jim Jones

Assistant Administrator

Office of Chemical Safety & Pollution Prevention

[DateTime]

Improving the Safety of Chemicals

- Issues in Chemical Safety
- Three Pillars of EPA's Existing Chemicals Program
- TSCA Reform

Chemical Safety
Why should you care?

- The initial TSCA inventory, published in 1979, included about 62,000 chemicals already on the market which were allowed to remain in commerce with no assessment of their safety.
- Since TSCA became law, approximately 22,000 chemicals have been reviewed through the new chemicals Pre-Manufacture Notice (PMN) process.
- TSCA Inventory has more than 84,000 chemicals which are allowed in U.S. commerce.
- Relatively few existing chemicals (pre-1979) from from the original TSCA inventory have been assessed for safety.
- 1000+ chemicals are known to have some hazard and/or high levels of exposure

Chemical Safety
Why should you care?

- TSCA has no mandate for EPA to review or assess the safety of chemicals already in commerce.
- 1991 5th Circuit case interpreting TSCA Section 6, which overturned EPA's ban of most uses of asbestos, set high bar for banning or regulating existing chemicals.
- For 28 years, EPA stopped trying to use TSCA Section 6, which requires a risk analysis and a benefits analysis.

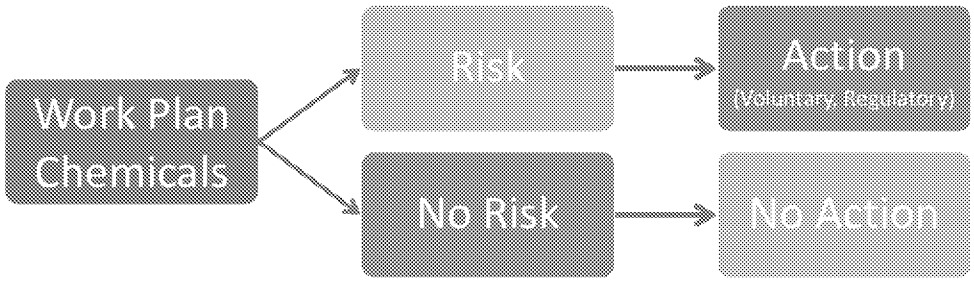
Three Pillars of EPA's Existing Chemicals Program

1. Risk Assessment and Reduction
   - Comprehensive assessment of highest priority chemicals with risk management, where appropriate.
2. Increasing Access to Chemical Data
   - Providing data to users allows for more informed decision makers.
3. Promote the Design and Use of Safer Chemicals
   - Incentivize the development of safer chemicals and make it easier for consumers to find these options in the marketplace.

EPA United States Environmental Protection Agency

1 Risk Assessment and Reduction

Assessing Chemicals for Safety



1 Risk Assessment and Reduction

Completed Work Plan Assessments

After a 28 year hiatus, EPA is performing assessments for priority chemicals to inform possible risk management

- Four of the initial five draft assessments are now final
  - Two final assessments indicated risks
    - Trichloroethylene (TCE)
    - Methylene Chloride or Dichloromethane (DCM)
  - Two final assessments did not indicate risks
    - 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta-[γ]-2-benzopyran (HHCB)
    - Antimony Trioxide (ATO)
  - Final assessment on N-Methylpyrrolidone (NMP) in 2015
- Consideration of risk reduction actions, both voluntary and regulatory, are underway for TCE and DCM.
- Gov't safety findings carry weight independent of regulatory outcome.

1 Risk Assessment and Reduction

Other Assessments Underway

- Medium & long-chain chlorinated paraffins
- 1-Bromopropane
- 1,4-Dioxane
- Flame Retardants
  - Brominated Phthalates Cluster (TBB & TBPH)
  - Brominated Bisphenol A Cluster (TBPA)
  - Chlorinated Phosphate Esters Cluster (TCEP)
  - Cyclic Aliphatic Bromides Cluster (HBCD)

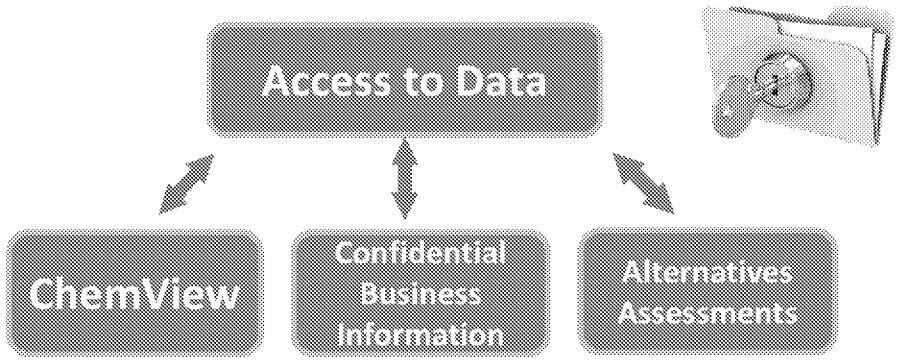
1 Risk Assessment and Reduction

Reducing Risk Through SNURs

- Significant new use rules (SNURs) ensure that, once a chemical has been phased out or taken off the market for certain uses, no company can resume manufacturing or processing the chemical for that use without prior notice to the Agency. This prevents older chemical substances now known to be dangerous from returning to the market.
  - 2012
    - Benzedine Dyes, Alkanes, DNPP, PBDEs, and HBCD – Proposed SNURs
  - 2013
    - Perfluorinated chemicals in carpet – Final SNUR
  - 2014/15
    - NP/NPE, HBCD, Ethylene Glycol Ethers, Benzidine Dyes, Alkanes, and DNPP— Final SNURs
    - Long-Chain Chlorinated Perfluoros and PFAs, Toluene Diiosocyanates – Proposed SNURs

2 Increasing Access to Chemical Data

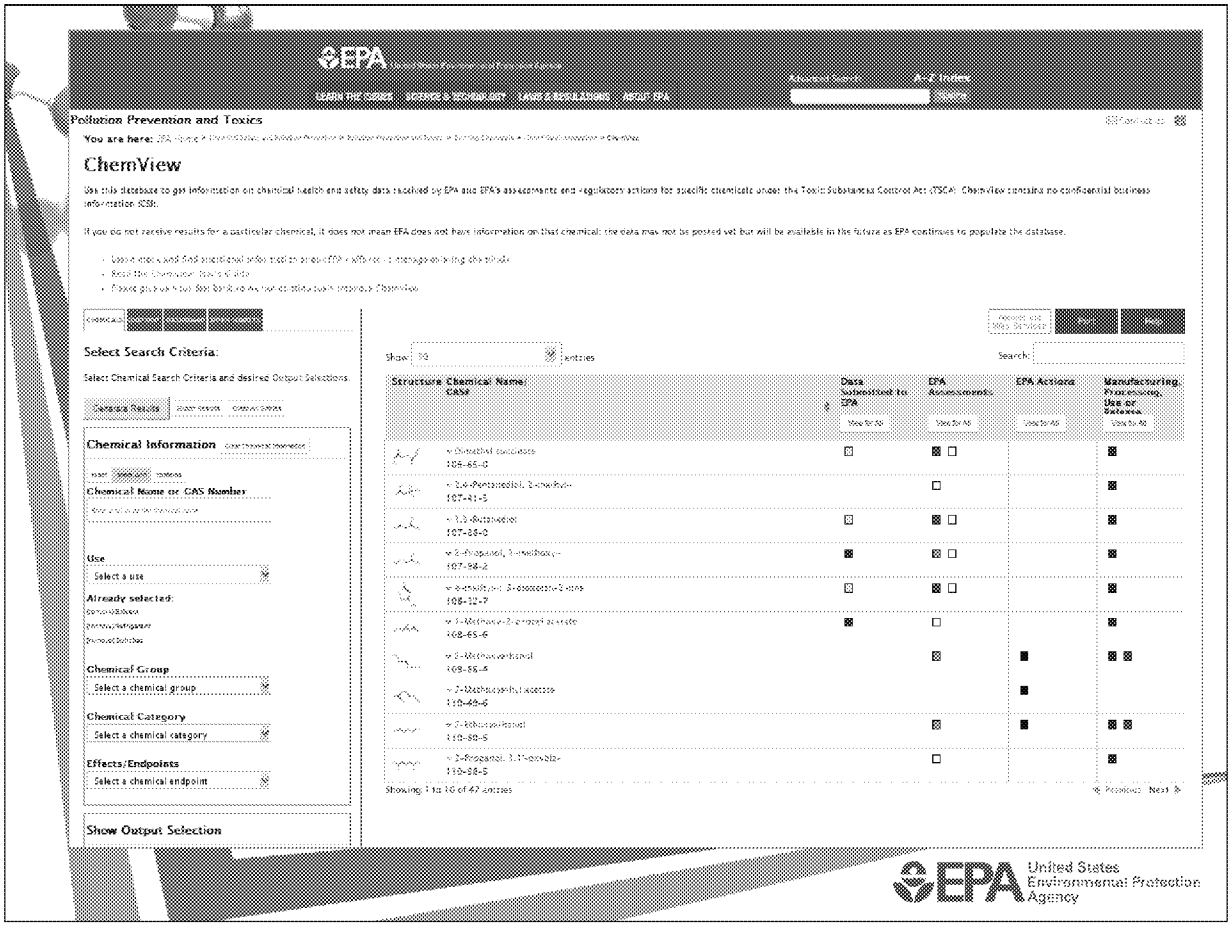
Increasing public access to chemical information and reducing claims of confidentiality are a key component of EPA's Existing Chemicals Management Program.



2 Increasing Access to Chemical Data

ChemView

- In Sept. 2013, launched ChemView, an innovative on-line tool that is providing enhanced access and use of EPA's chemical information.
  - Currently contains detailed information on nearly 10,000 chemicals.
  - Will continue to improve functionality and add data to help people make more informed chemical safety decisions.


EPA
Pollution Prevention and Toxics
ChemView
Select Search Criteria:
Chemical Information
Chemical Name or CAS Number
Use
Select a use
Already selected:
Chemical Group
Select a chemical group
Chemical Category
Select a chemical category
Effects/Endpoints
Select a chemical endpoint
Show Output Selection
Structure
Chemical Name; CAS#
Data Submitted to EPA
EPA Assessments
EPA Actions
Manufacturing, Processing, Use or Release
Search:
Showing 1 to 10 of 42 entries
Previous
Next
United States Environmental Protection Agency

3 Promote the Design and Use of Safer Chemicals

- EPA is promoting the design and use of safer chemicals through a number of key programs and activities.

EPA United States Environmental Protection Agency

3 Promote the Design and Use of Safer Chemicals

DfE Safer Product Labeling Program

- Promotes design of safer consumer, industrial and institutional chemical-based products
- Over 2,500 DfE-labeled cleaning and other products
  - Meet stringent human and environmental health criteria
  - Ensure products are safer and perform well
  - Contain the safest possible ingredients
- Program is growing and gaining prominence in the marketplace

3 Promote the Design and Use of Safer Chemicals

NEW

Partner of the Year Awards

- 2015 Awards will recognize stakeholders who have furthered the safer chemistry goals of the Safer Product Labeling Program to date
  - Applications due January 30, 2015
  - Awards ceremony in Washington, DC – late Spring 2015
- 2016 Awards will recognize leadership promoting the new label
- For more information, visit: www.epa.gov/DfE/Awards

EPA United States Environmental Protection Agency

3 Promote the Design and Use of Safer Chemicals

DfE Label Redesign

- To more clearly convey the benefits of Safer Product Labeling Program
- Extensive stakeholder and public outreach underway
- New label expected to launch mid-2015

3 Promote the Design and Use of Safer Chemicals

Current Safer Product Labeling Program Logo

Design for the Environment
U.S. EPA

Recognized for Safer Chemistry

www.epa.gov/dfe

3 Promote the Design and Use of Safer Chemicals

Safer Product Labeling Program Logo Redesign Options

A

SAFER CHOICE
MEETS U.S. EPA CRITERIA
epa.gov/saferchoice

B

SAFER CHOICE
MEETS U.S. EPA SAFER CHEMISTRY CRITERIA

C

Meets U.S. EPA Safer Ingredient Criteria
epa.gov/saferproduct

D

Meets U.S. EPA Safer Product Standards
epa.gov/saferproduct

EPA United States Environmental Protection Agency

3 Promote the Design and Use of Safer Chemicals

Safer Chemical Ingredients List (SCIL)

- Chemicals that meet Safer Product Labeling Program criteria
- Nearly 650 chemicals
- New initiative to expand in new & existing classes
- Invite manufacturers to submit chemicals for evaluation & listing
- Steps to SCIL listing: www.epa.gov/dfe/howtoscil

To learn more about TSCA and EPA's Chemical Management & Pollution Prevention Programs:

http://www.epa.gov/oppt

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/15/2015 5:53:50 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA Reform TA on preemption and PCBs

Dimitri,
Following up on your question below,

In Section 26, it is fine to use "Act," as originally drafted, if you prefer. We suggested "Chapter" because ultimately "Act" would be replaced by "Chapter" when CSIA is codified into the U.S. Code.

In Section 18, it is similarly fine to use "Act," if you prefer. If you prefer a more focused reference, it would also be fine to say "Title" or "Subchapter." All of the types of action that can trigger preemption under current TSCA's preemption provision are located in Subchapter I (aka Title I) of TSCA, so we don't think there will be any difference in operation whether the word "Act", "Title", or "Subchapter" is used.

Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, January 15, 2015 9:47 AM
To: Kaiser, Sven-Erik
Subject: RE: SEPW TSCA Reform TA on preemption and PCBs

Thanks Sven – quick follow up questions. We haven't used the term "chapter" before in the bill, what exactly is meant there? Would "title" be more appropriate? Limiting it in the section 18 seems to make more sense to me than section 26 because that is meant to apply to all of TSCA. Just trying to clarify which term may be most appropriate where.

Thanks for your help

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, January 15, 2015 9:10 AM
To: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA Reform TA on preemption and PCBs

Dimitri,
Thanks for talking with us yesterday about the requested technical assistance. We do not see any problems with the suggested language, except a suggestion to change "Act" to "Chapter" where indicated below. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

In the bill but not amending actual TSCA

Nothing in this Act shall be construed as requiring the Administrator to modify or withdraw any rule or order promulgated or issued under this Act prior to the effective date of the Chemical Safety Improvement Act.

In the bill amending actual TSCA (perhaps Section 26?)

Nothing in the Chemical Safety Improvement Act shall be construed as requiring the Administrator to modify or withdraw any rule or order promulgated or issued under this Chapter ~~Act~~ prior to the effective date of the Chemical Safety Improvement Act.

In Section 18

Nothing in this section shall be construed as modifying the effect under this section as enacted prior to the effective date of the Chemical Safety Improvement Act of any rule or order with respect to a chemical substance, mixture or article promulgated or issued under this Chapter ~~Act~~ prior to the effective date of the Chemical Safety Improvement Act.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/14/2015 7:48:51 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: TSCA Reform TA

Got it, thanks, we'll look at it and let you know if any questions. Best,
Sven

On Jan 14, 2015, at 2:45 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

From: Richard Denison [mailto:rdenison@edf.org]
Sent: Wednesday, January 14, 2015 2:44 PM
To: Karakitsos, Dimitri (EPW)
Subject: RE: language we just discussed

In the bill but not amending actual TSCA

Nothing in this Act shall be construed as requiring the Administrator to modify or withdraw any rule or order promulgated or issued under this Act prior to the effective date of the Chemical Safety Improvement Act.

In the bill amending actual TSCA (perhaps Section 26?)

Nothing in the Chemical Safety Improvement Act shall be construed as requiring the Administrator to modify or withdraw any rule or order promulgated or issued under this Act prior to the effective date of the Chemical Safety Improvement Act.

In Section 18

Nothing in this section shall be construed as modifying the effect under this section as enacted prior to the effective date of the Chemical Safety Improvement Act of any rule or order with respect to a chemical substance, mixture or article promulgated or issued under this Act prior to the effective date of the Chemical Safety Improvement Act.

This e-mail and any attachments may contain confidential and privileged information. If you are not the intended recipient, please notify the sender immediately by return e-mail, delete this e-mail and destroy any copies. Any dissemination or use of this information by a person other than the intended recipient is unauthorized and may be illegal.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/14/2015 4:24:32 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA Reform Bill
Attachments: Udall-Vitter Draft - SLC word doc - (1-14-15).doc; Udall-Vitter Draft - SLC redline to September draft - (1-14-15).doc; Udall-Vitter Draft - SLC - (1-14-15).pdf

Jonathan,
What's your sense of timing for sitting down to go through the new draft together. Looks like we'll need to read through the new draft and reconcile it with the comments on the old draft. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, January 14, 2015 9:37 AM
To: Jones, Jim; Vaught, Laura; Distefano, Nichole
Subject: January Draft

FYI...

We didn't get the EPA technical assistance until yesterday, so we didn't have time to include comments/responses to that in what we gave to legislative counsel Monday night, beyond what we have verbally talked about.

Here is the version we are now working with and will want to sit with your team to review.

It shouldn't be dramatically different from what you have reviewed.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/14/2015 2:39:23 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: SEPW TA Request on TSCA Reform

Personal Phone / Ex. 6 code Personal Phone / Ex. 6

On Jan 14, 2015, at 9:35 AM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

That works great for both Richard and I. Can you please provide a call in number?

Thanks very much Sven

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, January 14, 2015 9:27 AM
To: Karakitsos, Dimitri (EPW)
Subject: Re: SEPW TA Request on TSCA Reform

Does 2 pm today work?

On Jan 13, 2015, at 6:01 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven,

Appreciate you reaching out. Sorry for the delay in my response today I was trying to get a few things in order prior to getting this scheduled. Any chance 11am, 1pm, or 2pm could work tomorrow? I would also like to include Richard Dennison in the call if that is not a problem for you all. He and I had a good discussion today with some of the folks directly concerned with this and I think he has a great grasp of what they need and what he believes would work for everyone. Those times work for both of us if any of them work for your folks.

thanks,

Dimitri

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, January 13, 2015 10:42 AM
To: Karakitsos, Dimitri (EPW)
Subject: FW: SEPW TA Request on TSCA Reform

Dimitri,
We're still not sure what you are trying to achieve. Let's have a call with our TSCA lawyers to go through it and see whether the proposed language does what you want. Best times today or tomorrow? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, January 09, 2015 4:43 PM
To: Vaught, Laura
Subject: FW: SEPW TA Request on TSCA Reform

Laura,

Attached is the TA we received which I mentioned earlier. Would love to get to the bottom line on this paragraph as soon as possible. Please let me know if you want to discuss or have any questions.

Thanks,

Dimitri

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, December 10, 2014 3:51 PM
To: Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TA Request on TSCA Reform

Dimitri,
Below is the requested technical assistance on the additional language. The technical assistance on the larger, separate package should be ready to send to you and the others by the end of the week. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill and the draft language. Please let me know if any additional questions. Thanks,
Sven

Nothing in this section shall be construed as requiring the Administrator to modify or withdraw~~,~~ any rule or order under section 5 or 6 of this Act, or as modifying the effect of this section as enacted prior to the effective date of the Chemical Safety Improvement Act with respect to any substance for which ~~on~~ any rule or order has been promulgated or issued under section 5 or 6 of this Act prior to the effective date of the Chemical Safety Improvement Act.

1. Regarding the first part of this paragraph: "Nothing in this section shall be construed as requiring the Administrator to modify or withdraw, any rule or order under section 5 or 6 of this Act,"

    a. the preservation of existing EPA regulations and orders is an issue that doesn't have anything to do with state preemption and it should therefore be addressed elsewhere in the bill. It needn't actually appear as a codified amendment to TSCA. It could simply be a provision of CSIA.
    b. Also, if only rules and orders under section 5 and 6 are preserved, is the intent that enactment of CSIA would oblige EPA to modify and/or withdraw current EPA rules and orders issued under other sections of current TSCA?

2. Regarding the revisions to the latter half of this paragraph: "[Nothing shall be construed as] modifying the effect of this section as enacted prior to the effective date of the Chemical Safety Improvement Act with respect to any substance for which any rule or order has been promulgated or issued under section 5 or 6 of this Act prior to the effective date of the Chemical Safety Improvement Act."

    a. These revisions to § 18(c)(3) would create a bifurcated preemption scheme, in which both pre-CSIA section 18 and post-CSIA section 18 remain effective law.
    b. Pre-CSIA section 18 would continue to apply indefinitely, even though it will be deleted from the current U.S. Code, with respect to a major category of chemicals (e.g., all those for which 5(e) orders or SNURs have been issued pre-CSIA).

c. For example, with respect to a SNUR'd chemical: Even if EPA subsequently determined the chemical was safe, or issued a 6(d) rule, CSIA preemption would never apply to such a chemical substance. Was that the intent?

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
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202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Wednesday, December 10, 2014 9:48 AM
To: Kaiser, Sven-Erik
Subject: Re: SEPW TA Request on TSCA Reform

Morning Sven - just wanted to follow up on this and see if there are any thoughts or suggestions or major issues? I have a meeting with some folks in a bit and I know they are going to ask so I just wanted to check on the status of this and the larger request if you can share any updates.

Thanks,

Dimitri

From: Karakitsos, Dimitri (EPW)
Sent: Thursday, December 04, 2014 04:03 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: SEPW TA Request on TSCA Reform

Yes it is separate, it can go to both of us or just me, either way we will be discussing at some point. Just a longstanding issue that we need to do some homework on. Thanks again

---

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 04, 2014 3:58 PM
To: Karakitsos, Dimitri (EPW)
Subject: SEPW TA Request on TSCA Reform

Dimitri,
Thanks for the additional language. Is this separate from the language that Jonathan sent over? Does the response go only to you? Best,
Sven

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To: Kaiser, Sven-Erik
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Dimitri J. Karakitsos
Republican Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Message

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Sent: 1/14/2015 1:27:54 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: SEPW TA Request on TSCA Reform

Dimitri,
I'm checking on availability. Thanks,
Sven

On Jan 13, 2015, at 6:01 PM, "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven,

Appreciate you reaching out. Sorry for the delay in my response today I was trying to get a few things in order prior to getting this scheduled. Any chance 11am, 1pm, or 2pm could work tomorrow? I would also like to include Richard Dennison in the call if that is not a problem for you all. He and I had a good discussion today with some of the folks directly concerned with this and I think he has a great grasp of what they need and what he believes would work for everyone. Those times work for both of us if any of them work for your folks.

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Sent: Wednesday, December 10, 2014 9:48 AM

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Subject: Re: SEPW TA Request on TSCA Reform

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Dimitri

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Subject: Extra TA

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Dimitri J. Karakitsos
Republican Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/13/2015 5:37:29 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
Subject: TSCA Reform TA on 9.3.14 draft of CSIA rev 12.3.14
Attachments: EPA.TSCA TA.Issues Digest on 9_3_14 draft rev 12_3_14.docx; EPA.TSCA TA.Line by line on 9_3_14 draft rev 12_3_14.docx

Jonathan and Dimitri,
Please find attached the requested technical assistance on the 9.3.14 draft of CSIA as revised on 12.3.14. There are two files – a summary of issues and a line by line version with edits and comments directly on the text. This technical assistance is provided by EPA in response to your request and intended for your use only. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

Full Digest of Drafting Issues with
December 3, 2014 Draft of Udall-Vitter

Note #1: Bracketed citations [A###] are references to the ID numbers of inline comments marked on the 9/3/14 draft of CSIA. Please refer to that document for further details.

Note #2: Some comments (generally comments on post-September revisions to CSIA) do not have a bracketed cross-reference back to inline comments on the 9/3/14 draft of CSIA.

Note #3 The ID numbers assigned to particular comments on the 9/3/14 draft of CSIA might not be visible in the "Print Preview" mode of Microsoft Word. Switch to "Draft" mode, or print out the document, to view comment numbers.

Residual Language from Current TSCA:

- Section § 9, largely un-amended by the bill, is in significant tension with other portions of the bill. For example, the section 9 process of referrals to other agencies may make it impossible for EPA to meet the § 6(a) risk management deadlines for referred chemicals; relatedly, EPA would be unable to act on a referred chemical that it found did not meet the safety standard if the other agency disagrees, leaving the chemical in limbo. In general, the principle underlying § 9 – that TSCA is a "gap filler" – may not be as good as good a fit under CSIA.
- Remaining references to "unreasonable risk" (e.g., at § 5(d)((3)(H) and § 12(a)(4)) should be replaced by references to the "safety standard," to make clear that the statute is referring to modified concept of "unreasonable risk" that is health only. [A105, A147]
- The bill would retain § 2(b)(3) policy language, which suggests that balancing of economic costs is a uniformly relevant consideration in all TSCA actions, even though consideration of cost is elsewhere barred for some actions (e.g., safety determinations) [A1].

Definitions:

- The definition of "information" at § 3(7) is overly narrow. This could result in documents not qualifying as "information" on the grounds that they are not related to chemical hazards, use, or exposure (e.g., customer lists). These documents could not be CBI under TSCA section 14, since that section only relates to "information." [A4]
- The phrase "reasonably known" in "intended or reasonably anticipated conditions of use," in § 3(8), is problematic because it suggests some sort of knowledge might be "unreasonably known", and thus excluded. This doesn't make sense. Also, the list of possible issues should be joined with an "or", not an "and" [A5, A6]
- With respect to the phrase "organizations and entities" in the penalties provision of §16, it is not clear what the intended distinction is between an "organization" and an "entity." Could a natural person be an "entity"? [A231]

Development of policies/procedures/guidance:

- The bill requires EPA to establish guidance that is binding on outside entities (§§ 14(d)(1)(C), 14(d)(2), 14(d)(3), 14(e)(4)(A), 14(e)(5)(A)) [A188, A192, A195, A197] and the Agency itself (§§

ED_002117_00009858-00001

3A(g)(3)(C), 3A(g)(3)(D), 3A(h)(2)(C)(ii), 3A(h)(2)(C)(iv), 4A(b)(1) [A15, A16, A27, A31, , A56]. "Guidance" in the general administrative law context connotes a non-regulatory document that does not impose binding requirements, so the bill's use of "guidance" is anomalous. The most concrete effect of making these guidance documents binding is that they (at least the ones imposing requirements on outside entities) will likely be deemed judicially reviewable, unlike guidance in other contexts. In addition, the requirements to establish guidance to bind the Agency appears to leave room for little or no discretion on the Agency's part; thus, it may be more efficient to simply build those directives into the statute. [A15, A16, A27, A31,, A56]

- In § 4(d)(3)(B), why not simply direct that the applicant provide fair and equitable reimbursement, instead of directing that EPA direct that the applicant provide fair and equitable reimbursement? [A42]
- Is there a reason why the safety determination policies and procedures are to be established by rule, at § 3A(h)(2)(A), whereas the other policies and procedures in section 3A are apparently to be established via guidance (with required notice and comment)? [A24]
- The bill uses the terms "policies," "procedures," "guidance," and "guidelines" in different combinations in different places throughout the bill, e.g., compare § §3A(b), 3A(c)(2), and 3A(d), but it is not clear whether this reflects any definite differences in intention. If not, the litany of terms should be standardized to avoid unintended inferences (e.g., that EPA is required to provide notice and comment on all policies, procedures and guidelines, but only on significant guidance). [A8, A9, A12]
- At § 3A(f), the bill requires EPA to consider a broad range of hazard and exposure information "in making any decision" under §§ 4, 4A, 5, or 6, despite the fact that some of those underlying provisions appear to allow EPA to make decisions on a narrower basis (e.g., per section 4A, EPA can identify a chemical as high priority based on either hazard or exposure). [A13]
- In § 3A, the criteria for what will be adequate policies/procedures/guidance are often nebulous. [A10, A11, A25, A26, A28, A29, A30]
- The requirement to develop guidance in § 8(a)(5) seems to be a vestige of earlier versions. The bill doesn't indicate any substantive topic for this guidance. [A119]

<u>Testing:</u>

- Compliance-related testing is mentioned as a possible feature of § 6(d)(3(B)(iii) risk management, and testing under § 4 is mentioned (in § 5(d)(5)(C)) as a possible response to a lack of information for evaluating a PMN or SNUN. Yet neither of these reasons for requiring testing is found in the list of valid grounds for testing at § 4(a)(1). [A84, A103].
- The Interagency Testing Committee (ITC) created in § 4, retained in CSIA, may be obsolete, given the new FACA created in § 3A, and the new provisions for information development and safety determinations [A32]
- There is a lack of clarity on the intended scope of the animal welfare provisions: Is the concern with all animals, or just vertebrate animals? [A17, A36, A37, A38, A39]
- Section 3A(g)(4)(C) contains an overly narrow paraphrase of the scope of the type of tests authorized under section 4, and the scope of the purposes for which testing would be conducted [A21, A22]
- The specification of the duration of a test rule/order (or exemption), at § 4(d)((1)(B), is garbled; e.g., the provision for termination of exemptions would require termination of all exemptions even if the entities designated to conduct testing meet all testing obligations [A40, A41, A43]

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Prioritization

- The heading of §4A(a): "Establishment and List of Substances" does not make sense. What is EPA being directed to establish? [A44]
- The practical significance of the amendment to § 4A(a)(1) is likely to be a matter of confusion within EPA and the courts. Elsewhere in the bill EPA is directed to establish "criteria". Here EPA is being directed to establish "explicit criteria." What is the difference between a regular criterion and an explicit criterion?
- At § 4A(a)(2)(A)(i), the directive to "take into consideration" the list doesn't make sense. How can EPA take the list into consideration before it even establishes the list? [A45]
- §4A(a)(2)(A)(ii) should be deleted, not amended. The bill already imposes an *obligation* to conduct safety assessments and safety determinations at § 6(a). Including an *authorization* to conduct safety assessments and safety determinations serves no purpose, and could compromise the intended operation of § 6. [A46]
- In § 4A(a)(2)(B), the bill should refer to "chemical substances" not "substances," unless the intention is to imply that EPA should be conducting safety assessments of mixtures.
- §4A(a)(3)(A)(i) and (ii) are garbled. Leg counsel added the phrase "In carrying out paragraph (1)", but this makes no sense as drafted. Paragraph (1) relates to the promulgation of the process rule. How can EPA consider particular substances when promulgating a process rule? If the intention is for EPA to incorporate the requirements of paragraph (3) into its process rule, when carrying out paragraph (1), that should be more clearly stated. [A47, A48]
- It is odd for §4A(a)(3)(A)(ii)(I)(bb) to require hazard <u>and</u> exposure, while §4A(a)(3)(ii)(II)(bb) requires hazard <u>or</u> exposure. This would seem to make it easier for EPA to prioritize chemical substances that have already been banned, and thus would be less likely to need further study. [A49]
- The repopulation provision at § 4A(a)(3)(A)(iii) only kicks in when substances are removed because they have safety determinations completed, creating the potential for the high priority list to shrink if substances are removed because they were simply re-prioritized from high to low. [A50]
- The repopulation provision at § 4A(a)(3)(A)(iii)(II) presupposes the existence of unlisted "high-priority substances," from which EPA can draw for repopulation purposes. Does this make sense under the structure of § 4A? As a general matter, it seems that what makes a substance "high-priority" is being placed on the high priority list. But if that is true, then § 4A(a)(3)(A)(iii)(II) seems oddly circular.
- In § 4A(a)(3)(B), it is inconsistent to trigger the start of prioritization based on when the prioritization process rule is effective, given that the initial priority list is required to be established before then. [A51]
- §4A(a)(3)(C) should be deleted, not modified. EPA already has all the authorization it needs to act on chemical substance categories, under § 26(c). Reiterating the authority in a more limited context would either have no effect or have the effect of impliedly limiting EPA's existing authority. [A52]
- § 4A(a)(4)(C) requires EPA to consider significant changes in use conditions in addition to intended or reasonably anticipated uses, which is confusing since significant changes that might relevant to prioritization of a chemical should already be included in intended or reasonably anticipated conditions of uses. [A53]

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- §4A(a)(4)(F) was garbled by leg counsel amendments and needs to be fixed so that it is comprehensible. Unless fixed, this could make it difficult to incorporate new production volume data into the prioritization process [A54]
- The operation of § 4A(b) would be clearer if it were a requirement about how EPA should prioritize chemicals, rather than a requirement about how EPA should write rules about prioritizing chemicals. [A56]
- The bill indicates that EPA can base a high priority decision on the potential for either high hazard or widespread exposure (§ 4(b)(3)), but confusingly also indicates that EPA must apply a range of criteria in prioritizing (§ 4A(b)(1)) and integrate any available hazard and exposure information (§ 4(b)(2)). This tension is compounded by a provision retained from current TSCA in section 2, requiring EPA to consider the environmental, economic and social impact of any action under TSCA (§ 2(c)), despite the fact that the prioritization provisions don't seem to require such an analysis. [A57]
- In § 4A(b)(4), delete "applicable." Referring to the applicable safety standard suggests that there are multiple safety standards, whereas § 3 defines only one safety standard. [A59]
- In § 4A(b)(5), the bill discusses specific criteria for deferring a prioritization decision, but this is somewhat misleading because there would generally not be any underlying deadlines for those decisions. The bill also requires, at § 4A(b)(7), notice and comment on any deferral of a prioritization decision, which seems of questionable value since there would generally not be any underlying deadlines upon which to seek comment. This provision (and § 4A(c)(5)(A)(ii)) also raises the question whether EPA can defer a state expedited prioritization request beyond the 180-day deadline provided). [A60]
- Overall, §4A(b)(9) suggests that state regulation would weigh *in favor* of making a chemical substance a high priority for a safety assessment, since this provision mandates the automatic delivery of risk assessment-related data from the state to EPA. The addition of this provision makes the retention of §4A(a)(4)(F), which suggests the opposite, confusing.
- §4A(b)(9)(A): "restrict or prohibit" doesn't make sense. A prohibition is a kind of restriction.
- §4A(b)(9)(A): States don't "enact" administrative actions. They take administrative actions, or adopt regulations. Only statutes are enacted.
- The requirement in (9)(A) that a state submit "any relevant information available to the state", in conjunction with some of the specific information elements listed, suggests that states may need to assemble information that they did not actually consider in regulating. Is that intended?
- §4A(b)(9)(B) indicates that the State should submit information *prior* to enactment, yet the duty of disclosure (under (9)(A)) is based on the State having already *enacted* a statute or administrative action. When is paragraph 9 triggered? Before or after the State acts?
- §4A(b)(11), "distribution" should be replaced by "distribution in commerce," which is the TSCA defined term. This should be done globally throughout the bill. [A63]
- The procedures governing "expedited prioritization petitions," at § 4A(c)(1), suggest that EPA could keep the 180-day clock from ever even starting to run if a request for low-priority information is not accompanied by "relevant information justifying" the prioritization. Was that the intent? [A64]
- §4A(c)(3) may be inadequate to countermand (b)(8). The issue isn't whether the state is required to submit new information. The real issue (only implicitly addressed by §4A(c)(3)) is whether EPA is authorized to grant the petition even though the state doesn't submit new information. [A65]

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- In §4A(d)(1)(A) the phrase "high priority for a safety assessment and safety determination" should be shortened to the defined term "high priority substance".
- The requirement that EPA develop guidance specifying the criteria to be used for industry petitions in §4A(d)(1)(B) creates two issues:
    - Why would decisions on such petitions be made based on criteria other than the general prioritization criteria? Aren't the ultimate decision criteria those appearing in §4A(b)(3) and (4)? This issue is compounded by §4A(d)(3)(B), which appears to distinguish high priority decisions made pursuant to industry petition from high priority decisions made under §4A(b)(3) (rather than treating such petitions as requests for action under §4A(b)(3)) . This relates to the above comment regarding confusion over what the criteria are for prioritization decisions generally.
    - This provision appears to call for EPA to establish requirements through guidance. In ordinary administrative law usage, guidance cannot establish requirements.
- § 4A(d)(2) appears to indicate that the existence of state regulation would militate in favor of a high priority designation, which seems inconsistent with §4A(4)(H).
- In § 4(d)(5), it would be helpful to more clearly specify the way in which § 4A(a)(3)(A)(iii) does not apply. Presumably, when EPA completes a safety determination for a chemical substance designated as high priority at the behest of industry, there would be no obligation to repopulate.
- If a chemical substance is added to the high priority list at industry behest, under § 4(d), would that chemical count as one of the ten that EPA has to have designated? Section 4(d)(5) suggests that the answer is no. Since there would be no repopulation triggered when the safety determination is completed, that suggests that industry-requested high priority chemicals would not count towards EPA's minimum list of 10 ongoing priority chemicals. Was that the intention?
- §4A(e) still contains a cross reference to § 18(e)(6)(B), which has been deleted. This subsection should be revised accordingly.

<u>Section 5 Notices and Review:</u>

- The bill is insufficiently clear at § 5(c)(1) about exactly what information needs to be submitted in the PMN about intended conditions of use. What does the PMN submitter need to provide? Just *some* information regarding conditions of use? *All known* information? All information *known or reasonably ascertainable?* [A68]
- The bill isn't sufficiently clear (at §§ 5(d)(1)(A)(iii), 5(d)(6), and 5(d)(7)) on whether EPA *always* makes an affirmative determination on every incoming PMN/SNUN. Also, the bill doesn't spell out what happens if EPA determines that a chemical isn't likely to pass the safety standard, but fails to develop a risk management response within the review period deadline. Does the chemical just move forward by default? Or is it barred from commerce until EPA takes appropriate risk management? [A70, A86]
- 40 CFR 720.45 and 720.50 currently interpret current TSCA § 5(d)(1), relating to the content of PMNs. The bill would replace § 5(d)(1) itself with a cross-reference to the regulations (§ 5(c)(1)(A). This is confusing and seems to serve no purpose [A67]
- In § 5(d)(4)(A) "prohibit or restrict" doesn't make sense. A prohibition is a kind of restriction. A similar comment at § 5(d)(4)(C)([A72, A77]
- In § 5(d)(4)((B)(i), it doesn't make sense to include "for a new use," in the list of covered activities, because you've already included "use" in general [A74]

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- SNURs that broaden the applicability of consent orders (§ 5(d)(4)(B)) should be "consistent with" the consent order, not "in compliance with" the consent order. [A75]
- §§ 5(d)(4)(C)(i) gives EPA authority to require warnings and instructions with respect to use, distribution and disposal, not but manufacture and processing. Was that intended? [A78]
- Should § 5(d)(4)(C)(ii) apply to manufacturers *or* processors? It currently specifies a requirement that would apply to manufacturers *and* processors. [A79]
- Sections 5(d)(4)(C)(iii) and 5(d)(4)(C)(iv)(I) seem to be subsumed by 5(d)(4)(C)(v), which makes the overall paragraph confusing to read [A80, A801].
- Why does § 5(d)(4)(C)(v) refer to "a prohibition or other appropriate restriction," while § 5(d)(4)(C)(iv) refers to "a prohibition or other regulation"? The language should be standardized unless a distinction was intended. [A82].
- Regarding workplace exposure, it may be hard to complete required OSHA consultation (§ 5(d)(4)(D)) within statutory timeframe for evaluating PMN [A83]
- What caveat is intended to be supplied by the phrase "Subject to paragraph 4(B)," in § 5(d)(6)? [A85]
- Language establishing that SNUN provisions apply to processors is missing from §§ 5(d)(6) and 5(d)(7). [A87, A88,]
- Language relating to processors should be stricken from the section on notice of commencement (NOCs) at § 5(e). Since an NOC is a signal to add a chemical to the inventory, only manufacturers file an NOC, following a PMN. Processors may need to submit a SNUN, but there is no subsequent obligation to file an NOC, since the chemical substance is already on the inventory. [A89]

<u>Section 6: Safety Determinations and Risk Management</u>

- The subsection redesignation at the beginning of section 6 seems wrong – it seems to skip from subsection (f) to (h). Perhaps new "(j) Prior Actions" was intended to be "(g) Prior Actions"? [A92]
- It would be better if the word "a" were changed to "any necessary" in § 6(a)(4), since a regulation will not always be needed. [A93]
- It would be better if "and any deferral" were changed to "including any deferral" in § 6 (a)(5), since a deferral is a form of extension. [A95]
- § 6(b)(1)(A) refers to "policies and procedures". Elsewhere in the bill, various recitations of the terms "policies," "procedures," "guidance," and "guidelines" appear, in a variable fashion. Here (and throughout the bill) the litany of of "policies", procedures", "guidance", and/or "guidelines" and the like should be conformed. [A96]
- The reference to the "intended or reasonably anticipated conditions of use" in § 6(c)(1)(B)(i) is redundant, since this concept is already incorporated into the safety standard. Including it twice in an inconsistent manner could dilute the application of the definition elsewhere. [A97]
- The distinction among restrictions on one hand, and bans and phaseouts on the other, in § 6(c)(1)(B) is confusing, since bans and phaseouts are a form of restriction (and are included among the restrictions enumerated in § 6(d)(3)). [A98]
- In § 6(c)(4), it is unclear whether the guidance is to be applied at the Administrator's discretion, or whether the "draft safety assessment" is to be applied at the Administrator's discretion.
- The provision directing EPA to "apply" "draft safety assessments" at the Administrator's discretion may suggest that such assessments are to be given preferential weight in the EPA safety assessment process. If this is not intended, the draft could be revised to direct the

Administrator to "develop guidance to assist interested persons in developing *their own* safety assessments" (rather than "draft safety assessments"), and to provide that such assessments are "to be *considered*" (rather than "applied") at EPA's discretion.

- Unless there is a specific reason to think that EPA would be otherwise barred from using national consensus standards in the § 6(c)(4) guidance, drop the authorization. Authorizing activities that EPA is already authorized to do actually has the potential to limit EPA's authority.
- In § 6(d)(2)(C), the reference to OSHA consultation on section 6 rules doesn't follow from the preceding text . [A99]
- § 6(d)(3)(A) gives EPA authority to require warnings and instructions with respect to use, distribution and disposal, not but manufacture and processing. [The same is true for § 5(d)(4)(C).] Was that intended? [A101]
- The word "and" in § 6(d)(3)(B) should probably be "or". [A102]
- § 6(d)(3)(D) seems to subsume § 6(d)(3)(C) and (E). (Similarly 5(d)(4)(C)(v) seems to subsume 5(d)(4)(C)(iii) and (iv)). [A104]
- Reference to "unreasonable risk" in § 6(d)(3)(H) should be replaced by references to the "safety standard," to make clear that the statute is referring to the modified concept of "unreasonable risk" that is health only. [A105]
- § 6(d)(5) suggests that exemptions from restrictions can be granted only in the initial rulemaking establishing the restrictions, although it doesn't expressly say that and that may not be the intent: § 6(d)(5)(A) is ambiguous in this regard, and a number of procedural and substantive requirements for establishing exemptions in § 6(d)(5)(B) through (F) apply only if an exemption is established as part of the initial rulemaking. Is that intended? [A106, A107]
- § 6(d)(5)(D) is very confusing. [A108]
- § 6(d)(5)(E) could suggest that EPA needs to establish that the safety standard is being met in order to justify a § 6(d)(5) exemption, or it could create confusion as to what the safety standard requires. [A109]
- § 6(d)(5)(F)((ii) authorizes EPA to extend, modify or limit exemptions – authority that EPA has anyway and may actually be limited by this provision. [A110]
- It is strange to have a defined time limit, at § 6(d)(5)(F)(iii)(II), on the length of an exemption extension, when there is no such time limit on the original exemption. Also, why limit this principle to exemptions from a ban or phase-out? [A111]

<u>Reporting and Inventory Issues</u>

- Instead of directing EPA to use its existing § 8 authority to develop information necessary for §§ 4 and 6, the bill adds an entirely new reporting authority (§ 8(a)(4)) to do the job. 8(a)(4) reporting is such as "would assist in the effective implementation of this Act," while existing § 8(a)(1) reporting is based on what EPA may "reasonably require." There are other subtle differences between the new and existing authorities. It would be better to modify § 8(a)(1) as needed, instead of creating a new authority from scratch. Creating an entirely new, partially overlapping authority is liable to generate confusion and litigation. [A113, A114, A116, A117, A118]
- Revisions to § 8(e), authorizing the public to submit information to EPA, confer no substantive benefit, as the public needs no additional legal authority to submit information to EPA. Furthermore, such provisions could confuse existing *mandatory* reporting provisions in § 8(e) . [A141, A142]

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- In § 8(b)(3)(A)(i), EPA is to "maintain" certain nomenclature conventions in Section 8 in perpetuity, but these conventions might not remain useful into the future. [A120]
- In § 8(b)(4), it would be more straightforward if the bill itself implemented the Inventory Reset, instead of directing EPA to write rules that will implement the Inventory Reset, since the bill leaves EPA little or no discretion [A121, A122, A123, A130]. [Note: this is similar to the issue identified above re directives to develop guidance with little or no discretion.]
- In § 8(b)(5)(B), it doesn't make sense to "update" the list of active chemicals based on information in CDR reports. The CDR report should never be EPA's first indication that a chemical has become active, since a notice to intent to activate should always precede manufacture, under § 8(b)(5)(C). [A131, A132]
- Under § 8(f)(2), there is no way for active substances to ever become "inactive" again. Was that intended? [A143]

<u>CBI and Other Information Management Issues</u>

- Transparency requirements under § 5(g)(1) are overbroad; they cover "all notices, determinations, consent agreements, regulations, and orders of the Administrator," even ones that have nothing to do with TSCA [A91].
- The bill mixes together the following two CBI standards: "likely to harm the competitive position of the person," § 14(d)(1)(C)(i)II)(bb) or "likely to cause substantial harm to the competitive position of the person" § 14(d)(1)(B)(iii). This needs to be standardized. The latter standard is the familiar standard from CBI case law. [A190].
- Language barring CBI protection for chemical IDs that aren't on the confidential inventory, at §§ 8(b)(4)(F), 8(b)(5)(C)(II), and 14(c)(5), has multiple drafting problems. For example, either the chemicals are on the public inventory (in which case they can't be CBI because they are already disclosed) or they aren't yet in commerce at all (in which case it isn't clear why CBI protection is inappropriate). [A127, A128, A129, A133, A134, A181]
- A provision ensuring that information releasable under the bill is not subject to protection under other provisions of law (§ 14(c)(2)) applies only to a portion of the releasable information, which could result in the withholding of information the drafters intend to be releasable [A175]
- In places, the bill confuses the issue of *whether something is CBI* with determinations of *whether release of CBI is warranted* under. Confusion on this distinction may give rise to problems implementing the CBI program. ([A200, A220, A224, A226]. For example:
    - EPA is allowed an exception, at § 14(e)(9) to release CBI if the information is publicly available. But publicly available information isn't even supposed to *be* CBI.
    - In § 14(g)(2)(A), the exception subsection § 14(e) is listed as a CBI determination provision, whereas it is really a provision for the release of information that is *CBI*.
    - In § 14(g)(2)(B)(ii), provisions for notifying data owners about the release of CBI are mixed with provisions for notifying data submitters about denial of CBI claims.
    - It is not clear whether the judicial appeals provision (§ 14(g)(3)) applies only in the case of denials of CBI claims, or also to release of information that is CBI.
- Shouldn't it be possible for a submitter to assert a CBI claim that would sunset in fewer than 10 years? Section 14 allows CBI claims to be voluntarily withdrawn at any time, so it is odd to not have the ability to specify an automatic sunset period, less than 10 years in length. [A124, A135, A202, A207]

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- New language at § 8(a)(7), relating to public availability of inventory information, seems to add very little substantive, and like it would function primarily as a litigation hook. [A137, A138, A139, A140]
- The paragraph discussing the segregability of CBI from non-CBI in a single document, § 14(c)(4), is garbled and probably unnecessary [A180]
- The CBI certification provision at § 14(d)(4) suggests that there would need to be CBI certification as to the veracity of the underlying information, not just the veracity of the basis for claiming CBI. This probably wasn't intended. [A194]
- The 5-year deadline to complete review of CBI claims on active chemicals, § 8(b)(4)(E), is not (but presumably was intended to be) limited to claims in existence at the time of the inventory reset [A125]
- The structure of §14(b)(6) doesn't make sense. Section 14(b)(6) is supposed to define types of information are presumptively not CBI. But qualifying for § 14(b)(6) itself requires an EPA determination. What's the value of a presumption of non-CBI status that itself requires a determination of CBI status? If one could make the determination, one wouldn't even need § 14(b)(6). [A172]
- § 14(b)(7) assumes that all new chemicals come in via a PMN notice; it needs to also account for § 5 exemption chemicals. [A173]
- § 14(c)(3)(D) is garbled (description of certain information not subject to CBI protection) [A179]
- It is unclear what is being required to be certified where bill requires CBI certification that "information is not required to be disclosed . . . in connection with 1 or more uses subject to this Act." [A186]
- § 14(d)(2) refers to paragraphs (1) through (7) of subsection (b), but there are no other paragraphs in subsection (b). Why not just refer to subsection (b)? [A191]
- The bill presumes that the data submitter will be in a position to ask emergency personnel to complete confidentiality agreements, § 14(e)(6)(B), but doesn't actually obligate any notice to the data submitter of the intended release. Also, the bill presumes that it would be possible to negotiate an after-the-fact confidentiality agreement with the emergency personnel, but provides no legal incentive for such personnel to acquiesce in such agreements. [A198, A199]
- Deadlines for EPA processing of CBI claim extensions, at § 14(f)(1)(B)(ii)(II) could generate anomalous results if there is a delay between submission and receipt of a request for an extension. If EPA receives the statement after it is submitted, EPA action could come after the expiration of the claim. It would probably be better if the deadline for this obligation were the date of expiration. [A206]
- Reference to CBI substantiation required "to comply with" a FOIA request, § 14(f)(2)(B)(i), does not make sense. While FOIA imposes requirements, a FOIA request does not. Similarly at § 14(f)(2)(B)(ii), 5 USC § 552(b)(4) does not literally set forth "requirements" [A211, A212].
- 14 § (f) and (g) conflict on whether requests for renewals of CBI claims on information types listed under (b) are subject to EPA review, and the bill appears to require review of all CBI renewal requests even though EPA is obligated to review only 25% of initial CBI claims [A205, A215]
- Does it make sense to perpetuate arguably antiquated requirements from current TSCA that notification be by certified mail? See § 14(g)(2)(A). [A223]

<u>Import/Export</u>

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- Section 13(b) contains a reference to whether certain chemical substances or mixtures are "subject to this Act." The way to exclude a substance from TSCA jurisdiction under § 3 is to provide that it is neither a chemical substance nor a mixture. As stated, this suggests that another layer of possible jurisdictional exclusions, beyond those in § 3. [A160]
- Section 13(b)(4) establishes a confusing and legally novel replacement for the general concept of fair notice of regulations published in the *Federal Register*. Notice must be presented in a manner "that would be readily understood in import transactions." [A166]
- The import ban provisions at § 13(a)(1) are stated in an overly complicated manner and may result in unintended consequences (i.e., they suggest a duty to conduct safety determinations on mixtures, that judicial orders issued under section 7 are not orders "under this Act", and they eliminate the requirement to refuse entry of PCBs based on the statutory ban) [A155, A156, A157, A158, A159]
- For chemicals that do not or are unlikely to meet the safety standard, there is no obvious rationale for limiting export notification to those chemicals for which EPA has already established risk management regulations. See §§ 12(b)(1)(A) and (B). [A150, A152].
- As revised, TSCA § 12(a)(2) indicates that manufacture solely for purposes of export would be generally subject to regulation under TSCA, once a chemical is either found not likely to meet the safety standard (under § 5) or not to meet the safety standard (under § 6). This is a significant change from TSCA, under which exported chemicals are generally exempt from TSCA regulation unless unreasonable risk would result in the US. Among other things, this change could suggest that EPA could or should regulate on the basis of risks to human health and the environment outside the U.S. [A145]
- Including several specific references to coverage of "a chemical substance or a mixture containing a chemical substance," [§§ 13(b)(1)(A) and (B), § 13(c)(1), and 13(c)(2)], may suggests that chemical substances are not subject to regulation under other provisions of TSCA if they are contained in mixtures. [A149, A151, 167, 168]
- Was it intentional to drop § 7 action from the list of actions that would trigger export notification under § 12? [A148]
- Was it intentional to leave section 7 orders and Title IV orders outside the scope of the import certification in § 12(b)? [A161]
- Where the bill talks about articles containing chemical substances "subject to regulation under section 5 or 6," § 13(b)(2)(A), one can't tell if regulation is being used literally (i.e., just rules) or broadly (i.e., any action that "regulates" industry) Also, this seems to preclude requiring article certification on the basis of the article containing a constituent chemical that isn't on the Inventory. [A163, A164]

<u>Preemption</u>

- § 18(a)(1)(A) contains a typo: "to require ~~for~~ the development . . ."
- In § 18(a)(1)(B) (and throughout § 18) "prohibit" should not be distinguished from "restrict"; a prohibition is a form of restriction.
- The phrase "consistent with the scope of the determination" is used in § 18(a)(1)(B) to define the scope of preemption. It's not clear exactly what the intent is. If the intent is to limit preemption to the intended or reasonably anticipated conditions of use, that could be said more clearly.
- The wording of § 18(a)(1)(C) should be modified to reflect the fact that SNURs require notification of *manufacture and processing* for use, not for use itself.

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- What, if anything, does § 18(a)(2) provide that is not already stated in § 18(a)(1)? Saying the same thing twice is likely to generate confusion. If retained, it should be expressly limited to § 18(a)(1)(B).
- Similarly, §18(c)(1) and (c)(2) seem to be two competing drafts of the same basic provision. Covering the same ground twice, in slightly different ways, is confusing. Whatever § 18(c)(2) contains that § 18(c)(1) lacks should be incorporated into § 18(c)(1), and the rest of § 18(c)(2) should be deleted.
- Also, § 18(c)(1)(C) is a nullity as drafted; any state law that meets the criteria for exception (i.e., that it doesn't restrict manufacture, etc) will not qualify for preemption in the first place.
- Adopted "under the authority" of Federal law will not, read literally, cover most of the various environmental activities of states that are conducted under cooperative federalism regimes. A fuller approach would be: "adopted to implement, adopted under the authority of, authorized under, delegated pursuant to, or adopted to comply with any other Federal law"
- The litany of state actions that are not preempted in § 18(c)(2) is broader than the list of things that are preempted in the first place. Since (c) is an exception provision, it should not be broader than the provision it provides an exception from.
- The text of § 18(c)(3) is baffling: Why is there specific concern that revisions to § 18 would be construed as requiring EPA to withdraw or modify any pre-CSIA rules or orders? Also, the paragraph suggests the confusing view that TSCA Section 18 affects EPA actions, whereas the function of a preemption provision is actually to preempt certain *state* actions.
- If the intent behind § 18(c)(3) is to ensure the preservation of existing TSCA regulations and orders, even though TSCA itself is being amended, then that is an issue that should be built into the text of the bill, not codified as an amendment to TSCA itself. Also, if TSCA actions under §§ 5 and 6 are specifically preserved, that implies that other existing rules and orders issued by EPA may need to be withdrawn or modified as a result of CSIA. Was that the intention?
- The phrase "that prohibits or restricts chemical manufacturing, processing, distribution in commerce or use" in § 18(d) should be conformed to the wording in § 18(a)(1)(B).
- § 18(e)(1) and (2) provides for waiver of preemption for a state law that "relates to the effects or exposure to any chemical substance ". This phrasing is not used elsewhere in the bill. It should be conformed to the wording in § 18 (a).
- The word "and" in § 18(e)(1)(B) should probably be "or".
- The wording of the subparagraphs in § 18(e)(2) should be conformed to section § 18(e)(1) except where differences are intended.
- The wording of § 18(e)(2) suggests, by contrast with § 18(e)(1), that waivers can be granted for state laws that unduly burden foreign commerce. Is that intended? It may create international trade issues.
- It may be difficult to provide for notice and comment on state waiver requests in § 18(e)(4) in the timeframes imposed by § 18(e)(3).
- § 18(e)(6) provides that a preemption waiver for a state requirement imposed on a high priority chemical remains in effect until the EPA "safety assessment and determination is completed". It would probably be more consistent with the rest of the section to have the waiver remain in effect until EPA finds that the chemical meets the safety standard or until the effective date of EPA's control rule.
- It would be more consistent with the rest of TSCA to subject determinations on state waiver requests to section 19 than to create a separate judicial review provision in § 18(e)(7).
- The savings provision of § 18(e)(8) should be its own subsection, not a paragraph under § 18(e), since it does not pertain specifically to waivers.

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- Also, § 18(e)(8) contains a great deal of redundant, inconsistent and confusing text; it should be shortened to say once what is intended. For example:
    - Both § 18(e)(8)(A) and (B) contain language that could exempt from preemption state laws that are presumably intended to be preempted (e.g., § 18(e)(8)(A) exempts "any state or Federal statute creating a remedy for civil relief"; the intent is presumably to exempt only the civil relief provisions, not the entire statutes.)
    - The litanies of EPA actions that do not preempt various state actions differ in § 18(e)(8)(A) and (B), although there does not appear to be a reason for them to differ.
    - § 18(e)(8)(C)(ii), which provides that CSIA does not affect the authority of courts to make use of CSIA, seems inconsistent with § 18(e)(8)(C)(i), which does seem to limit the use of CSIA in judicial proceedings.

<u>Fees:</u>

- The requirement to establish fee rules within one year of enactment applies only to the section 5 fee rule (§ 26(b)(1)(A)), not to the fee rule for sections 4A, 8, and 6 (§ 26(b)(1)(B)). Was that intended?
- The imposition of fee obligations on manufacturers and processors that submit active chemical notices required under section 8 (§ 26(b)(1)(B)(i) and (ii)) may excuse from the fee pool manufacturers and processors that violated the section 8 notice requirements, or did not submit the required notices because were not aware they manufactured or processed active substances.
- Information management costs (including CBI management costs) apply to all information collected under TSCA. But the fees authority explicitly associates fees with just a subset of the authorities under which EPA collects data. For example, data submitters under §§ 4, 8(e) and 8(a)(1) are not explicitly referenced. Was that intended?
- The reference to "chemical" in § 26(b)(1)(B)(iv) (and throughout the bill) should be changed to "chemical substance".
- There are drafting errors in § 26(b)(2)(A)(ii): the references to § 5(c) should be to § 5(d), and an "and" should be "any". Also, the authority in this clause, to apply fees toward determinations on and regulation of new chemicals, should be expanded to cover the *review* of new chemical submissions as well, assuming that's what is intended.
- Isn't the requirement to "not collect excess fees" under § 26(b)(2)(D) redundant with the requirement in § 26(b)(3)(C) to collect no more than XX percent of the actual cost of conducting the fee-supported activities?
- If it is not redundant, what exactly would be the intended additional obligation to avoid "excess" fees under § 26(b)(2)(D)? What does this requirement add (if anything) to the prior requirement at § (b)(1)(A) that fees be "reasonable"? Does this mean absolutely no fees in excess of XX percent? If so, isn't that in conflict with next prohibition against retaining a "significant amount of unused fees"? The latter prohibition seems less stringent.
- Subsection (b)(3) - subparagraphs (A) and (C) are redundant. (A) directs the administrator to consider the costs, but (C) actually provides the direction that the Administrator should collect fees to support the costs of the program up to XX%.
- Subsection (b)(3)(D) – "establish appropriate criteria for manufacturers or processors that results in a <u>proportionate</u> assessment of fees" – proportionate to what? The size of the concern? The number of notices submitted per year? If proportionate to the size of the concern, is this duplicative with subsection (b)(3)(B)'s direction to establish lower fees for small businesses? If

the drafters don't have specific details in mind, does this provision contribute to anything the general command in § 5(b)(1)(A) that the fees need to be reasonable?

- There are two paragraph labeled § 26(b)(3)(E).
- In second paragraph labeled § 26(b)(3)(E), it would be clearer to simply say that FACA and NRA do not apply to these meetings, or alternatively say that "no obligation . . . is applicable with respect to these meetings"
- §26(b)(3)(F) seems to introduce another standard for fee-setting: "no more than reasonably necessary to defray" There may already be up to five other standards in the bill: (b)(1) "reasonable fees"; (b)(2): no "excess" fees; (b)(2) unused fees shall not be "significant"; (b)(3) "not to exceed XX percent"; and (b)(4) (for industry-sponsored chemicals) "sufficient to defray the costs."
- Overall, the standard (or array of standards) for fee setting should be simplified.
- There should be a reference to paragraph (E) (the first one) in § 26(b)(3)(F)(i), along with the reference to paragraph (C).
- What does § 26(b)(3)(F)(iii) add to § 26(b)(3)(F)(i)?
- In several places, the bill refers to activities identified or described "in paragraph (1)", where the intended reference seems to be to paragraph (2), which is the paragraph identifying activities the cost of which can be defrayed by fees: § 26(b)(3)(C), § 26(b)(3)(F)(i); § 26(b)(4)(B); § 26(b)(5)(B)(iv). It also appears that the reference to "that paragraph" in § 26(b)(3)(C) should be to paragraph (2). (In other places, the draft correctly refers to activities in paragraph (2): e.g., § 26(b)(3)(A).)
- It is not clear what the phrase "shall not otherwise be available for any purpose other than implementation of this Act" adds to § 26(b)(4)(B) – this obligation seems to be subsumed by the obligation not to use fees for any purpose not specified in paragraph (1). And as noted above, the reference to paragraph (1) seems probably intended as a reference to paragraph (2).
- In § 26(b)(4)(B), what does the following language mean? "...shall not be subject to restrictions on expenditures applicable to the Federal government as a whole." The intended effect should be stated more clearly here, so that it can be properly implemented.
- It appears that the reference to "this paragraph" in § 26(b)(4)(C) should be to "this subsection".
- The reference to "section" in § 26(b)(5)(B) is confusing, since it contemplates an audit specifically targeted to EPA's implementation of TSCA § 26. Was a broader scope (all of TSCA?) or a narrower scope (just fees collection under this subsection?) intended?
- § 26(b)(4)(D) seems to assume that there will be a defined amount of money specifically appropriated for TSCA implementation activities. However, Congress does not appropriate funds for particular agency functions. Implementing this provision as it is currently written will be legally and practically difficult as it will require the agency to rely on generally non-binding documents to assume how much Congress would have appropriated for those functions.
- In § 26(b)(4)(D), the bill should address whether fees are cut off in the event that overall appropriations to EPA drop below 201X levels, but the percentage budgeted for TSCA implementation *does not drop* below the percentage budgeted in 201X.
- There appears to be duplicative or garbled wording in § 26(b)(5)(B)(iv). The topic of interest is presumably the allocation of overhead, not the allocation of overhead allocation.
- There are two paragraphs numbered § 26(b)(5).

<u>Miscellaneous</u>

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

- Most of § 15 (Prohibited Acts) can now be deleted as redundant since penalties can now be attached to any violation of the Act of a regulation or order under the Act [A230]
- The litany of actions subject to judicial review in § 19 needs to be updated. Some actions have dropped out even though judicial review remains, and new types of action have been added without judicial review [A235]
- Recurring drafting problem: Imprecise or inconsistent use of key terminology, without a clear logic or evidence of intention: e.g., deviation from established terms of art found in TSCA statute, use of multiple words to describe a single concept in the bill itself [A2, A7, A14, A19, A20, A34, A35, A61, A73, A75, A96, A126, A136, A153, A154, A162, A169, A170, A177, A203, A204, A219, A222, A228, A232]
- Recurring drafting problem: "belt-and-suspender" provisions (i.e., provisions intended to reiterate a legal principle already established elsewhere). Because they are superfluous, and because the law presumes that no statutory text is superfluous, they add unnecessarily complexity to the bill and in some cases may actually have the unintended effect of watering down the very principles they are trying to reinforce. [A90, A115, A167, A168, A171, A174, A178, A182, A183, A208, A209, A210, A214, A217, A227, A239]
- The description of the standard of review for a *de novo* review of EPA's action on a § 21 petition seeking a § 4 rule (§21(b)(4)(B)(ii)(I)(aa)) doesn't make sense in light of the revisions to sections 4. EPA needn't establish that "the information available to the Administrator is insufficient . . .to perform an action described in section 4 or 6(d)" in order to justify issuing a rule or order under section 4. And yet that is what the petitioner must demonstrate to be the case. [A241]
- It seems to make little sense to add petitions for actions under § 5(d) and 6(d) to the litany of possible § 21 petition topics. Both of these provisions are already governed by statutory deadlines. A mandatory duty suit would make more sense for a party seeking a judicial remedy.[A242, A243]
- Recurring drafting problem: Text in wrong location, or mismatched with the label of the paragraph headings [A3, A18, A23, A146, A184, A185, A193, A196, A213, A229]
- Recurring drafting problem: Broken or incomplete cross-references [A33, A69, A71, A92, A94, A165, A176, A187, A189, A201, A216, A218, A221, A225, A234, A236, A237, A238, A240]

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Title: To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Chemical Safety Improvement Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(a) of the Toxic Substances Control Act (15 U.S.C. 2601(a)) is amended—

(1) in paragraph (2)—

(A) by striking "injury" and inserting "harm"; and

(B) by striking "and" at the end;

(2) by redesignating paragraph (3) as paragraph (4); and

(3) by inserting after paragraph (2) the following:

"(3) reform of this Act in accordance with the amendments made by the Chemical Safety Improvement Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief; and".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (7), (8), (9), (10) , (11), (12), (13), and (14) as paragraphs (9), (10), (11), (13), (14), (19), (20), and (21), respectively;

(2) by inserting after paragraph (6) the following:

"(7) INFORMATION.—The term 'information' means any qualitative, quantitative, or descriptive facts, data, analysis, or assessment related to chemical hazards, use, or exposure (including the nature and extent of exposure to a chemical substance), including from health

Commented [A1]: This retains the mandatory economic and social considerations of 2(c) for "any action." The bill is now clear that some actions (eg, safety determinations, and probably prioritization decisions) have no economic component, so this provision seems overbroad.

Commented [A2]: The bill uses "injury" numerous times, as does existing TSCA. Should be consistent, or have a reason for using injury in some places and harm in others.

Commented [A3]: 1.This appears under "Findings" (subsection (a)), but (3) provides implementation direction, not findings. 2. Consider simply providing that "This Act shall. . . ." Over time, the distinction between CSIA portions and earlier portions will be obscure, and CSIA largely replaces Title I in any event.

Commented [A4]: This definition is too narrow for the entire statute. Under this, commercial information cannot be CBI under section 14, because it is not information at all. There may be additional places in the bill and TSCA where "information" is also used more broadly.

and safety studies.

"(8) INTENDED OR REASONABLY ANTICIPATED CONDITIONS OF USE.—The term 'intended or reasonably anticipated conditions of use' means the circumstances the Administrator determines are those under which a chemical substance is intended, reasonably known, or reasonably anticipated to be manufactured, processed, distributed in commerce, used, and disposed of.";

Commented [A5]: What does "reasonably known" mean?

Commented [A6]: Should probably be "or".

(3) by inserting after paragraph (11) (as so redesignated) the following:

"(12) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the intended or reasonably anticipated conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (14) (as so redesignated) the following:

"(15) PUBLICLY AVAILABLE.—

"(A) IN GENERAL.—The term 'publicly available', with respect to information, means information that is—

"(i) generally accessible and available to the general public; or

"(ii) in the public domain.

"(B) INCLUSIONS.—The term 'publicly available', with respect to information, includes information that has been published in periodicals, books, print, an electronic format, or other media available for general distribution to any member of the public.

"(16) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the intended or reasonably anticipated conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(17) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the intended or reasonably anticipated conditions of use.

"(18) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance under the intended or reasonably anticipated conditions of use, including no unreasonable risk of harm to—

Commented [A7]: TSCA Title I generally uses "health", not "human health", although there is some of both. It would be most consistent with the portions of Title I being retained to use just "health".

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

Commented [A8]: Are policies and procedures something other than guidance? It appears from (a) that only significant guidance need be subject to notice and comment; does the same limitation apply to the obligation for policies and procedures?

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to make the basis of decisions clear to the public.

Commented [A9]: How about guidance? This section is inconsistent on the use of these three terms.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

Commented [A10]: Among other things, EPA has a duty to establish "procedures. . . [to] describe how the Administrator will ensure that. . . decisions made by the Administrator. . . are based on. . . procedures. . . employed in a manner consistent with the best available science." This is a fairly convoluted set of commands.

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

Commented [A11]: This seems to mixing concepts of WoE with systematic review, which would be one of the procedures, processes or methods by which the Agency typically ensures that assumptions/methods are clearly and completely described and documented, i.e. (ii) above

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

Commented [A12]: How do guidelines and policies relate to policies, procedures and guidance?

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating to the hazards and exposures of a chemical substance under the intended or reasonably anticipated conditions of use that is reasonably available to the Administrator, including information that is—

Commented [A13]: This seems potentially too broad. Eg, per 4A, EPA can apparently identify a substance as high priority based on the potential for either high hazard or high exposure. This provision seems to suggest that EPA must, eg, conduct an active search for exposure information before designating a chemical as high priority even for a high hazard chemical.

"(1) submitted to the Administrator pursuant to any regulation, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

Commented [A14]: Throughout, leg counsel changed "rule" to "regulation". Existing TSCA uses "rule" (eg, in the judicial review provisions in section 19, and in retained portions of section 5), and it will be confusing to to have both terms used. Suggest sticking with "rule".

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of human health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

Commented [A15]: 1.In ordinary usage, guidance cannot impose requirements. Guidance that does so would likely be viewed as a final, reviewable agency action. 2. This is one of many places in the bill where it might make more sense for the bill to impose the requirement on EPA, rather than to instruct EPA to impose the requirement on itself. There seems to be no exercise of discretion here.

Commented [A16]: Same comment re imposing requirements through guidance.

Commented [A17]: Vertebrate animal?

Commented [A18]: Note that paragraph 4 imposes direct requirements on EPA, and so is a little out of place in this section on policies, procedures and guidance.

Commented [A19]: (A) says EPA can employ tests or assessments. This suggests that screening level tests are required. Terminology should be consistent throughout this paragraph.

Commented [A20]: Are these something other than tests or assessments?

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential human health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by regulation, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

"(ii) require the Administrator—

"(I)(aa) to identify the hazards, exposures, intended or reasonably anticipated conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

Commented [A21]: These are not the only purposes of testing identified in section 4. Is there a reason these are singled out here?

Commented [A22]: Should this phrase be dropped? Section 4 specifies the allowable purposes for testing; why paraphrase here?

Commented [A23]: Note that paragraph 1 imposes direct requirements on EPA, and so is a little out of place in this section on policies, procedures and guidance.

Commented [A24]: Is there some reason these policies and procedures are established by regulation, in contrast to the other policies, procedures and guidance in this section? 3A(b) imposes a notice and comment requirement on guidance, so rulemaking isn't necessary to ensure that.

Commented [A25]: It is doubtful that EPA can limit the information that may be submitted.

Commented [A26]: Which information? The info submitted by interested individuals and entities?

Commented [A27]: Same comment as above re whether it makes more sense for the bill to impose these requirements directly.

Commented [A28]: How will EPA identify these in advance of the safety assessment itself? Does this require EPA to generate an identification document prior to conducting the safety assessment? And, per cc, is a separate notice and comment process required on this identification?

"(bb) to explain the basis for those identifications; and

"(cc) to accept comments regarding the identifications; and

"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the intended or reasonably anticipated conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on human health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies; and

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination.

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

Commented [A29]: Again, must this description occur before the assessment itself?

Commented [A30]: How can the policy and procedure document itself explain the basis for the consideration of exposure in a final safety assessment?

Commented [A31]: Same comments as above re whether it makes more sense for the bill to impose these requirements directly.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "regulation, testing consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4);

"(C) pursuant to section 12(a)(4); or

Commented [A32]: It may be confusing and distracting to retain the interagency testing committee, established by 4(e). Its purpose – to advise EPA on testing priority – is arguably obsolete, given the new general FACA created in 3A and the clearer role of testing as it relates to section 6 in the bill, compared to TSCA. Sec 4(e) has a set of criteria for the ITC to consider, which may not align with priorities as established by the bill.

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(f), the Administrator may require the development of test data and information described in paragraph (1) or (2) by—

"(A) promulgating a regulation;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A regulation, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a regulation, entering into a testing consent agreement, or issuing an order for the development of additional information (including

Commented [A33]: 1.If reference to the testing subsection of 3A is intended, that should be 3A(g). 2. 3A has nothing to say about the form of testing requirements and does not instruct EPA to develop guidance along these lines; does it make sense to reference it here? What's intended?

Commented [A34]: Here and anywhere else it appears, data should be stricken, since information subsumes data.

Commented [A35]: Same comment re data. This needs a global search.

information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the regulation, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a regulation or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

Commented [A36]: Vertebrate animals?

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

Commented [A37]: Vertebrate animal tests?

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information used in safety assessments and safety determinations under section 6 that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) beginning on the date that is 5 years after the date of enactment of the Chemical Safety Improvement Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(C) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any safety assessment or safety determination under section 6.

Commented [A38]: Presumably this means "in any testing for purposes of conducting any safety assessment. . . ." EPA would not use animals in the assessments and determinations themselves.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

Commented [A39]: The title of (c) uses "vertebrates". This title uses "animal". The text uses "vertebrate animals" and "animals". Should be consistent.

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the regulation, testing consent agreement, or order; but

"(ii) subject to paragraph (3), before the period ending on the date that is 180 days after the end of the period described in this section.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a regulation, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that a person covered by the exemption has failed to comply with the regulation, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the

Commented [A40]: Should probably be promulgation date, to avoid possible gap in coverage, if this is supposed to pick up where (1)(A) leaves off.

Commented [A41]: What period described in this section? Even if that were clear, it's hard to see how this makes sense. And why is ii in particular subject to para 3?

Commented [A42]: Why doesn't the bill directly require this, rather than having EPA require it? And why have EPA direct private parties to comply with their own agreements?

Commented [A43]: This doesn't make sense – termination should be triggered by failure of the designee to comply, not failure of an exempted person. This error was introduced by leg counsel changes.

third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by regulation, a risk-based screening process and criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the regulation under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances; and

"(ii) pursuant to section 6(b)(2), may initiate or continue safety assessments and safety determinations for those chemical substances.

"(B) REQUIREMENTS.—The initial list of high-priority substances shall contain at least 10 chemical substances.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

Commented [A44]: Establishment of substances? What does it mean to establish a substance?

Commented [A45]: What does it mean to take into consideration a list that doesn't exist yet?

Commented [A46]: This should be dropped. The bill already requires safety assessments and determinations for high priority chemicals, and the requirement is imposed by 6(a), not 6(b)(2), so the citation is confusing.

Commented [A47]: It doesn't make sense for EPA to take into consideration active substances when promulgating the process rule, which is what paragraph 1 requires. This was a leg counsel change.

Commented [A48]: Same comment.

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final regulation under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the prioritization screening of all active substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a regulation, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate safety assessments and safety determinations.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than

Commented [A49]: The use of "or" here and "and" in (I)(bb) leads to the odd result that the bar for prioritizing banned substances is lower than the bar for non-banned substances.

Commented [A50]: This 1-for-1 scheme, which is the forcing mechanism in this section, accounts for removal of substances via completion of safety determinations, but not for removal via re-prioritizing from high to low per (b)(8). This creates the possibility that the priority list could shrink below 10 substances.

Commented [A51]: This seems inconsistent with the requirement to establish the initial high priority list before the regulation is done. More generally, why not even start prioritizing until 180 days after the effective date (which presumably will be some time after the promulgation date)?

Commented [A52]: EPA can already do this (or anything else) by category under sec 26(c). Specifically providing for this here will call the breadth of that section into question.

once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including specific scientific classifications and designations by authoritative governmental entities;

"(C) the intended or reasonably anticipated conditions of use or significant changes in the conditions of use of the chemical substance;

Commented [A53]: Wouldn't intended or reasonably anticipated uses cover significant changes in uses?

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a regulation promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

Commented [A54]: This provision was redrafted by leg counsel and now does not make sense.

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

Commented [A55]: Does it make sense that state regulation is a factor in designating a substance as low priority, which will preempt further state regulation?

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

Commented [A56]: Consider whether this would this be better imposed directly by the bill.

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

Commented [A57]: Does this mean EPA must apply all of the criteria in every prioritization decision? (b)(3) provides that EPA can designate a chemical high priority based on potential for high hazard or widespread exposure, whereas this provision suggests a much more involved analysis.

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

Commented [A58]: Similar comment to the previous one. The requirement to integrate any hazard and exposure information creates tension with the authority to prioritize based on either.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the applicable safety standard.

Commented [A59]: "Applicable" should be dropped. There's only one safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

Commented [A60]: In general, this section does not provide for deadlines to be deferred. The only deadline is under the expedited screening process, in (c). Is EPA intended to have authority to defer that?

Commented [A61]: Changed from "needed" by leg counsel. "Needed" was better, as "required" could suggest a legal requirement.

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a regulation, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

Commented [A62]: Does it really make sense to require notice and comment on "deferral" of a prioritization decision, given that there are no deadlines (except in (c))? The forcing mechanism for this section is the 1-for-1 repopulation requirement, rather than deadlines for individual prioritization decisions.

"(B) provide an opportunity for public comment.

"(8) REVISION BASED ON NEW INFORMATION.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on new information made available to the

Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(10) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Expedited Prioritization Screening.—

"(1) IN GENERAL.—Not later than 180 days after the date on which the Administrator receives from the Governor of a State or a State agency with responsibility for protecting health and the environment a recommendation and relevant information justifying that an active substance be identified as a high-priority substance or a low-priority substance, the Administrator shall make a prioritization screening decision for the active substance.

"(2) LIMITATION.—The Governor of a State or a State agency with responsibility for protecting health and the environment may annually recommend not more than 2 chemical substances for prioritization screening under paragraph (1).

"(3) RECOMMENDATION.—Notwithstanding subsection (b)(8), a recommendation by the Governor of a State or a State agency with responsibility for protecting health and the environment with respect to a chemical substance that has been previously prioritized shall not be required to be based on new information.

"(4) NOTICE AND COMMENT.—The public shall be provided notice and an opportunity to comment regarding the recommendations submitted under this subsection.

"(5) EXPLANATION OF REASONS.—The Administrator shall—

"(A) make available to the Governor or State agency, as applicable, and to the public a brief explanation of the reasons for—

"(i) identifying a chemical substance recommended by the Governor or State agency for prioritization screening as a high-priority substance or a low-priority substance; or

"(ii) deferring a prioritization screening decision; and

Commented [A63]: Should use "distribution in commerce" throughout the bill — it's a defined term. Should do a global search for this.

Commented [A64]: When does the 180-day clock start running? From date of receipt of any submission, or from date of receipt of a submission that EPA concludes contains "relevant information justifying" a priority designation?

Commented [A65]: Ideally, the bill should also provide that EPA can grant such a petition; (b)(8) restricts EPA's authority to re-prioritize, not the content of petitions.

Commented [A66]: Per above comments, does this indicate that EPA can defer beyond the 180-day deadline created by this subsection?

"(B) identify the information relied on in making that identification.

"(d) Treatment.—Except as provided in section 18(e)(6)(B), an action by the Administrator under this section shall not be—

"(1) considered to be a final agency action; or

"(2) subject to judicial review.".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding intended or reasonably anticipated conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

Commented [A67]: Note that this reference to EPA regulations, including successor regulation, provides no statutory content. What was the reason for replacing existing TSCA 5(d)(1)?

Commented [A68]: All known or reasonably ascertainable information? As written, this provides a very minimal requirement (apparently any information) for a key element of new chemical review.

(i) in the matter preceding subparagraph (A), by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and based on the information described in paragraph (2), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (5);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action

Commented [A69]: In addition, the reference to (a) in this matter must be changed to (b).

Commented [A70]: Should be changed to "a determination". A determination will always be necessary.

Commented [A71]: Should be (4)

under paragraph (5).

"(4) RESTRICTIONS.—

"(A) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b), the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a regulation pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or restriction under subparagraph (A) may include, as appropriate—

"(i) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(ii) a requirement that manufacturers and processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

Commented [A72]: This is confusing – a prohibition is a restriction.

Commented [A73]: "consider" would make more sense – this was a leg counsel change..

Commented [A74]: This phrase doesn't make sense – the preceding litany already covers new uses.

Commented [A75]: "consistent with" would probably be better, since the order does not impose obligations on anyone other than the submitter.

Commented [A76]: [Placeholder for prior comment, now superseded]

Commented [A77]: Same comment about prohibition and restriction. Sections 5 and 6 should be scrubbed for consist use of "restriction" as encompassing all measures, including prohibition, ban and phaseout.

Commented [A78]: No authority to prescribe warnings/instructions for manufacture and processing?

Commented [A79]: Does the requirement have to apply to both?

"(II) for a particular use;

"(iv) a prohibition or other regulation of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other appropriate restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or restriction under this subsection to address workplace exposures.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a regulation, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.

"(6) REGULATION PENDING DEVELOPMENT OF INFORMATION.—Subject to paragraph (4)(B), the Administrator may permit manufacture for commercial purposes of a chemical substance to commence pending receipt of the additional information, subject to compliance with any restrictions under paragraph (4) determined by the Administrator to be sufficient to ensure that the chemical substance is likely to meet the safety standard.

"(7) COMMENCEMENT OF MANUFACTURE.—Subject to paragraphs (4), (5), and (6), at the end of the applicable period for review under paragraph (1), the submitter of a notice under subsection (a) may commence manufacture for commercial purposes of a chemical substance or a chemical substance for a significant new use.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer or

Commented [A80]: This is subsumed by (v).

Commented [A81]: Doesn't (v) subsume (iii)? If use and disposal were added to (v), it seems like it would subsume all the other "inclusions".

Commented [A82]: Why not "other regulation of", as in iv?

Commented [A83]: This required consultation may add to the difficulty of issuing the order or consent agreement by the end of the notice period.

Commented [A84]: This basis for testing is not included in 4(a). It should be added.

Commented [A85]: Not clear what this adds.

Commented [A86]: This suggests that manufacture would otherwise be barred, whereas (7) suggests that manufacture can commence at the end of the notification period unless EPA prevents it.

Commented [A87]: How about processing, in the case of a SNUN?

Commented [A88]: Now about processing, in the case of a SNUN?

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

processor that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer or processor shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer or processor; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, regulations, and orders of the Administrator; and

"(2) all information submitted or issued under this section.";

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4),"; and

(11) by adding at the end the following:

"(i) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw

Commented [A89]: References to processor and processing should be stricken in this subsection. It's a holdover from when this subsection provided for NOCs for SNUNs.

Commented [A90]: (f) is unnecessary, since EPA has authority to do this under 4A, and it could create arguments as to the scope of the 4A authority.

Commented [A91]: Should add "under this section". Also, this provision suggests that notices are "of the Administrator".

any regulation or order promulgated pursuant to this section before the date of enactment of the Chemical Safety Improvement Act.".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (h) and (i), respectively;

Commented [A92]: There doesn't seem to be a (g).

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(3) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(4) shall promulgate a final regulation pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

Commented [A93]: "any necessary" would be better, since there won't always be a need.

"(5) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (3) and (4) and any deferral under subsection (c)(2) does not exceed 2 years.

Commented [A94]: Also need to refer to paragraph 5.

Commented [A95]: "including any deferral" would be more accurate, since a deferral is a form of extension.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Chemical Safety Improvement Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

Commented [A96]: Per comments in 3A and 4A, should be consistent re use of policies, procedures, guidance, and other such terms.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or regulation solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or regulation shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by regulation under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the intended or reasonably anticipated conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a regulation, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Regulation.—

Commented [A97]: This should be dropped – it's covered by the definition of the safety standard, and its inclusion in some specific places will cause confusion.

Commented [A98]: This is confusing, because bans and phaseouts are forms of restriction – they are included among the "restrictions" enumerated in (d)(3).

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a regulation establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—The regulation promulgated pursuant to this subsection—

"(A) may—

"(i) apply to mixtures containing the chemical substance, as appropriate; and

"(ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

"(B) shall include dates by which compliance is mandatory, which—

"(i) shall be as soon as practicable; and

"(ii) as determined by the Administrator, may vary for different affected persons.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or restriction under this subsection to address workplace exposures.

Commented [A99]: This clause does not follow grammatically from the chapeau.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

Commented [A100]: [Placeholder for prior comment, now superseded]

"(A) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

Commented [A101]: No authority to impose warning/instructions for manufacture and processing?

"(B) a requirement that manufacturers and processors of the chemical substance shall—

Commented [A102]: Should this be "or"?

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any regulation under this subsection;

Commented [A103]: This test authority is not included in 4(a); it should be added.

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other regulation regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

Commented [A104]: Doesn't D subsume C and E, and couldn't it subsume everything if use and disposal were added?

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to restrict, ban, or phase out, or any other regulation of, any method of commercial use of the chemical substance;

"(G) a requirement to restrict, ban, or phase out, or any other regulation of, any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of unreasonable risks of harm to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

Commented [A105]: Throughout the bill (and existing TSCA), consider whether to change unreasonable risk to a reference to the safety standard. It is clear that the safety standard does not consider nonrisk factors; it's less clear that unreasonable risk operates the same way.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a regulation under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a regulation under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a regulation under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a regulation promulgated under paragraph (1) if the Administrator determines that—

Commented [A106]: Does this mean that the exemption has to be part of the rulemaking under (1)? Or does "in a regulation promulgated under paragraph (1)" just modify "any restriction"? If the latter, must EPA do rulemaking to create an exemption, or can it be done by order?

"(i) the regulation cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack

of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to human health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a regulation under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

Commented [A107]: B, C, E, and F impose requirements if the exemption is part of the rulemaking under paragraph 1, but not otherwise. Is the intent that EPA can create an exemption only in the control rule under paragraph 1?

"(C) STATEMENT REQUIRED.—In making final a regulation under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the intended or reasonably anticipated conditions of use if the regulation is promulgated.

Commented [A108]: It is very difficult to follow what D is instructing EPA to do.

"(E) CONDITIONS.—As part of a regulation promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect human health and the environment while achieving the purposes of the exemption.

Commented [A109]: This is confusing, because presumably this is what EPA is trying to do by requiring compliance with the safety standard, which an exemption would waive at lleast in part. Could say: "necessary to protect health and the environment to the extent practicable while achieving the purposes. . . ."

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a regulation under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by regulation, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

Commented [A110]: EPA has authority to do this anyway, and this provision if anything might be argued to constrain that authority by adding hurdles.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue

exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a regulation requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

Commented [A111]: Why have a time limit on renewals only? And why only for bans and phaseouts?

"(e) Immediate Effect.—The Administrator may declare a proposed regulation under subsection (d) to be effective on publication of the regulation in the Federal Register and until the effective date of final action taken respecting the regulation, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed regulation or any combination of those activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before the effective date; and

"(B) making the proposed regulation so effective is necessary to protect the public interest; and

"(2) in the case of a proposed regulation to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final regulation promulgated under subsection (d), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final regulation.";

(4) in subsection (h) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4); and

(5) by adding at the end the following:

"(j) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section, as in effect on the day before the date of enactment of the Chemical Safety Improvement Act.".

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) REGULATION, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

"(i) a decision by the Administrator under section 4A, 5(d)(3), or 6(c)(1); or

"(ii) a regulation, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

Commented [A112]: 1.Reference to rule or order under Title IV is missing; it's in current section 7. 2. It seems preferable to refer to any actions under section 4, 4A, 5, or 6. The current text seems to capture all the relevant actions under the revised title I, but section 7 does not currently refer to individual subsections, and there's a risk that something has been omitted.

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) REGULATIONS.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the

Chemical Safety Improvement Act, the Administrator shall promulgate regulations requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including regulations requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.

"(ii) MODIFICATION OF PRIOR REGULATIONS.—In carrying out this subparagraph, the Administrator may modify, as appropriate, regulations promulgated before the date of enactment of the Chemical Safety Improvement Act.

"(B) CONTENTS.—The regulations promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting requirements on manufacturers and processors;

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported; and

"(iii) shall apply only in cases in which the Administrator determines that the submission of reports would assist in the effective implementation of this Act.

"(C) ADMINISTRATION.—In implementing this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the regulations on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

"(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the regulations promulgated under this subsection.";

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Chemical Safety Improvement Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph

Commented [A113]: This does not allow EPA to require maintenance of records by processors, as EPA can require for manufacturers. Was that intentional?

Commented [A114]: The relationship between this new authority and the (a)(1) authority is not clear. Is (a)(4) the exclusive authority for information related to sections 4 and 6, and (a)(1) to be used for other purposes?

Commented [A115]: EPA has this authority anyway, so this provision doesn't do anything.

Commented [A116]: It's not clear what this means. Is the intent to limit the persons to whom a rule would apply, and if so how does this differ from (C)(iii), below? Is the intent to limit EPA's authority to issue such rules at all? To limit the information that EPA can require (which might be suggested by the fact it's under "Contents")? Also, this references only submission of reports; does it not apply to maintenance of records.

Commented [A117]: The Act, or sections 4 and 6, per the scope of (i)?

Commented [A118]: This title, or sections 4 and 6?

Commented [A119]: The content of this provision has been eliminated over various drafts; consider whether it makes sense to drop it.

Commented [A120]: This and the following provisions in (3) apparently require that these systems and conventions be maintained forever. Is that the intent?

(1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) REGULATIONS.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator, by regulation, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the regulation, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Chemical Safety Improvement Act.

Commented [A121]: Consider whether it makes more sense for the bill to require this directly. There does not seem to be any room for discretion here.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The regulation promulgated by the Administrator pursuant to subparagraph (A) shall require—

Commented [A122]: Again, why does the bill not require this directly?

"(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a regulation that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

"(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

Commented [A123]: Why doesn't the bill just directly impose the requirements and encouragement referenced in D? There does not appear to be any room for discretion.

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) require the Administrator, in accordance with section 14—

"(I) to review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

Commented [A124]: Even if the person requests a shorter period?

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for

protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(F) LIMITATION.—The specific identity of any chemical substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.

"(G) CERTIFICATION.—The regulation under this subsection shall require a manufacturer or processor—

"(i) to certify the accuracy of each report of the manufacturer or processor carried out under the regulation; and

"(ii) to retain a record supporting that certification for a period of 5 years beginning on the last day of the submission period.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations);

Commented [A125]: This provision reinforces the comment on (C) above that the Plan should pertain only to pre-existing claims. EPA could not complete review if the Plan covered new claims.

Commented [A126]: "applicable" doesn't make sense.

Commented [A127]: This paragraph is unnecessary and potentially confusing; under section 14, a public chem. id could not be CBI – it's already disclosed.

Commented [A128]: Literally, this would preclude CBI treatment for chemicals that aren't on the inventory at all. Presumably that's not the intent.

Commented [A129]: If this paragraph is retained, the highlighted language should be dropped. The inventory is an ongoing list, so "subsequently added" chemicals are already covered by the first phrase in this sentence.

Commented [A130]: Why doesn't the bill require this directly?

Commented [A131]: B makes no sense. Any chemical reported under CDR must already be an active substance, so there should be no occasion to update the list.

Commented [A132]: Most recent as of when? Is this intended to be a one-time obligation or recurring?

and

"(ii) the regulations promulgated pursuant to subsection (a)(4).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—

"(I) IN GENERAL.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(aa) in the notice submitted under clause (i), assert the claim; and

"(bb) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(II) LIMITATION.—The specific identity of any inactive substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.

Commented [A133]: This phrase should be dropped if the subclause is retained.

Commented [A134]: This subclause is unnecessary, for the reason stated in the comment on (4)(F), and for the additional reason that it duplicates (4)(F).

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less than 10 years, unless, prior to the expiration of the period—

Commented [A135]: Not consistent with other provisions, which specify 10 years.

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the regulation required under this subsection, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Chemical Safety Improvement Act, as the initial list of active substances for the purposes of section 4A.

"(7) PUBLIC PARTICIPATION.—Subject to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) APPLICABILITY.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to human health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the

Commented [A136]: Should be interim.

Commented [A137]: This paragraph is largely unnecessary and confusing. The only thing is seems to add is an obligation to make public the accession number, etc., for chemicals on the confidential portion of the inventory. We suggest just saying that, if that's the goal

Commented [A138]: If the specific id is on the nonconfidential portion of the list, it's already public; what is added by instructing EPA to make it available?

Commented [A139]: This means that if the claim is among the 75% that EPA is not required to review, EPA is not required to make this information public. This should just refer to chemicals on the confidential portion of the inventory; let section 14 take care of itself.

Commented [A140]: (C)Is subsumed by (A).

Commented [A141]: This provision doesn't accomplish anything (other than possibly confuse 8(e) for the reason stated below); any person may already submit such information, without the need for statutory permission.

Commented [A142]: Note that manufacturers, processors and distributors are already *required* by 8(e) to submit such information; it might be confusing to have a broader requirement allowing them (and others) to submit it.

following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Chemical Safety Improvement Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

Commented [A143]: Note that, under these definitions, active substances can never become inactive (although inactive substances can become active). A substance that meets the terms of the definition of active substance on the day of enactment will always meet those terms, and never meet the terms of the inactive substance definition.

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7"; and

(C) in paragraph (3), by striking "section 6 or 7" and inserting "section 6(d) or 7"; and

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

Commented [A144]: Consider whether 9(a), even as amended by the draft bill, remains a good fit for the amended TSCA. Current TSCA was intended as a "gap filler", hence the requirement to defer to other agencies with adequate authority to regulate unreasonable risks. If CSIA is envisioned as the principal statute to regulate chemical risks, then section 9(a) does not seem like a good fit. Among other things, 9(a) would allow another agency to overrule EPA's conclusion that a chemical does not meet the safety standard, creating the potential for inconsistent regulation of chemicals. In any event, if it is retained, edits should be made to the mandatory rulemaking schedule in 6(a), since the absolute deadlines there are inconsistent with 9(a)'s deferral to other agencies.

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

"(A) under section 5 is not likely to meet the safety standard; or

"(B) under section 6 does not meet the safety standard.

"(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture presents an unreasonable risk of harm to human health within the United States or to the environment of the United States.";

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture subject to a prohibition or restriction pursuant to a regulation, order, or consent agreement in effect under this Act; or

"(E) a chemical substance or mixture for which the submission of information is required under section 4.

"(2) REGULATIONS.—

"(A) IN GENERAL.—The Administrator shall promulgate regulations to carry out paragraph (1).

"(B) CONTENTS.—The regulations promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

Commented [A145]: As revised, TSCA § 12(a)(2) indicates that manufacture solely for purposes of export would be generally subject to regulation under TSCA, once a chemical is either found not likely to meet the safety standard (under § 5) or not to meet the safety standard (under § 6). This is a significant change from TSCA, under which exported chemicals are generally exempt from TSCA regulation unless unreasonable risk would result in the US. Among other things, this change could suggest that EPA could or should regulate on the basis of risks to human health and the environment outside the U.S.

Commented [A146]: This doesn't seem like the right word to capture the content of the paragraph, which seems to concern whether mixtures and articles are covered by the exception in 2.

Commented [A147]: Applying the unreasonable risk standard makes sense under current TSCA, since this is the test for determining whether to regulate the exported chemical, but it does not seem to make sense here.

Commented [A148]: TSCA requires notification of chemicals subject to section 7 judicial actions; this paragraph does not. Is that intentional?

Commented [A149]: This should be deleted, since the mixture containing the chemical substance is captured by the reference to the chemical substance.

Commented [A150]: Consider dropping this phrase. The logic of notification is that the US should notify a foreign country of the import to that country of chemicals for which the US has identified concerns; whether EPA has yet regulated does not seem very relevant. (If this is retained, "prohibition" and "restriction" should not be distinguished.)

Commented [A151]: Same comment re mixture

Commented [A152]: Same comment as above re this phrase.

Commented [A153]: This subsumes most of A and B as they are currently drafted. This appears to add only judicial section 7 orders (but, per above comment, it does not add section 7 actions).

"(ii) indicate whether, or to what extent, the regulations apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, regulation, order, consent agreement, requirement, or designation;

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14. IMPORTS.

Section 13 of the Toxic Substances Control Act (15 U.S.C. 2612) is amended to read as follows:

"SEC. 13. IMPORTS.

"(a) Refusal of Entry.—

"(1) IN GENERAL.—The Secretary of Homeland Security shall refuse entry into the customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry, if—

"(A) the Administrator—

"(i) has determined under section 6(c) that the chemical substance or mixture does not meet the safety standard; and

"(ii) has promulgated a regulation pursuant to section 6(d) banning the chemical substance or mixture, as of the effective date of the regulation;

"(B) the chemical substance—

"(i) is not included on the list under section 8(b)(1); and

"(ii) is not exempt from any requirement to be included on that list by this title or a regulation promulgated by the Administrator pursuant to this title; or

"(C) the chemical substance, mixture, or any article containing the chemical

Commented [A154]: A, B and D don't seem to involve designations.

Commented [A155]: 13(a) could be greatly simplified by simply saying that DHS shall refuse entry of "any chemical substancel, mixture, or article containing a chemical substance or mixture offered for such entry if the entry would violate this Act or any regulation ["rule" would be better], consent agreement or order in effect under this Act." The intent seems to be to prevent unlawful import, and a simpler formulation will do that without the complications of trying to summarize complex requirements.

Commented [A156]: A is subsumed by C and should be dropped.

Commented [A157]: Mixtures are not subject to safety determinations.

substance or mixture is offered for entry in violation of—

"(i) a regulation, consent agreement, or order in effect under this Act; or

"(ii) an order issued in a civil action brought under section 7 or title IV.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance, mixture, or article containing a chemical substance or mixture is refused entry under paragraph (1), the Secretary of Homeland Security—

"(i) shall notify the consignee of the entry of the refusal;

"(ii) shall not release the chemical substance or mixture to the consignee; and

"(iii) shall cause the disposal or storage of the chemical substance or mixture under such regulations as the Secretary may prescribe, if the chemical substance or mixture has not been exported by the consignee during the 90-day period beginning on the date of receipt of the notice of the refused entry.

"(B) EXCEPTION.—

"(i) IN GENERAL.—The Secretary of Homeland Security, pending a review by the Administrator, may release to the consignee the chemical substance or mixture if the consignee—

"(I) executes a bond for the amount of the full invoice of the chemical substance or mixture (as set forth in the customs entry); and

"(II) pays a duty on the chemical substance or mixture.

"(ii) ADMINISTRATION.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security on demand, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond executed under clause (i)(I).

"(C) STORAGE.—All charges for storage, cartage, and labor on or for the disposal of a chemical substance or mixture that is refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(b) Certification.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture subject to this Act for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that—

"(A) after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is in compliance with any applicable regulation, consent agreement, or order under section 5 or 6; and

"(B) the chemical substance—

Commented [A158]: Isn't ii subsumed by i? It seems like a section 7 judicial order would be an order in effect under this Act. Also, Title IV does not create a specific judicial action, so it's not clear what the reference to Title IV covers. If ii is included, it will suggest that judicial orders under section 7 are not orders under the Act, which will suggest that section 7 orders are not included in the export provisions of 12(b)(1)D).

Commented [A159]: In contract to TSCA, nothing in 13(a) as drafted bars import of PCBs on the grounds that import violates the statutory PCB ban (although the import would be barred by virtue of EPA regulations codifying the ban).

Commented [A160]: Should drop this – all chemical substances and mixtures are subject to TSCA. The jurisdictional exclusions are built right into the definition of "chemical substance."

Commented [A161]: Note that this does not require certification of compliance with section 7 judicial orders or Title IV. Is there a reason the scope of the certification requirement is not the same as the scope of the refusal-of-entry requirements?

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from any requirement to be included on that list by this title or a regulation promulgated by the Administrator pursuant to this title.

"(2) ARTICLES.—

"(A) IN GENERAL.—The Administrator, by regulation, may require certification under paragraph (1) for an article containing a chemical substance or mixture that is subject to regulation under section 5 or 6.

"(B) REQUIREMENT.—The regulation under subparagraph (A) shall identify, with reasonable specificity, the types of articles, including parts or components of articles, that will be subject to the certification requirement.

"(C) FACTORS FOR CONSIDERATION.—In determining the need for and content of a certification regulation under this paragraph, the Administrator shall take into consideration—

"(i) the utility of the certification to enforcement of the applicable regulation, consent agreement, or order under section 5 or 6;

"(ii) the contribution of imported articles to the potential risk presented by exposure to the chemical substance or mixture subject to regulation under section 5 or 6;

"(iii) the impact on commerce and potential for the certification to impede or disrupt import of articles;

"(iv) the frequency or duration of the certification requirement; and

"(v) specification of the concentration of a chemical substance in an article that would subject the article to the certification requirement.

"(3) REASONABLE INQUIRY.—

"(A) IN GENERAL.—For purposes of a certification under paragraph (1), reasonable inquiry shall include good faith reliance by an importer on—

"(i) a safety data sheet or similar declaration provided by a supplier that documents the specific identity of the chemical substance or the specific identities of all chemical substances in a mixture; or

"(ii) for chemical substances or mixtures claimed by the supplier as confidential, or not otherwise disclosed by the supplier, a certification by the supplier that the imported chemical substance or mixture satisfies the applicable certification requirements under paragraph (1).

"(B) ARTICLES.—For purposes of a certification under paragraph (2), reasonable inquiry shall include good faith reliance by an importer on a certification by the supplier that the imported article satisfies the applicable certification requirements in a regulation promulgated pursuant to paragraph (2).

"(4) INFORMATION REGARDING IDENTITY.—For purposes of this subsection, the

Commented [A162]: Should be "the requirement".

Commented [A163]: Why use this formulation here rather than the "regulation, consent agreement, or order" formulation used elsewhere in this section? This could suggest that only regulations are covered. (This is another reason to use "rule" rather than, as leg counsel prefers, "regulation" in the bill, so that generic reference to "regulation" is not construed as being limited to legislative rules.)

Commented [A164]: This provides no authority to require certification for articles containing chemicals that are not on the inventory. Is that intentional?

Commented [A165]: Technically the certification is under paragraph (1), even for articles.

Commented [A166]: The intent of this seems to be to ensure that importers have fair notice of chem ids. If so, what does this add to general fair notice caselaw? And how would the information needed to understand chem id in import transaction differ from the information needed in other contexts?

Administrator shall provide publicly accessible information regarding the identity of a chemical substance or mixture subject to regulation under this Act that would be readily understood in import transactions.

"(c) Notice.—A person offering a chemical substance for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—

"(1) the chemical substance or chemical substance in a mixture is a high-priority substance;

"(2) the chemical substance or chemical substance in a mixture is 1 for which the United States is obligated to provide export notification by treaty; or

"(3) the chemical substance or chemical substance in a mixture—

"(A) is the subject of a safety assessment and safety determination conducted pursuant to section 6; and

"(B) has been found not to meet the safety standard.

"(d) Regulations.—

"(1) IN GENERAL.—The Secretary of Homeland Security, after consultation with the Administrator, shall promulgate regulations to carry out this section.

"(2) APPLICATION.—The regulations under paragraph (1) may modify the application of any requirement of this section, as appropriate for the efficient and effective implementation of this Act.".

SEC. 15. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsection (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

Commented [A167]: This phrase should be stricken. Reference to the chemical substance captures the substance in a mixture, and this phrase could suggest otherwise.

Commented [A168]: Same comment.

Commented [A169]: 3 is subsumed by 1 – every chemical that has had a safety assessment and determination will be a high priority substance.

Commented [A170]: The current TSCA wording is: "pursuant to subsection (a) of section 552 of Title 5 by reason of subsection (b)(4) of such section". We understand that the intent was to mirror that language.

Commented [A171]: This proviso applies only to the (b) information, not to other CBI. Is that intentional? (It's not clear this provision is necessary at all. CBI prevents disclosure only by EPA. Is the intent to ensure that EPA obey court requirements or that other parties obey court requirements? If that letter, this provision is unnecessary and may suggest a broader reach of 14(a) than is warranted by its terms)

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

Commented [A172]: When will the Administrator make this determination? Isn't the point of (b) to identify information that is protected without the need for a finding? If EPA makes the finding described here, then this information would be protected without the need for the presumption.

"(7) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

Commented [A173]: What if the chemical is subject to a section 5 exemption? Or what if the claimant has not yet submitted a section 5 notice?

"(B) the claim has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (e), (f)(2), or (g).

Commented [A174]: This should be true of all CBI claims, not just chem id claims, and stating here could call that into question. Also, the reference to (e) in here is wrong, since (e) does not pertain to whether information is CBI – this is a recurring issue in this section.

"(c) Information Not Protected From Disclosure.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

"(i) any health and safety study that is submitted under this Act with respect to—

"(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"(II) any chemical substance or mixture for which—

"(aa) testing is required under section 4; or

"(bb) a notification is required under section 5; or

"(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

"(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

"(ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

"(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(A) For information submitted after the date of enactment of the Chemical Safety Improvement Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"(B) A safety assessment developed, or a safety determination made, under section 6.

"(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is otherwise eligible for protection under this section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"(5) LIMITATION.—Except as provided in paragraph (1)(B), the specific identity of any chemical substance that is not on the confidential portion of the list published under section 8(b)(1) or subsequently added to the confidential portion of the list pursuant to this section shall not be eligible for protection from disclosure.

"(6) BAN OR PHASE-OUT.—If the Administrator promulgates a regulation pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—

"(A) any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply; and

"(B) the Administrator promptly shall make the information public.

"(d) Requirements for Confidentiality Claims.—

Commented [A175]: This paragraph (2) should be moved to the end of (c) and made applicable to both the (1) and (3) information.

Commented [A176]: (1)(A) would be clearer.

Commented [A177]: This should be framed in parallel with the wording in (c)(1): "subsection (a) does not prohibit the disclosure of . . ."

Commented [A178]: (A) should be dropped. Meeting the requirements of D is a prerequisite for ANY CBI, and it's confusing to specify that for chemi id.

Commented [A179]: This appears to modify all that follows and apply to eg consumer uses of a chemical substance. Is that intentional?

Commented [A180]: This is a confusing provision, in part because it is based on the idea of protectable information appearing in "a submission described in this subsection". This subsection does not really describe "submissions"; it describes information elements that are not protectable, so this provision is not necessary. If retained, it would be clearer to say: Any information that is eligible for protection under this section and is submitted along with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d)." The final phrase does not seem necessary.

Commented [A181]: This subclause is confusing. Literally read, it prevents CBI treatment for chemicals that are not on the inventory at all. If the intent is merely to refer to chemicals whose specific id's appear on the non-confidential portion of the inventory, the provision is unnecessary because those id's won't qualify as CBI anyway.

Commented [A182]: This doesn't make sense. If the specific chem id is publicly listed on the inventory, it can't be CBI, even if it meets the (1)(B) criteria.

Commented [A183]: This phrase should be dropped; the inventory is a "living" list, there is no need to say that references to it include chemicals added over time.

Commented [A184]: Looks like this should be a subclause of (3). Also note that the sweep of this paragraph is very broad – eg, customer lists pertaining to a chemical would no longer be CBI if the chemical is banned or phased out.

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such regulations regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the chemical identity;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law in connection with 1 or more uses subject to this Act;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the conditions that—

"(i) the generic name shall—

"(I) conform with guidance prescribed by the Administrator under paragraph (3)(A); and

"(II) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(aa) that are considered to be confidential; and

"(bb) the disclosure of which would be likely to harm the competitive position of the person.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the regulations promulgated and guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under

Commented [A185]: This should presumably refer to information generally, since (d)(1) is not speciffic to chem id

Commented [A186]: The effect of this language is obscure.

Commented [A187]: There is no (ii).

Commented [A188]: Per comments on 3A, requiring conformance to guidance will likely render the guidance final agency action.

Commented [A189]: Drop parentheses around A.

Commented [A190]: This formulation is different from the formulation in (1)(B)(iii). The latter seems more consistent with CBI caselaw.

Commented [A191]: This should be dropped, since it encompasses all of (b).

Commented [A192]: Same comment as above re requiring conformance with guidance.

paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) shall be disclosed if—

"(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of human health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) the Administrator determines that disclosure is necessary to protect human health or the environment;

"(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

"(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

"(5) a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

Commented [A193]: This is out of place under (d), since it does not pertain to requirements of claims.

Commented [A194]: "The information" seems to literally refer to the content of the submission that is subject to the CBI claim. Presumably the intent is narrower: to require certification that the given basis for the CBI claim is true and correct.

Commented [A195]: Same comment as above re requiring conformance with guidance.

Commented [A196]: It's odd that notification is handled here for this provision, but in (g) for all other provisions of (e).

Commented [A197]: Same comment about requiring conformance with guidance.

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

Commented [A198]: Per (g)(2), EPA has no obligation to notify the submitter of a release under (6). How will the submitter know to request this?

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

Commented [A199]: It's not clear how this post-disclosure requirement will work. What happens if the terms of the statement and agreement cannot be worked out? Or if the recipient doctor, nurse, etc, does not agree to provide the statement and agreement? That might create a question as to whether the information could be shared with a patient.

"(7) the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee;

"(9) the information is publicly available; or

"(10) the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

"(B) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—

"(aa) review the request;

"(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of not more than 10 years; or

"(BB) deny the claim.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—

Commented [A200]: This should be dropped. If deals with whether information is CBI and is out of place in (e), which is about release of CBI. Also, publicly available information can't be CBI.

Commented [A201]: Need to add reference to (a), which contains the substantive CBI standard.

Commented [A202]: Per earlier comment, consider whether it makes sense to impose a fixed 10-year period, which will apply even if the submitter doesn't need or request that much time.

Commented [A203]: The person that asserted the claim, consistent with wording in (B)(i)? What other affected person could submit this notification?

Commented [A204]: It would be clearer to say that "the information no longer qualifies for confidential treatment under subsection (a)", or something like that. "Substantiated" has a particular meaning in this section.

Commented [A205]: This appears to require review and determination on every claim for extension. In contrast, (g) does not require review and determination for (b) information, and allows EPA to act on as little as 25% of other claims. Is that intentional?

Commented [A206]: If EPA receives the statement after it is submitted, EPA action could come after the expiration of the claim. Would probably be better if the deadline for this obligation were the date of expiration.

Commented [A207]: Is this intentional or a holdover?

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

Commented [A208]: Should drop this. Subsec (a) already describes the scope of this section and uses different words. Dropping will require minor rewording later in setence.

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating regulations pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

Commented [A209]: This is true of i through iii as well and should be dropped. It is clear without this that iv authorizes only the imposition of a substantiation requirement, not disclosure. (If retained, the reference should be to (a), not (d).)

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

Commented [A210]: Should be dropped, per above comment.

"(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

Commented [A211]: FOIA does not literally impose a requirement on EPA to require substantiation.

"(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

Commented [A212]: Missing words. Also, 552(b)(4) supplies a standard; it does not exactly impose requirements.

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).

"(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under

Commented [A213]: (3) seems out of place under (f).

Commented [A214]: This proviso does not seem to be included in other release provisions, which could create issues. Seems best to let (g)(3) function on its own.

Commented [A215]: This appears to exempt (b) information from the review provisions under (f), but per comments above, (f) does not read that way.

Commented [A216]: (f) does not seem to provide any grounds for exception from this provision.

Commented [A217]: 1. This should not be limited to chem id – it is a general provision. 2. This subclause is unnecessary; it's already true that EPA must approve a claim if it meet the requirements of (a) and (d). 3. A refers to claims and requests, and B(i) refers only to claims; seems like they should be consistent.

Commented [A218]: Should be "or".

Commented [A219]: Or request?

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to human health or the environment, in which case no prior notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), (9), or (10) of subsection (e), no prior notification shall be necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable

Commented [A220]: This should be dropped. (e) does not involve denial or modification of claims.

Commented [A221]: Seems like this should be dropped. (f) does not appear to provide exceptions to the provisions of (g)(2), and in fact refers to the procedures in (g)(2) as applicable.

Commented [A222]: Or request?

Commented [A223]: Consider whether this carries over from TSCA an outdated form of notification.

Commented [A224]: (ii) is out of place. It deals with notification of release under (e) of information that IS CBI; it does not involve denial or modification of CBI claims. So these provisions are not "exceptions" to (g)(2)(B)(i).

Commented [A225]: Paragraph (e)(5) is not addressed in B. (And per above comment, (e)(4) for some reason is addressed in (4) rather than here.)

Commented [A226]: Due to confusion about scope in paras 1 and 2, it's not clear if 3 applies only denials and modifications, or also to releases under (e).

court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

Commented [A227]: 1.These are not EPA's only CBI regulations – eg, EPA has some CDR-specific CBI regulations in Part 711. Could just refer to applicable procedures in title 40. 2. This provision has no effect, since it just says that EPA will follow whatever rules it has in place.

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Chemical Safety Improvement Act; or

Commented [A228]: Should be consistent with the language in (a).

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) PRIOR ACTIONS.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such regulations applicable to those claims as the Administrator may promulgate after the date of enactment of the Chemical Safety Improvement Act.".

Commented [A229]: 1.Despite the title, this paragraph seems to pertain to post-CSIA actions. 2. This seems inconsistent with (i)(1).

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

SEC. 16. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any regulation promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any regulation promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any regulation promulgated or order issued pursuant to title II;".

SEC. 17. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by inserting "this Act or a regulation or order promulgated or issued pursuant to this Act, including" after "a provision of"; and

(ii) by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "section 15 or 409" and inserting "this Act";

(C) by striking "$25,000" and inserting "$50,000"; and

(D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS AND ENTITIES.—An [organization or entity] that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not

Commented [A230]: The addition of this text to section 16 renders most of section 15 unnecessary. Currently, section 15 circumscribes the violations of TSCA that are "prohibited acts", and section 16 establishes penalties for those prohibited acts. If section 16 is expanded to subject to penalties any violation of the Act or any requirements thereunder, then 15(1), (3) and (4) have no function.

But 15(2) would still have a function, since it makes unlawful activity that would otherwise not be unlawful.

Also, if section 16 is expanded in this way, section 17 should probably be expanded too.

Commented [A231]: Is it clear that "entity" refers exclusively to an organization, not a natural person?

more than $1,000,000 for each violation. [Client note: The other laws that have this provision (CAA, CWA, RCRA, etc.) read as follows: 'Any person committing such violation which is an organization ... .' The intent is to distinguish between individuals and organizations – do we need 'entity' here then?]

"(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—

Commented [A232]: Why "another individual" here but "an individual" above?

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by another individual may not be attributed to the defendant.".

SEC. 18. PREEMPTION.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended to read as follows:

"SEC. 18. PREEMPTION.

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish or continue to enforce a law or administrative action—

Commented [A233]: This had previously said "a statute". The change is substantive, since it would create a stronger argument that state common law can be preempted.

Note: This issue from September 2014 seems to have already been resolved in the December 2014 revision of CSIA.

"(A) relating to the development of information regarding a chemical substance or category of chemical substances that is reasonably likely to produce the same information as is required under section 4, 5, or 6 in—

"(i) a regulation promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator;

"(B) to prohibit or restrict the manufacture, processing, distribution in commerce, or use of a chemical substance—

"(i) for a chemical substance found to meet the safety standard and consistent with the scope of the safety determination made under section 6; or

"(ii) for a chemical substance found not to meet the safety standard, after the effective date of the regulation promulgated pursuant to section 6(d) for the chemical substance, consistent with the scope of the relevant safety determination made by the Administrator; or

"(C) requiring the notification of a use of a chemical substance—

"(i) that the Administrator has specified as a significant new use; and

"(ii) for which the Administrator has required notification pursuant to a

regulation promulgated pursuant to section 5.

"(2) EFFECTIVE DATE FOR CERTAIN PREEMPTION.—For purposes of this subsection, Federal preemption of State laws and administrative actions applicable to specific chemical substances—

"(A) shall be consistent with the scope of the determination made by the Administrator; and

"(B) shall not take effect until the date on which, as applicable—

"(i) the Administrator determines that the chemical substance meets the safety standard; or

"(ii) compliance with the applicable regulation promulgated pursuant to section 6(d) is required.

"(b) New Laws and Administrative Actions.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish, after the date of enactment of the Chemical Safety Improvement Act, any law or administrative action that prohibits or restricts the manufacture, processing, distribution in commerce, or use of a chemical substance that—

"(1) is a high-priority substance identified under section 4A, as of the date on which the Administrator commences a safety assessment under section 6; or

"(2) is a low-priority substance identified under section 4A, as of the date on which the Administrator designates the substance as a low-priority substance.

"(c) Exceptions.—

"(1) IN GENERAL.—Subsections (a) and (b) shall not apply to a requirement, prohibition, or restriction of a State or a political subdivision of a State that—

"(A) is adopted pursuant to any other provision of Federal law;

"(B) implements a reporting, monitoring, or information collection requirement not otherwise required—

"(i) by the Administrator under this Act; or

"(ii) under any other provision of Federal law; or

"(C) is adopted pursuant to a law of the State or political subdivision of the State relating to water quality, air quality, or waste treatment or disposal that—

"(i) does not impose a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) is not otherwise required or inconsistent with an action by the Administrator under section 5 or 6.

"(2) NO PREEMPTION.—Nothing in this Act (including any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented under this Act) affects the right of a State or a political subdivision of a State to adopt or enforce any regulation, requirement, standard of performance, safety determination, scientific

assessment, or provision for protection for public health or the environment that—

"(A) is adopted or authorized to comply with any other provision of Federal law;

"(B) implements a reporting, monitoring, or information collection requirement not otherwise required—

"(i) by the Administrator under this Act; or

"(ii) under any other provision of Federal law; or

"(C) is adopted pursuant to a law of the State or political subdivision of the State relating to water quality, air quality, or waste treatment or disposal that—

"(i) does not impose a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) is not otherwise required or inconsistent with an action by the Administrator under section 5 or 6.

"(3) EXISTING REGULATIONS AND ORDERS.—Nothing in this section—

"(A) requires the Administrator to modify or withdraw any regulation or order under section 5 or 6; or

"(B) modifies the effect of this section, as in effect on the day before the date of enactment of the Chemical Safety Improvement Act, on any regulation or order promulgated or issued pursuant to this Act before that date of enactment.

"(d) Preservation of Certain State Law.—Nothing in this section preempts or otherwise affects any warning requirement relating to consumer products or substances that is established pursuant to a State law that was in effect on August 31, 2003, unless a regulation, consent agreement, or order is issued under section 6 imposing a warning requirement, which shall preempt a chemical-specific State warning requirement consistent with the scope of a determination of the Administrator under section 6.

"(e) State Waivers.—

"(1) IN GENERAL.—On receipt of an application of a State or political subdivision of a State, the Administrator may provide a waiver from the requirements of subsections (a) and (b)(1) regarding a law or administrative action of the State or political subdivision relating to the effects or exposure to any chemical substance under the intended or reasonably anticipated conditions of use, if—

"(A)(i) the State or political subdivision determines that waiting until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and safety determination established under section 4A is not practicable; and

Commented [A234]: Should be section 6.

Note: This issue from September 2014 seems to have already been resolved in the December 2014 revision of CSIA.

"(ii) the Administrator determines that—

"(I) compelling State or local conditions warrant granting the waiver to protect human health or the environment;

"(II) compliance with the proposed requirement of the State or political subdivision will not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(III) compliance with the proposed requirement of the State or political subdivision would not cause a violation of any applicable Federal law, regulation, or order; and

"(IV) in the judgment of the Administrator, the proposed requirement of the State or political subdivision is consistent with sound objective scientific practices, the weight of the evidence, and the best available science;

"(B)(i) the Administrator determines that a safety assessment or safety determination has been unreasonably delayed; and

"(ii) the State certifies that—

"(I) the State has a compelling local interest to protect human health or the environment;

"(II) compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(III) compliance with the proposed requirement would not cause a violation of any applicable Federal law, regulation, or order; and

"(IV) the proposed requirement is grounded in reasonable scientific concern; or

"(C)(i) the State has entered into a contract with the National Academy of Sciences to assess the hazard, use and exposure, and risk of a chemical substance;

"(ii) the report complies with the requirements of the Federal Advisory Committee Act (5 U.S.C. App.); and

"(iii) based on the best available evidence described in the report of the National Academy of Sciences, the State establishes a requirement relating to the effects of or exposure to a chemical substance.

"(2) APPROVAL OF REQUEST.—The Administrator shall determine whether to grant or deny a waiver application under paragraph (1) by not later than, as applicable—

"(A) 180 days after the date on which an application under paragraph (1)(A) is submitted; or

"(B) 90 days after the date on which an application under paragraph (1)(B) is submitted.

"(3) NOTICE AND COMMENT.—The application of a State or political subdivision of a State shall be subject to public notice and comment.

"(4) FINAL AGENCY ACTION.—A determination of the Administrator regarding the application of a State or political subdivision shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(5) DURATION OF WAIVERS.—A waiver granted under—

"(A) paragraph (1)(A) shall remain in effect unless the waiver is found to be in conflict with a completed safety assessment and safety determination; and

"(B) subparagraph (B) or (C) of paragraph (1) shall remain in effect until such time as the applicable safety assessment and safety determination are completed.

"(6) JUDICIAL REVIEW.—

"(A) IN GENERAL.—Not later than 60 days after the date on which the Administrator makes a determination regarding an application of a State or political subdivision under paragraph (1), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

"(B) JUDICIAL REVIEW OF PRIORITIZATION SCREENING DECISION.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(c) to designate a chemical substance as a low priority, the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation, as applicable, may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

"(7) SAVINGS PROVISION.—

"(A) IN GENERAL.—Nothing in this Act (including any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented under this Act) preempts, displaces, or supplants any Federal or State—

"(i) common law right; or

"(ii) law that creates—

"(I) a remedy for civil relief, including for civil damage; or

"(II) a penalty for a criminal conduct.

"(B) CLARIFICATION.—Notwithstanding any other provision of this Act, nothing in this Act preempts or precludes any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any Federal, State, maritime, or common law or statutory theory.

"(C) NO EFFECT ON PRIVATE REMEDIES.—Nothing in this Act (including any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented under this Act)—

"(i) is dispositive in any civil action in favor of any plaintiff or defendant; or

"(ii) affects the authority of any court to make a determination in an adjudicatory proceeding under applicable Federal or State law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 19. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d)(4), 6(d), or 8"; and

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting ["a regulation promulgated pursuant to section 6(d)"]; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1)—

(A) in subparagraph (B)—

(i) in clause (i)—

(I) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), 5(d)(4), or 6(d)"; and

(II) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(ii) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the regulation, except as part of the rulemaking record, taken as a whole."; and

[(B) by striking subparagraph (C).]

Commented [A235]: Several things have dropped in this substitution of citations: significant new use rules; PCB rules; and any rules under Title II or IV. In addition, there are significant new actions under this bill that would probably make sense to have reviewed under section 19: eg, positive safety determinations, new chemical determinations under 5(d)(3), maybe denials of section 18 Governor petitions.

Commented [A236]: This bracketed insert is wrong; section 6(d) rules are covered above. Consider, though, whether some orders to be issued under this bill should be subject to these judicial review provisions – eg, test orders, section 5 orders.

Commented [A237]: Should be stricken. There are no 5d4 rules.

Commented [A238]: Reference to PCB rules has been dropped. Reference should be to 6g or h, depending on final codification.

Commented [A239]: This is an imprecise relocation of language from a stricken provision of section 19. Suggest deleting it – it's unnecessary.

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a regulation pursuant to section 4, 5(d), 6(b), 6(c), 6(d), or 8 or an order issued under section 4 or 5(d), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a regulation or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4 or 6(d);

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a regulation under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a regulation under section 8, there is a reasonable basis to conclude that the regulation is necessary to protect human health or the environment from an unreasonable risk of harm to human health or the environment.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to human health or the environment alleged by the petitioner is less than the extent of risks to human health or the environment with respect to which the Administrator is taking action under this Act; and

Commented [A240]: Why enumerate the specific subsections here, when (a)(1) and (b)(1) just list the sections?

Commented [A241]: This doesn't make sense – it's not the standard for a section 4 rule or order. In particular, the reference to an action under section 4 makes no sense, and the 6(d) reference is too narrow.

Commented [A242]: Sec 5(d) orders do not seem to be a good candidate for citizen petition. Section 5 creates EPA duties to decide whether new chemicals are likely to meet the safety standard and to issue orders under 5(d) for chemicals that are not likely to meet the standard. I seems like a citizen's recourse would be a mandatory duty suit under section 20 or an unreasonable delay suit, not a citizen petition under section 21. Also, the PMN review period does not provide enough time for a citizen petition to be effective.

Commented [A243]: Similar comment. Section 6 imposes mandatory schedules for issuing control rules, which can be enforced by citizens under section 20.

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26(e) of the Toxic Substances Control Act (15 U.S.C. 2625(e)) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METHODS.

Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a regulation, testing consent agreement, or order under section 4;".

EPA is providing this technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill.

1 # SEC. 28. EFFECTIVE DATE.

2 Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is
3 amended by striking "Except as provided in section 4(f), this" and inserting "This".
4

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2015 9:27:28 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]; 'john_glennon@epw.senate.gov' [john_glennon@epw.senate.gov]
Subject: EPA Testimony for March 18 Hearing on TSCA
Attachments: EPA final test TSCA 3.18.15.pdf

Please find attached a copy of EPA's testimony for the March 18, 2015 hearing on TSCA. 100 hard copies will be delivered tomorrow. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2015 9:01:06 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall Inquiry on User fees

Jonathan,
In response to your inquiry, typically, EPA collects about a $1M per year from user fees for new chemical reviews. The money goes to the treasury. We don't have an aggregate number of fees. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, March 16, 2015 12:52 PM
To: Kaiser, Sven-Erik
Subject: User fees...

Can you confirm how much user fees are currently collected by the EPA for TSCA?
Do you have an aggregate number of how many fees are currently collected?

This is what I have:

- EPA can only charge fees to cover testing requirements or new chemicals
- No fees can be charged to defray the typically much higher costs of EPA reviews of existing chemicals or the collection, management or evaluation of information on existing chemicals
- Fees are capped at $2,500 per company ($100 per small company)
- Any fees collected go to the general treasury and are not available to directly cover EPA's costs.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2015 4:59:57 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: User fees...

Checking

On Mar 16, 2015, at 12:51 PM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Can you confirm how much user fees are currently collected by the EPA for TSCA?
Do you have an aggregate number of how many fees are currently collected?

This is what I have:

- EPA can only charge fees to cover testing requirements or new chemicals
- No fees can be charged to defray the typically much higher costs of EPA reviews of existing chemicals or the collection, management or evaluation of information on existing chemicals
- Fees are capped at $2,500 per company ($100 per small company)
- Any fees collected go to the general treasury and are not available to directly cover EPA's costs.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2015 3:02:00 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]
Subject: RE: Sen. Booker Request for TSCA Reform TA

Adam,
Just heard from Laura V. along the same lines. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Monday, March 16, 2015 10:58 AM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker Request for TSCA Reform TA

Sven we can cancel – I ended up speaking with Laura Vaught this morning and she answered my questions. Thanks. Adam

---

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, March 16, 2015 9:51 AM
To: Zipkin, Adam (Booker)
Subject: Re: Sen. Booker Request for TSCA Reform TA

Adam,
Ok for 1:30pm today. Call me at 202-566-2753. Thanks,
Sven

On Mar 16, 2015, at 9:48 AM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Sven good morning. My weekly staff meeting is getting pushed back so 11 now likely will not work. Is any time between 1-3 still open? Also, it would be good to see EPA testimony for Wednesday hearing in advance of our call if possible, do you know when that will be sent out?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 13, 2015 2:51 PM
To: Zipkin, Adam (Booker)
Subject: RE: Sen. Booker Request for TSCA Reform TA

Adam,
I'm open afternoon today and Monday open at 11 and 1-3. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Friday, March 13, 2015 2:35 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker Request for TSCA Reform TA

Sorry for delayed response. What does your Monday look like?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, March 12, 2015 10:24 AM
To: Zipkin, Adam (Booker)
Subject: RE: Sen. Booker Request for TSCA Reform TA

Adam – what's a good time for a call? I'm available until 11 and then any time after 1. Best number to call you?
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Thursday, March 12, 2015 8:40 AM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker Request for TSCA Reform TA

Sven good morning. Could we talk tomorrow re next week EPW hearing?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, January 29, 2015 10:11 AM
To: Zipkin, Adam (Booker)
Subject: Sen. Booker Request for TSCA Reform TA

Adam,
Thank you for organizing the technical assistance meeting yesterday. There were a number of possible followup items including the judicial review provisions for new chemicals. Please let me know if you want technical assistance on any questions including that one. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/12/2015 5:24:44 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
CC: Roberts, Alyssa (Tom Udall) [Alyssa_Roberts@tomudall.senate.gov]
Subject: Sen. Udall Inquiry on TSCA Stats

Jonathan and Alyssa,
Thank you for the request. Please see our responses below and let me know if any additional questions. Best, Sven

How many new chems go to market each year? **Typically we receive about a thousand new chemical notices a year and about 500 new chemicals begin production annually.**

How many new chemicals since 1976? **There were originally about 60,000 chemicals on the inventory and it now has 84,000 chemicals. The additional 24,000 chemicals could be considered the amount of new chemicals since 1976.**

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 12, 2015 12:32 PM
To: Kaiser, Sven-Erik
Cc: Roberts, Alyssa (Tom Udall)
Subject: RE: need a stat ASAP...

Please cc: Alyssa. Thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, March 12, 2015 12:31 PM
To: Black, Jonathan (Tom Udall)
Subject: Re: need a stat ASAP...

Checking

On Mar 12, 2015, at 12:24 PM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

From: Roberts, Alyssa (Tom Udall)
Sent: Thursday, March 12, 2015 12:21 PM
To: Black, Jonathan (Tom Udall)
Subject: Chem stat

Hi— do you know how many new chemicals go to market each year? And/or, how many new chemicals since 1976?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2015 3:35:10 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Jim Jones

Thanks

On Mar 11, 2015, at 11:06 AM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

There are minor changes in the introduce version.

(1) <!--[if !supportLists]--><!--[endif]-->Changed "injury" to "harm" in the Safety Standard definition, per the AAJ request. (p.2 of redline)
(2) <!--[if !supportLists]--><!--[endif]-->AAJ, technical to New Chemicals (pp 20 and 22 – insert (g) in "subject to section 18" since new chemicals aren't subject to sec. 18 preemption, but they wanted a reference to their savings clause
(3) <!--[if !supportLists]--><!--[endif]-->AAJ technical to preemption (p. 58) re-order savings clause and insert "law" after maritime and state.
(4) <!--[if !supportLists]--><!--[endif]-->EPA technical (p.58) judicial review
(5) <!--[if !supportLists]--><!--[endif]-->Dimitri technical – p. 63 – clarified wording.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 11, 2015 11:00 AM
To: Black, Jonathan (Tom Udall)
Subject: Re: Jim Jones

Jonathan , I'll follow up on the request. Also, is the introduced bill the same text as the discussion draft of March 4. If not, is there a redline of the changes. Thanks,
Sven

On Mar 11, 2015, at 10:58 AM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Laura, Sven and Jim:

Our office would like to visit with you all - today or tomorrow.

Please let me know what times you are available to come in.

Thanks,
---Jonathan
<redline - compare S.697 and March 4 Version.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/10/2015 7:20:56 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Udall, Vitter Introduce Landmark Legislation to Protect Our Families from Toxic Chemicals

Thanks

On Mar 10, 2015, at 3:09 PM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

From: Tom Udall Press Office
Sent: Tuesday, March 10, 2015 2:31 PM
To: Tom Udall Press Office
Subject: Udall, Vitter Introduce Landmark Legislation to Protect Our Families from Toxic Chemicals

[cid:823CA620-182C-4375-84CF-B67BF18EFFCE]
FOR IMMEDIATE RELEASE: March 10, 2015

Udall, Vitter Introduce Landmark Legislation to Protect Our Families from Toxic Chemicals
The Frank R. Lautenberg Chemical Safety for the 21st Century Act fixes broken chemical regulatory scheme, ensures EPA can act based on latest science to protect all Americans

WASHINGTON – Today, U.S. Senators Tom Udall (D-N.M.) and David Vitter (R-La.) introduced major bipartisan legislation to protect Americans from toxic chemicals by enacting common-sense and necessary reforms to update the United States' wholly ineffective, outdated chemical regulatory program. The Frank R. Lautenberg Chemical Safety for the 21st Century Act is the result of nearly two years of deliberations and negotiations with stakeholders, affected communities and a bipartisan group of lawmakers who believe that Americans deserve certainty that the Environmental Protection Agency (EPA) is overseeing the safety of chemicals in the marketplace. The legislation creates a predictable and transparent federal system to regulate the safety of chemicals based on the latest science, providing greater regulatory certainty to the chemical manufacturing industry and striking a balance between state and federal roles in chemical safety management.

The current 40-year-old law governing the use of chemicals in everyday products, the Toxic Substances Control Act (TSCA), is widely considered to be ineffective as it has failed to ban even dangerous chemicals like asbestos. After years of unsuccessful efforts to rewrite the law, in 2013, the late Senator Frank R. Lautenberg joined Vitter to introduce the first ever bipartisan proposal to update TSCA, which the New York Times editorial board endorsed as "a significant advance over the current law."<http://www.nytimes.com/2013/05/30/opinion/a-senate-opening-to-strengthen-chemical-regulations.html?_r=1> Udall joined Vitter in the effort to carry the torch and further strengthen the bill after Lautenberg passed away.

The new Udall-Vitter bill builds on and strengthens the 2013 proposal by ensuring that cost cannot be considered in determining the safety of a chemical, defining "vulnerable populations" and requiring their protection, strengthening deadlines for the EPA to evaluate existing chemicals, adding new structure and requirements for confidential business information claims, and mandating that new chemicals cannot be manufactured until the EPA has approved them.

Fifteen cosponsors joined Udall and Vitter to introduce the bill, including seven Democrats and eight Republicans.

"Americans are exposed to a toxic soup of more than 80,000 different chemicals, but we have no idea what the impact of those chemicals is on our bodies – or those of our children. Current law has failed to protect Americans from dangerous carcinogens like asbestos, and Congress can't afford to stand on the sidelines any longer," Udall said. "This bill represents the best opportunity to strengthen safeguards against dangerous chemicals and dramatically improve existing law, while allowing innovation in the industry. I've worked closely with experts, environmental leaders and community groups to craft this bipartisan proposal, and am proud that we've come to a consensus on a bill that will break the logjam and protect our families."

"The Frank R. Lautenberg Chemical Safety for the 21st Century Act is a hugely important step into a new era of chemical safety that will better protect our future generations while promoting innovation and growth within our economy," Vitter said. "TSCA reform is too important for consumers and job-creating businesses to not follow through, especially when you consider the fact that chemicals are used to produce 96 percent of all manufactured goods consumers rely on every day. Our legislation is a solid, balanced, bipartisan compromise that will provide the necessary reforms to our nation's most important chemical safety law."

“Frank believed that fixing America’s chemical law could be his most significant legacy – in a career devoted to protecting public health,” said Bonnie Lautenberg, widow of Frank R. Lautenberg. “The new bipartisan proposal from senators Tom Udall and David Vitter builds important improvements upon the solid foundation Frank laid with Senator Vitter in 2013. I strongly encourage senators in both parties to step up and help finish the job of ensuring our families are protected from toxic chemicals.”

Original cosponsors include Sens. Joe Manchin (D-W.Va.), Jim Inhofe (R-Okla.), Tom Carper (D-Del.), Roy Blunt (R-Mo.), Chris Coons (D-Del.), John Boozman (R-Ark.), Joe Donnelly (D-Ind.), Mike Crapo (R-Idaho), Martin Heinrich (D-N.M.), Shelley Moore Capito (R-W.Va.), Heidi Heitkamp (D-N.D.), John Hoeven (R-N.D.), Debbie Stabenow (D-Mich.), Rob Portman (R-Ohio) and Bill Cassidy (R-La.).

Core provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act:

Strengthens the Safety Standard
- Mandates that EPA base chemical safety decisions solely on considerations of risk to public health and the environment. The legislation makes clear that costs and benefits may not factor into a chemical safety evaluation.
- Eliminates TSCA’s “least burdensome” requirement for regulating a chemical, which prevented EPA from banning asbestos.

Mandates safety reviews for new and existing chemicals
- Requires that all chemicals in commerce, including those "grandfathered" under TSCA, undergo safety reviews.
- Requires a safety finding for new chemicals before they can enter the market.

Strengthens Protections for the Most Vulnerable
- Places greater emphasis on and requires protection of those who may be more exposed or particularly vulnerable to the effects of exposure to chemicals, and clearly defines them for the first time as including infants, children, pregnant women, workers and the elderly.

Sets Aggressive and Attainable Deadlines
- Imposes at least 15 deadlines for EPA action, developed with input from the Agency.

Creates additional requirements and sets reasonable limits on Confidential Business Information claims
- Requires that confidentiality claims be substantiated up front and imposes a 10-year, renewable time limit on such claims.
- Requires EPA to review claims that protect the identities of chemicals in commerce.

Preserves Existing Private Rights of Action
- Clarifies that the existing right of Americans to sue and seek damages when they believe harm has been done is not affected by the bill.
- Makes clear that nothing in the bill affects the ability of litigants to obtain confidential information in a judicial proceeding.

Balances State and Federal Regulations
- Grandfathers in state regulations on chemicals enacted prior to Jan. 1, 2015.
- States can act to restrict a chemical until and unless EPA takes up that same chemical and addresses the same uses.
- State actions that do not restrict a chemical or are taken to address a different problem are not affected.
- Includes a waiver process for states to set different regulations than EPA during the safety assessment and after a final rule.
- Once EPA acts on a chemical substance, a uniform federal standard is applied across the nation, which creates more regulatory certainty and equally protects citizens across the country.

A full overview of the Udall-Vitter bill can be found HERE<http://www.scribd.com/doc/258282642/Udall-Vitter-Fact-Sheet-on-Frank-R-Lautenberg-Chemical-Safety-for-the-21st-Century-Act>. Bill text is available HERE<http://www.scribd.com/doc/258283745/The-Frank-R-Lautenberg-Chemical-Safety-for-the-21st-Century-Act>.

###

Contacts: Jennifer Talhelm (Udall) 202.228.6870 / Cheyenne Klotz (Vitter) 202.224.4623
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<FRL21 - Section by Section - (3-10-15).pdf>
<FRL21 - TSCA flow chart (3-10-15).pdf>
<The Frank R. Lautenberg Chemical Safety for the 21st Century Act - (3-10-15).pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/28/2015 10:14:47 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Nomenclature
Attachments: Markey.TSCA TA.Nomenclature.docx

Michal,
Attached please find the requested technical assistance on nomenclature. Please let me know if you would like a call to discuss the TA. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/28/2015 10:13:30 PM
To: 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Merkley TSCA TA on Nomenclature
Attachments: Merkley.TSCA TA.Nomenclature.docx

Adrian,
Attached please find the requested technical assistance on nomenclature. Please let me know if you would like a call to discuss the TA. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Deveny, Adrian (Merkley) [mailto:Adrian_Deveny@merkley.senate.gov]
Sent: Wednesday, October 07, 2015 10:44 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Nomenclature

Sven
Can EPA provide a written explanation of its interpretation of the nomenclature section of the Lautenberg Act. Also, can you share any TA on the language, to the extent there are any drafting issues?
Thank you,
Adrian

ADRIAN DEVENY
Legislative Assistant
SENATOR JEFF MERKLEY
313 Hart Senate Office Bldg.
Washington, DC 20510 | (202) 224.3753
***
Sign up to receive Senator Merkley's e-newsletter
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This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill, the draft language and the comments.

Base text from Senate Report is in bold.

EPA interpretation and TA is in italics.

***

(3) NOMENCLATURE.—

(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

> **(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;**

EPA interprets this as a requirement to continue its current practice of allowing Class 2 chemical substances to be named and listed as discrete entries on the TSCA Inventory. EPA believes it would retain technical discretion to ensure that Class 2 chemical naming is done correctly.

> **(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and**

EPA interprets this as a requirement to continue its current practice of naming a certain subset of UVCB substances in a manner consistent with the particular naming convention set forth in the above-cited documents. In general terms, the substances at issue are the soap-like derivatives of certain fats and oils.

> **(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—**
>
> > **(I) cement, Portland, chemicals, CAS No. 65997– 15–1;**
> >
> > **(II) cement, alumina, chemicals, CAS No. 65997–16–2;**
> >
> > **(III) glass, oxide, chemicals, CAS No. 65997–17– 3;**
> >
> > **(IV) frits, chemicals, CAS No. 65997–18–4;**
> >
> > **(V) steel manufacture, chemicals, CAS No. 65997–19–5; and**
> >
> > **(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.**

The TSCA Inventory contains detailed descriptions of what categories of substances fall within the scope of the above listed CAS numbers. In general terms, whether these listings cover a substance depends on both the constituents of the substance <u>and</u> on whether the substance was manufactured in the course of making cements, glasses, frits, steel, or ceramics. EPA interprets this language as a statutory ratification of the scopes of these particular UVCB listings, as listed in the TSCA Inventory, in a manner consistent

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill, the draft language and the comments.

with appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a).

The drafting of this section could be improved in certain respects. First, it could be written to provide that the list of (I) through (VI) is an exclusive list, unless there is intent to ratify the scope of some other (unstated) descriptions found on the TSCA Inventory or elsewhere.

While EPA can interpret the phrase "all components of categories that are considered to be statutory mixtures under this Act," the phrasing is awkward and it could be improved to reduce the chance of confusion. The following would be clearer: "all chemical substances described by the following category listings, when manufactured as described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a)."

(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

(I) maintain the nomenclature conventions for substances; and

(II) develop new guidance that—

(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

The scope of this provision is determined by the extent of existing guidance allowing for multiple nomenclature conventions. EPA would interpret the reference to "guidance" as referring only to EPA guidance. EPA is not aware of any such existing EPA guidance.

(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

EPA is not currently aware of any chemical substance that is listed multiple times on the TSCA inventory, so it does not expect that this subparagraph would be operative. In the event such multiple listings were identified, EPA would likely delete the duplicate listing(s), obviating the need to develop guidance pursuant to this provision.

***

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/25/2015 9:02:31 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: TSCA Reform: Additional Technical Assistance
Attachments: Udall-Vitter Draft P and T redline 20150211 -- February Comments.docx

Dimitri and Jonathan,
Here is the TA requested at the recent meetings. CBI (in both sections 8 and 14) and preemption are particularly comment-rich areas. The version we commented on is the one we you sent, with your comments deleted (except where we are reacting directly to one of the comments. Please note that this technical assistance is provided in response to your request and does not necessarily represent the policy positions of the agency and the administration on the bill and comments. Also please note that due to formatting issues, we could not delete the names in the comment boxes, please disregard those. Let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

WORKING DRAFT P February 5, 2015
WORKING DRAFT P and T February 11, 2015
Reflecting changes to the September, 2014 draft

Title: To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Chemical Safety Improvement Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2~~(a)~~ of the Toxic Substances Control Act (15 U.S.C. 2601(a)) is amended—

(1) in ~~paragraph~~ subsection(2)—

~~(A)~~ by striking "injury" and inserting "harm"; ~~and~~

~~(B) by striking "and" at the end;~~

(2) ~~by redesignating paragraph (3) as paragraph (4); and~~

~~(3) by inserting after paragraph (2) the following:~~ in subsection (c)—

(A) by designating the existing paragraph as paragraph (1);

(B) by inserting at the end of paragraph (1) as so designated, "as provided under this Act."; and

(C) by inserting at the end of paragraph (1) (as so designated), the following:

"(2~~3~~) R~~r~~eform of this Act in accordance with the amendments made by the Chemical Safety Improvement Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief; and".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

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Commented [GB1]: Should consistently use "harm" or "injury" throughout TSCA.

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Commented [GB2]: Seems like the better verb would be "implementation". Also, even if the word is changed, this provision raises the question whether the portions of existing TSCA that are retained should not be administered to protect children, etc., and whether they displace common law rights. Eg, do section 7 actions displace common law rights?

(1) by redesignating paragraphs (7), (8), (9), (10) , (11), (12), (13), and (14) as paragraphs (9), (10), (11), (13), (14), (19), (20), and (21), respectively;

(2) by inserting after paragraph (6) the following:

"(7) INFORMATION.—The term 'information' means any qualitative, quantitative, or descriptive facts, data, analysis, or assessment related to the manufacture, processing, distribution in commerce, use or disposal of chemical substances or to chemical hazards, use, or exposure (including the nature and extent of exposure to a chemical substance), including from health and safety studies.

"(8) ~~INTENDED OR REASONABLY ANTICIPATED~~ CONDITIONS OF USE.—The term '~~intended or reasonably anticipated~~ conditions of use' means the intended, known or reasonably foreseeable circumstances under which the Administrator determines ~~are those under which~~ a chemical substance is ~~intended, reasonably known, or reasonably anticipated to be~~ manufactured, processed, distributed in commerce, used, ~~and~~ or disposed of. The term does not include intentional misuse for non-commercial purposes.";

(3) by inserting after paragraph (11) (as so redesignated) the following:

"(12) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the ~~intended or reasonably anticipated~~ conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (14) (as so redesignated) the following:

"(15) PUBLICLY AVAILABLE.—

"(A) IN GENERAL.—The term 'publicly available', with respect to information, means information that is—

"(i) generally accessible and available to the general public; or

"(ii) in the public domain.

"(B) INCLUSIONS.—The term 'publicly available', with respect to information, includes information that has been published in periodicals, books, print, an electronic format, or other media available for general distribution to any member of the public.

"(16) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(17) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the ~~intended or reasonably anticipated~~ conditions of use.

Commented [GB3]: It's awkward that chemical hazards, etc., is already covered by the new added phrase "manufacture", etc, since hazard, use and exposure information is part of information relating to manufacture, ect. Most obviously, "use" is listed twice. Might be most straightforward to end the definition after "assessment".

Commented [GB4]: Reasonably foreseeable circumstances under which a chemical substance "is" manufactured, etc., does not really make sense.

Commented [GB5]: This could be very broad. Is any "off label" use not included, even if it's widely practiced?

"(18) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use, including no unreasonable risk of harm to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

Commented [GB6]: Why not define "policies, procedures and guidance"? That is the phrase used in this section. If this purpose of this is to limit the notice and comment obligation imposed in (b), it leaves open the question whether even insignificant policies and procedures require notice and comment.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies, ~~and~~ procedures and guidance described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall ~~describe the manner in which the Administrator shall~~ ensure that —

Commented [SI_7]: This is an example of a guidance that appears to create requirements – it seems to require guidance that requires use of best available science, weight of evidence, etc.

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework

to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate,~~ existing relevant policies, procedures and guidance, as appropriate, and consistent with this Act, ~~hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.~~

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In carrying out~~making any decision with respect to a chemical substance under~~ sections 4, 4A, 5, ~~or~~ and 6, the Administrator shall take into consideration information relating to ~~the hazards and exposures of~~ a chemical substance, including hazard and exposure information, under the ~~intended or reasonably anticipated~~ conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any ~~regulation~~rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of human health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—In establishing t~~T~~he policies and procedures ~~established~~ under paragraph (1) the Administrator shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) ~~require~~ consult, as appropriate ~~the Administrator to consult~~ with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

~~"(4) TIERED TESTING.—~~

~~"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.~~

~~"(B) SCREENING-LEVEL TESTS.—~~

~~"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.~~

~~"(ii) USE.—Screening-level tests shall be used—~~

Commented [SI_8]: Doesn't make sense – says EPA must consult NIOSH prior to requiring epi studies in establishing the policies procedures and guidance.

Commented [SI_9]: This appears to require imposition of requirements through guidance. Also, as with previous comment, this seems to impose a requirement on individual EPA actions, but the overall context here is what EPA must do in establishing the guidance.

~~"(I) to screen chemical substances or mixtures for potential adverse effects; and~~

~~"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.~~

~~"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential human health or environmental effects or exposure potential.~~

~~"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.~~

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by ~~regulation~~guic, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—In establishing ~~At a minimum,~~ the policies and procedures under this paragraph the Administrator shall, at a minimum—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which ~~that~~ information submitted by interested individuals or organizations will be evaluated;

"(ii) require that each draft and final safety assessment and safety determination of the Administrator include a description of~~the Administrator~~—

"(I)(aa) ~~to identify~~ the hazards, exposures, ~~intended or reasonably anticipated~~ conditions of use of the chemical substance, and potentially exposed and susceptible populations that the Administrator has considered~~expects to consider in a safety assessment~~; and

"(bb) ~~to explain~~ the basis for those identifications ~~; and~~

~~"(cc) to accept comments regarding the identifications; and~~

~~"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and~~

~~"(bb) to explain the basis for the consideration of those items;~~

"(II~~iii~~) ~~describe~~ the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use ~~will be~~were considered, and ~~explain~~ the basis for that consideration ~~in the final safety assessment~~;

~~"(iv) require that each safety assessment and safety determination shall include~~—

"(III) ~~a description of~~ the weight of the scientific evidence of risk; and

"(IV) ~~a summary of~~ the information regarding the impact on human health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies; and

"(~~iii~~v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop guidance to assist interested persons in developing their own draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft safety assessment for consideration by the Administrator.

Commented [SI_10]: Why is this "Guidance" treated as separate from the "policies, procedures and guidance" required under A, rather than as a specific type of policy, procedure and guidance required? Does "guidance" here have a different meaning than it does in "policies, procedures and guidance" used elsewhere?

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), (e) and (g);

(2) by redesignating subsection~~s (e) and~~ (f) as subsection~~s (f) and~~ (g)~~, respectively~~;

~~(3) in subsection (f) (as so redesignated)—~~

~~(A) by striking "rule" each place it appears and inserting "regulation, testing consent agreement, or order";~~

~~(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and~~

~~(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";~~

(~~3~~4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(~~d~~e) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(~~g~~f), the Administrator may require the development of ~~test data and~~ information described in paragraph (1) or (2) by—

"(A) promulgating a ~~regulation~~rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A ~~regulation~~rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of ~~test data and~~ information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed

Commented [SI_11]: Would be better to add "any" before "reliable", to account for situations where there are none.

Commented [SI_12]: There remains tension in the bill as to whether the goal is to reduce all animal testing or only vertebrate animal testing.

in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; ~~and~~

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing, and

"(iii) the recommendations of other federal agencies respecting the chemical substances and mixtures to which the Administrator should give priority consideration under this section.

Commented [SI_13]: If the idea is to require EPA to consider recommendations of other agencies re testing priority, this doesn't do it. As placed under (B), this relates to how the Administrator carries out (A), which pertains only to the content of individual test rules and orders, not to which chemicals get tested.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a ~~regulation~~rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the ~~regulation~~rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

Commented [SI_14]: Again, ideally should reconcile "animals" and "vertebrate animals"

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a ~~regulation~~rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

Commented [SI_15]: Vertebrate animals, consistent with the subsection heading and intro text to the paragraph? We haven't flagged every instance of this discrepancy.

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information used in safety assessments and safety determinations under section 6 that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) beginning on the date that is 5 years after the date of enactment of the Chemical Safety Improvement Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(C) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing for the purposes of conducting a safety assessment or safety determination under section 6.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient

to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the ~~regulation~~rule, testing consent agreement, or order; but

"(ii) subject to paragraph (3), before the period ending on the date that is 180 days after the end of the period described in ~~this section~~the rule, testing consent agreement or order issued under paragraph (4)(A).

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a ~~regulation~~rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the

Commented [SI_16]: Why is (i) not subject to (3)?

Commented [SI_17]: This citation should be to 4(a)(4)(A), because otherwise it could be misconstrued as a reference to 4(d)(4)(A), since we're now in subsection 4(d).

Commented [SI_18]: This still doesn't make sense. "The period ending on the date. . ." doesn't have any beginning, so how can the manufacture commence before that period? What is actually envisioned here?

Administrator determines that ~~a person covered by the exemption has failed to comply~~no person has complied with the ~~regulation~~rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests that may be required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for a purpose described in section 4(a), the Administrator may require more advanced tests for potential human health or environmental effects or exposure potential.

Commented [SI_19]: Shouldn't this say "for such purpose", linking back to 4(a), rather than adding a new description of the purposes of testing under 4(a)?

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) ~~Establishment~~ Prioritization Screening Process and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, ~~by regulation~~rule, a risk-based screening process and **explicit** criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the ~~regulation~~ rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall ~~take into~~ consider~~ation~~ and publish an initial list of high-priority substances **and low-priority substances**; and

"(ii) pursuant to section 6(b)~~(2)~~, may initiate or continue safety assessments and safety determinations for those ~~chemical~~ **high-priority** substances.

"(B) REQUIREMENTS.—The initial list of ~~high-priority~~ chemical substances shall contain at least 10 ~~chemical~~ **high-priority substances and at least 10 low-priority** substances.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In ~~carrying out~~implementing the prioritization screening process under paragraph (1), the Administrator shall ~~take into~~ consider~~ation~~ active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In ~~carrying out~~implementing the prioritization screening process under paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

Commented [SI_20]: Add "by" back in

Commented [SI_21]: Does this mean that criteria established under other provision of the bill should not be explicit?

Commented [SI_22]: "May" is wrong. EPA must initiate safety assessments and determinations on high priority substances, and that is pursuant to 6(a), not 6(b).

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all ~~high-priority~~ chemical substances not designated as low-priority.

"(III) ~~LOW-PRIORITY SUBSTANCES~~REPRIORITIZATION.—

"(aa) **If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.**

"(bb) If a high-priority substance is subsequently designated as a low-priority substance, the Administrator shall remove that substance from the list of high-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) except as provided under paragraph (2), not later than 180 days after the effective date of the final ~~regulation~~rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the ~~prioritization screening~~ **designation** of all active **substances as high-priority substances or low-priority** substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a ~~regulation~~rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances **and designate high-priority substances** taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process

to allow for timely and adequate **designations of high-priority substances and low-priority substances and** safety assessments and safety determinations **for high-priority substances**.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish and provide an opportunity for public comment on a list of chemical substances ~~that~~—

"(i) that are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process~~, including those chemical substances~~;

"(ii) for which prioritization decisions have been ~~deferred~~postponed pursuant to subsection (b)(5), including the basis for such postponements; and

"(iii) that are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including specific scientific classifications and designations by authoritative governmental entities;

"(C) the ~~intended or reasonably anticipated~~ conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported pursuant to a rule promulgated under ~~under a regulation promulgated pursuant to~~ section 8(a) has significantly increased or decreased ~~during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance~~;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

Commented [SI_23]: This appears to suggest that existing regulation would militate in favor of a low priority designation. Is that what's intended? If so, it seems in tension with (b)(8), which seems to suggest that state regulation would militate in favor of a high priority designation. Overall, the bill is not clear which way existing regulation cuts.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—In implementing [T]he prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF REASONABLY AVAILABLE INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrateconsider any hazard and exposure information relating to the chemical substance that is reasonably available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the applicable safety standard.

"(5) DEFERRING A DECISION POSTPONING A DECISION.—If the Administrator determines that additional information is required needed to establish the priority of a chemical substance under this section, the Administrator may deferpostpone a the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a regulationrule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the

~~basis for the decisions; and~~

~~"(B) provide an opportunity for public comment.~~

"(~~7~~8) REVISION BASED ON NEW INFORMATION.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on new information made available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(~~8~~9) **OTHER INFORMATION RELEVANT TO PRIORITIZATION.—**

"(A) IN GENERAL.—If, after the date of enactment of the Chemical Safety Improvement Act, a State enacts a statute or takes an administrative action to ~~restrict or~~ prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the ~~intended~~ conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction ~~or prohibition~~, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a ~~restriction or a~~ prohibition or other

restriction **under a statute or administrative action in 2 or more States.**

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or subject a State to section 15.

Commented [SI_24]: What does this mean? It's probably not a big deal, but it could suggest that states are not otherwise subject to section 15, or be taken as providing some relief to a state under section15.

"(~~9~~**10)** REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

~~"(10)~~**"(**~~10~~**11)** EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Expedited Prioritization ~~Screening.—~~ **Screening Requested by States.—**

"(1) IN GENERAL.—Not later than 180 days after the date on which the Administrator receives from the Governor of a State or a State agency with responsibility for protecting health and the environment a recommendation and relevant information justifying that ~~an active~~ **a** substance be ~~identified~~ **designated under paragraph (3) or (4) of subsection (b)** as a high-priority substance or a low-priority substance, the Administrator shall make a prioritization screening decision for the ~~active~~ substance.

"(2) LIMITATION.—The Governor of a State or a State agency with responsibility for protecting health and the environment may annually recommend not more than 2 chemical substances for prioritization screening under paragraph (1).

"(3) RECOMMENDATION.—Notwithstanding subsection (b)(~~7~~**8**), a recommendation by the Governor of a State or a State agency with responsibility for protecting health and the environment with respect to a chemical substance that has been previously prioritized shall not be required to be based on new information.

"(4) NOTICE AND COMMENT.—The public shall be provided notice and an opportunity to comment regarding the recommendations submitted under this subsection.

"(5) EXPLANATION OF REASONS.—The Administrator shall—

"(A) make available to the Governor or State agency, as applicable, and to the public a brief explanation of the reasons for—

"(i) identifying a chemical substance recommended by the Governor or State agency for prioritization screening as a high-priority substance or a low-priority

substance; or

"(ii) ~~deferring postponing the a prioritization screening prioritization screening~~ decision on the chemical substance pursuant to section (b)(5); and

"(B) identify the information relied on in making that identification.

"(d) ~~Treatment.—Except as provided in section 18(e)(6)(B), an~~ **Additional Priorities for Safety Assessments and Determinations.—**

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance, or that has not been subject to or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E); and

"(B) provide guidance to submitters on the information to be provided in such requests, and specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(2) PREFERENCE.—Subject to paragraph (3), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) not more than 15 percent of the total number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section.

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the

Commented [SI_25]: It would probably be better to require development of a separate screening process here, rather than describe it as part of the process under (a). The screening process under (a) is described as a risk-based process for identifying high and low priority chemicals, but the apparent intent of this subsection is to develop a process to identify substances for safety assessments and determinations even thought they are not high priority and do not necessarily have potential for high hazard or high exposure.

Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(h) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

"(5) EXCEPTIONS.—Requests granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).

Commented [SI_26]: Would be clearer if this said: "Chemical substances for which requests have been granted under this subsection"

"(e) Treatment.—An action by the Administrator under this section shall not be—

"(1) considered to be a final agency action; or

"(2) subject to judicial review.".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

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"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) known or reasonably ascertainable information regarding ~~intended or reasonably anticipated~~ conditions of use and reasonably anticipated exposures.";

Commented [SI_27]: Consider adding "all" before "known", if that's the intent.

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by replacing "subsection (a)" with "subsection (b)";

(ii) by striking "or of data under subsection (b)";

(iii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iv) in subparagraph (B), by striking "; and" and inserting a period; and

(v) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make a~~ny necessary~~ determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and based on the information described in paragraph (2), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the

safety standard, in which case the Administrator shall take appropriate action under paragraph (~~4~~5);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b), the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) ~~take into~~ consider~~ation~~ whether to promulgate a ~~regulation~~ rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance~~, or of the chemical substance for a new use,~~ that does not conform to~~is not in compliance with~~ the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(ii) a requirement that manufacturers ~~or and~~ processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in

commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other ~~regulation~~ restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other ~~appropriate~~ restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health ~~prior to~~before adopting any prohibition or restriction under this subsection to address workplace exposures.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a ~~regulation~~rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.

"(6) ~~REGULATION RESTRICTIONS~~ PENDING DEVELOPMENT OF INFORMATION.—Subject to paragraph (4)(B), the Administrator may permit manufacture for commercial purposes of a chemical substance~~, or manufacture or processing of a chemical substance for a significant new use,~~ to commence pending receipt of the additional information, subject to compliance with any restrictions under paragraph (4) determined by the Administrator to be sufficient to ensure that the chemical substance ~~or significant new use~~ is likely to meet the safety standard.

Commented [SI_28]: This provision seems unnecessary in light of (d)(4) and has terms (eg, "permit") that seem confusing.

"(7) COMMENCEMENT OF MANUFACTURE ~~OR PROCESSING~~.—Subject to paragraphs (4), (5), and (6), at the end of the applicable period for review under paragraph (1), the submitter of

a notice under subsection (a) may commence manufacture for commercial purposes of a chemical substance or manufacture or processing of a chemical substance for a significant new use.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer ~~or processor~~ that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer ~~or processor~~ shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer ~~or processor~~; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, ~~regulations~~rules, and orders submitted under this section or made by ~~of~~ the Administrator under this section; and

"(2) all information submitted or issued under this section.";

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

Commented [SI_29]: Note that (7) (and section 5 generally) does not bar manufacture or processing in the face of a negative safety finding unless EPA has gotten the order under (4) in place by the end of the review period.

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4),". ~~; and~~

~~(H) by adding at the end the following:~~

~~"(i) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section before the date of enactment of the Chemical Safety Improvement Act.".~~

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g~~k~~) and (h~~i~~), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(3) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(4) shall promulgate a~~ny necessary~~ final ~~regulation~~ rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(5) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under ~~paragraphs (3) and (4)~~ this subsection, including ~~and~~ any deferral under subsection (c)(2), does not exceed 2 years.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Chemical Safety Improvement Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

Commented [SI_30]: Should be "policies, procedures and guidance", throughout the bill.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent

practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or ~~regulation~~ rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or ~~regulation~~ rule shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by ~~regulation~~ rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard ~~under the intended or reasonably anticipated conditions of use~~; or

"(ii) if the safety standard cannot be met with the application of other restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a ~~regulation~~rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) ~~Regulation~~Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a ~~regulation~~ rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—

"(A) The ~~regulation~~ rule promulgated pursuant to this subsection—

"(~~i~~A) may—

"(~~I~~i) apply to mixtures containing the chemical substance, as appropriate; and

"(~~II~~ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

"(~~ii~~B) shall include dates by which compliance is mandatory, which—

"(~~I~~i) shall be as soon as practicable; and

"(~~II~~ii) as determined by the Administrator, may vary for different affected persons.

"(~~B~~C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers ~~and~~or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any ~~regulation~~ rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban, ~~or~~ phase out, or ~~any~~ otherwise ~~regulation restrict regarding~~ the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ~~restrict,~~ ban, ~~or~~ phase out, or ~~any other regulation~~otherwise restrict ~~of,~~ any method of commercial use of the chemical substance;

"(G) a requirement to ~~restrict,~~ ban, ~~or~~ phase out, or otherwise restrict ~~any other regulation of,~~ any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) ~~unreasonable risks of harm~~ to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a ~~regulation~~ rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a ~~regulation~~ rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a ~~regulation~~rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may by rule or order exempt 1 or more uses of a chemical substance from any restriction in a ~~regulation~~ rule promulgated under paragraph (1) if the Administrator determines that—

"(i) the ~~regulation~~ rule cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to human health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a ~~regulation~~ rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a ~~regulation~~ rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more ~~technically and economically feasible~~ alternatives to the chemical substance the Administrator determines to be technically and economically feasible and most likely to be used in place of the chemical substance under the ~~intended or reasonably anticipated~~ conditions of use if the ~~regulation~~ rule is promulgated.

"(E) CONDITIONS.—As part of a ~~regulation~~ rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect human health and the environment to the extent practicable while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a ~~regulation~~ rule under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by ~~regulation~~rule, may extend, modify, or eliminate ~~an~~the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the

Commented [SI_31]: Although the addition of "or order" in (5)(A) partially addresses our earlier comment, (B) through (F) still create confusion. (B) through (F) apply only when EPA creates an exemption as part of the rulemaking under (1) – ie, the initial rulemaking establishing the restrictions for the chemical. They do not apply if EPA creates an exemption by order, or if EPA creates an exemption through a separate rulemaking after the rulemaking under (1) (assuming the intent is that EPA can do that). Was that the intent? It seems odd that the applicability of all these extensive analyses and limitations depends on the timing of when the exemption is created. This structure will create an argument that EPA can create exemptions only in the initial rulemaking under (1), at least when EPA acts by rule.

Commented [SI_32]: The rule establishing the exemption? The rule establishing the restrictions? It's hard to follow what (D) requires.

Commented [SI_33]: We have to do this by rule even if the exemption was created by order?

development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a ~~regulation~~ rule requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed ~~regulation~~ rule under subsection (d) to be effective on publication of the ~~regulation~~ rule in the Federal Register and until the effective date of final action taken respecting the ~~regulation~~rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed ~~regulation~~ rule or any combination of those activities is likely to result in ~~an unreasonable risk of~~ serious or widespread ~~injury~~ harm to health or the environment before the effective date; and

"(B) making the proposed ~~regulation~~ rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed ~~regulation~~ rule to prohibit ~~or otherwise restrict~~ the manufacture, processing, or distribution in commerce of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

Commented [SI_34]: This should be dropped. The point of (2) is to specify additional requirements to make a prohibition immediately effective.

"(f) Final Agency Action.—Under this section—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final ~~regulation~~ rule promulgated under subsection (d), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final ~~regulation~~rule.";

(4) in subsection (~~g~~h) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4)~~; and~~

~~(5) by adding at the end the following:~~

~~"(j) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section, as in effect on the day before the date of enactment of the Chemical Safety Improvement Act.~~".

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) ~~REGULATION~~RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

~~"(i)~~ a decision, rule, consent agreement, or order by the Administrator under section~~s~~ 4, 4A, 5~~(d)(3)~~, ~~or~~ 6~~(c)(1)~~ or Title IV; or

~~"(ii) a regulation, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or~~

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) ~~REGULATIONS~~RULES.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall promulgate ~~regulations~~ rules requiring the maintenance of records and the reporting of additional information known or reasonably ascertainable by the person making

the report, including ~~regulations requiring~~ processors, to report information, so that the Administrator has the information necessary to carry out ~~sections 4 and 6~~this title.

"(ii) MODIFICATION OF PRIOR ~~REGULATIONS~~RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, ~~regulations~~ rules promulgated before the date of enactment of the Chemical Safety Improvement Act.

"(B) CONTENTS.—The ~~regulations~~ rules promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.~~; and~~

~~"(iii) shall apply only in cases in which the Administrator determines that the submission of reports would assist in the effective implementation of this Act.~~

"(C) ADMINISTRATION.—In implementing the recordkeeping and reporting requirements under this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the ~~regulations~~ rules on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

~~"(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the regulations promulgated under this subsection.";~~

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) subject to section 3A(e), maintain the use of Class 2 nomenclature in use on the date of enactment of the Chemical Safety Improvement Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

Commented [SI_35]: This text is surplussage.

Commented [SI_36]: If this is intended to give EPA authority to modify the conventions codified in the paragraph, it doesn't do that because: 1. 3A(e) gives EPA authority only to review policies and procedures developed under 3A, not to change statutory requirements in other sections; and 2. This proviso applies only to (i), not (ii) and (iii).

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) REGULATIONS.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator, by ~~regulation~~rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the ~~regulation,~~ rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Chemical Safety Improvement Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall ~~, pursuant to paragraph (5)(A),~~ designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating ~~(~~The ~~regulation~~ rule ~~promulgated by the Administrator~~established pursuant to subparagraph (A) the Administrator shall ~~require~~—

"(i) ~~the Administrator to~~ maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) require a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) require the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a ~~regulation~~ rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

Commented [SI_37]: Seems like it would be clearer to instead say: "that are asserted under subparagraph (B)".

Commented [SI_38]: Inclusion of active substances identified under (f)(1) doesn't make sense here. It appears that the intent of the Plan is to ensure review of all *pre-existing* claims. There are separate provisions in the bill to address review of new claims or claims pertaining the inactive substances that become active. (C) should presumably be limited to claims under (B).

"(D) REQUIREMENTS OF REVIEW PLAN.—~~Under t~~The review plan under subparagraph (C), the Administrator shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) ~~require the Administrator,~~ in accordance with section 14—

"(I) ~~to~~ review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2);

and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of ~~applicable~~ claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(F) LIMITATION.—The specific identity of any chemical substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.

"(G) CERTIFICATION.—The ~~regulation~~ rule under this subsection shall require a manufacturer or processor—

"(i) to certify the accuracy of each report of the manufacturer or processor carried out under the ~~regulation~~rule; and

"(ii) to retain a record supporting that certification for a period of 5 years beginning on the last day of the submission period.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

~~"(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—~~

~~"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and~~

~~"(ii) the regulations promulgated pursuant to subsection (a)(4).~~

"(B~~C~~) CHANGE TO ACTIVE STATUS.—

Commented [SI_39]: This deadline reinforces the comment on (C), above, that the plan should be limited to pre-existing claims. How can EPA meet this deadline as to claims asserted in the future in new PMN submissions?

Commented [SI_40]: 1)Per conversations, at the very least this should be changed to avoid the result that identities of new chemicals cannot be CBI (because they are not on the confidential inventory). And if the intent is to address *how* CBI claims over the link between Chem ID and other data are asserted (i.e., not by masking the Chem ID itself) this needs to be phrased differently. That would not be a restriction on what can be claimed as CBI but rather a restriction on the manner in which a CBI claim can be asserted. These comments apply wherever similar language is used in the bill.

Commented [SI_41]: This is confusing. This subsection (b) requires two rules: the A rule for active/inactive, and the C rule establishing a review plan. Which is intended?

Commented [SI_42]: This is also confusing. Neither of these rules requires reports. Was G intended to apply to the (a)(4) rule, which is in a different subsection?

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—

"(I) IN GENERAL.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(aa) in the notice submitted under clause (i), assert the claim; and

"(bb) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(II) LIMITATION.—The specific identity of any inactive substance that is not on the confidential portion of the list published under paragraph (1) ~~or subsequently added to the confidential portion of the list pursuant to section 14~~ shall not be eligible for protection from disclosure.

Commented [SI_43]: Same comment as above.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of ~~not less than~~ 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the ~~regulation~~

rule required under this subsection, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Chemical Safety Improvement Act, as the ~~initial~~ interim list of active substances for the purposes of section 4A.

"(7) PUBLIC ~~PARTICIPATION~~INFORMATION.—Subject to this subsection, the ~~Administrator shall make~~following information shall be made available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) ~~except as provided in subparagraph (C)~~ the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received ~~and approved by the Administrator pursuant to section 14~~; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) ~~APPLICABILITY~~ADDITIONAL INFORMATION.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of ~~injury~~ harm to human health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Chemical Safety Improvement Act;

"(B) that is added to the list published under subsection (b)(1) after that date of

Commented [SI_44]: The (b)(4) rule?

Commented [SI_45]: This should be stricken, since the reference here is to the previous reports under the exiting rule.

Commented [SI_46]: This suggests that something in (C) allows the withholding even of accession number, etc., for confidential chemicals.

Commented [SI_47]: Consider rewording as: "a claim for protection against disclosure of the specific identity of the active chemical substance was not asserted as required by this subsection or section 14." The issue with the current wording is that not all CBI chem. id claims will be received under this subsection; claims for new chemicals will be asserted and received under section 14.

Commented [SI_48]: This is a good example of where the un-reconciled use of "harm" and "injury" will cause problems. TSCA 8(e) (retained here as 8(e)(1)) uses "injury"; the new 8(e)(2) would use "harm".

enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

Commented [SI_49]: Note that an active substance can never become inactive, so EPA will never to able to "reset" the inventory.

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7"; and

(C) in paragraph (3), by striking "section 6 or 7" and inserting "section 6(d) or 7"; and

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

Commented [SI_50]: At a minimum, Section 6 obligations to act should be relieved, to the extent that Section 9 forbids EPA to act.

In light of Section 6 deadlines, it would also be helpful to clarify:

(1) That the option to make a referral doesn't open up until *after* the EPA makes its own safety determination.

(2) That EPA is free to proceed with the 6(d) risk management process if the other federal agency is not timely and appropriately responsive.

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

"(A) under section 5 is not likely to meet the safety standard; or

"(B) under section 6 does not meet the safety standard.

"(3) ~~WAIVERS~~MIXTURES AND ARTICLES.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

Commented [SI_51]: This is a very significant change to current TSCA. TSCA generally exempts exported chemicals from otherwise applicable TSCA regulations, unless the exported chemical will present unreasonable risk *in the US*. The logic of section 12 is that TSCA is designed to protect US citizens, and it requires EPA to give notice of export of chemicals of concern so that foreign governments can protect their citizens. As revised, this would regulate exported chemicals any time an adverse section 5 or section 6 finding is made for the chemical as a whole (not for the exported fraction). This could suggest that EPA must consider risks beyond the US when regulating under section 5 and 6. It also largely eliminates the effect of 12(a)(1), since almost all chemicals that are regulated and potentially subject to the 12(a)(1) exemption will fall into the class of chemicals that are subject to this 12(a)(2) exception.

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture ~~presents an unreasonable risk of harm to human health~~meets the safety standard within the United States ~~or to the environment of the United States~~.";

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance ~~or a mixture containing a chemical substance~~ that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture ~~containing a chemical substance~~ that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture subject to a prohibition or other restriction pursuant to a regulation, order, or consent agreement in effect under this Act; ~~or~~

"(E) a chemical substance or mixture for which the submission of information is required under section 4; or

~~"(F) a chemical substance or mixture for which an action is pending or for which relief has been granted under section 7.~~

"(2) REGULATIONS.—

"(A) IN GENERAL.—The Administrator shall promulgate regulations to carry out paragraph (1).

"(B) CONTENTS.—The regulations promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the regulations apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D)

Commented [SI_52]: This paragraph is surplussage given the revisions to 12(a)(2). The purpose of this test authority in TSCA is so EPA can determine whether an exported chemical will present unreasonable risk in the US. The revised 12(a)(2) would except any chemicals for which adverse safety findings have been made under section 5 or 6; those sections already contain adequate authority to require testing.

Commented [SI_53]: Per discussion, this significantly changes the logic of 12(b). Current 12(b) is designed to give notice to foreign governments of export of chemicals of concern. Under that logic, it's not clear why notice would not be given until EPA actually establishes the prohibition or other restriction.

Commented [SI_54]: Should be deleted, consistent with change to (A).

Commented [SI_55]: Same comment above.

Commented [SI_56]: There is no accounting for the new subparagraph (F).

of paragraph (1), a notice of the determination, regulation, order, consent agreement, or requirement~~, or designation~~;

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14. IMPORTS.

Section 13 of the Toxic Substances Control Act (15 U.S.C. 2612) is amended to read as follows:

"SEC. 13. IMPORTS.

"(a) Refusal of Entry.—

"(1) IN GENERAL.—The Secretary of Homeland Security shall refuse entry into the customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry, if—

"(A) the Administrator—

"(i) has determined under section 6(c) that the chemical substance or mixture does not meet the safety standard; and

"(ii) has promulgated a regulation pursuant to section 6(d) banning the chemical substance or mixture, as of the effective date of the regulation;

"(B) the chemical substance—

"(i) is not included on the list under section 8(b)(1); and

"(ii) is not exempt from ~~any~~ the requirement to be included on that list by this title or a regulation promulgated by the Administrator pursuant to this title; or

"(C) the chemical substance, mixture, or any article containing the chemical substance or mixture is offered for entry in violation of—

~~"(i) this title or~~ a ~~regulation~~rule, consent agreement, or order in effect under this ~~chapter~~Act~~; or~~

~~"(ii) an order issued in a civil action brought under section 7 or title IV.~~

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance, mixture,

Commented [T57]: Flag for discussion. TA A155 suggests a simplification to refuse entry ti any chemical substance or mixture that violates the Act or any rule. Seems to be generally acceptable although it is not clear where TSCA explicitly bans the import of a substance not on the Inventory, which suggests (B) should be retained.

Commented [SI_58]: Agree the simplification would be cleanest, but have added specific comments in case that's not done.

Commented [SI_59]: Should add "of" before "any".

Commented [SI_60]: Mixtures are not subject to safety determations.

Commented [SI_61]: Should be deleted.

Commented [SI_62]: This should be "rule", right?

or article containing a chemical substance or mixture is refused entry under paragraph (1), the Secretary of Homeland Security—

"(i) shall notify the consignee of the entry of the refusal;

"(ii) shall not release the chemical substance or mixture to the consignee; and

"(iii) shall cause the disposal or storage of the chemical substance or mixture under such regulations as the Secretary may prescribe, if the chemical substance or mixture has not been exported by the consignee during the 90-day period beginning on the date of receipt of the notice of the refused entry.

"(B) EXCEPTION.—

"(i) IN GENERAL.—The Secretary of Homeland Security, pending a review by the Administrator, may release to the consignee the chemical substance or mixture if the consignee—

"(I) executes a bond for the amount of the full invoice of the chemical substance or mixture (as set forth in the customs entry); and

"(II) pays a duty on the chemical substance or mixture.

"(ii) ADMINISTRATION.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security on demand, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond executed under clause (i)(I).

"(C) STORAGE.—All charges for storage, cartage, and labor on or for the disposal of a chemical substance or mixture that is refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(b) Certification.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture ~~subject to this Act~~ for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that—

"(A) after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is in compliance with any applicable ~~regulation~~rule, consent agreement, or order under section 5, ~~or~~ 6, 7 or title IV; and

"(B) the chemical substance—

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from ~~any~~the requirement to be included on that list by this title or a ~~regulation~~ rule promulgated by the Administrator pursuant to this title.

"(2) ARTICLES.—

"(A) IN GENERAL.—The Administrator, by ~~regulation~~rule, may require certification under paragraph (1) for an article containing a chemical substance or mixture that is subject to regulation under section 5 or 6.

Commented [SI_63]: Why not use the formulation used elsewhere: "rule, consent decree or order"?

"(B) REQUIREMENT.—The ~~regulation~~ rule under subparagraph (A) shall identify, with reasonable specificity, the types of articles, including parts or components of articles, that will be subject to the certification requirement.

"(C) FACTORS FOR CONSIDERATION.—In determining the need for and content of a certification regulation under this paragraph, the Administrator shall take into consideration—

"(i) the utility of the certification to enforcement of the applicable regulation, consent agreement, or order under section 5 or 6;

"(ii) the contribution of imported articles to the potential risk presented by exposure to the chemical substance or mixture subject to regulation under section 5 or 6;

"(iii) the impact on commerce and potential for the certification to impede or disrupt import of articles;

"(iv) the frequency or duration of the certification requirement; and

"(v) specification of the concentration of a chemical substance in an article that would subject the article to the certification requirement.

"(3) REASONABLE INQUIRY.—

"(A) IN GENERAL.—For purposes of a certification under paragraph (1), reasonable inquiry shall include good faith reliance by an importer on—

"(i) a safety data sheet or similar declaration provided by a supplier that documents the specific identity of the chemical substance or the specific identities of all chemical substances in a mixture; or

"(ii) for chemical substances or mixtures claimed by the supplier as confidential, or not otherwise disclosed by the supplier, a certification by the supplier that the imported chemical substance or mixture satisfies the applicable certification requirements under paragraph (1).

"(B) ARTICLES.—For purposes of a certification under paragraph (2), reasonable inquiry shall include good faith reliance by an importer on a certification by the supplier that the imported article satisfies the applicable certification requirements in a regulation promulgated pursuant to paragraph (2).

"(4) INFORMATION REGARDING IDENTITY.—For purposes of this subsection, the Administrator shall provide publicly accessible information regarding the identity of a chemical substance or mixture subject to regulation under this Act that would be readily understood in import transactions.

"(c) Notice.—A person offering a chemical substance for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—

"(1) the chemical substance ~~or chemical substance in a mixture~~ is a high-priority substance;

"(2) the chemical substance ~~or chemical substance in a mixture~~ is 1 for which the United States is obligated to provide export notification by treaty; or

"(3) the chemical substance or chemical substance in a mixture—

"(A) is the subject of a safety assessment and safety determination conducted pursuant to section 6; and

"(B) has been found not to meet the safety standard.

"(d) Regulations.—

"(1) IN GENERAL.—The Secretary of Homeland Security, after consultation with the Administrator, shall promulgate regulations to carry out this section.

"(2) APPLICATION.—The regulations under paragraph (1) may modify the application of any requirement of this section, as appropriate for the efficient and effective implementation of this Act.".

SEC. 15. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsection (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer. ~~and~~

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"(~~8~~7) Except as otherwise provided in this section, the specific identity of a chemical

substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

"(B) the claim—

"(i) is not subject to an exception under subsection (e); or

"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (e), (f)(2), or (g).

Commented [SI_64]: 1.This is true of all claimed CBI, including all the other items in (b). Why specify this for chem. id only? 2. The inclusion of reference to (e) here is confusing, since (e) addresses whether CBI must be released, whereas this section addresses what is and is not CBI. The inclusion of (e) could be taken as saying that if EPA could hand out the information on a limited basis to people with a need-to-know under 14(e), then it furthermore can't be CBI at all, and it has to be made public to anyone who asks for it

"(c) Information Not Protected From Disclosure.—

"(1) Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(A1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(iA) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

"(i) any health and safety study that is submitted under this Act with respect to—

"(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"(II) any chemical substance or mixture for which—

"(aa) testing is required under section 4; or

"(bb) a notification is required under section 5; or

"(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

"(iiB) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

"(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

"(IIii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

"(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(B3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(iA) For information submitted after the date of enactment of the Chemical Safety Improvement Act, the specific identity of a chemical substance as of the date on which

the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"(iiB) A safety assessment developed, or a safety determination made, under section 6.

"(iiiC) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"(ivD) A general description of a process used in the manufacture or processing, and industrial, commercial, or consumer functions and uses of, a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(24) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is otherwise eligible for protection under this section and is submitted with contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"(35) LIMITATION.—Except as provided in paragraph (1)(B), Tthe specific identity of any chemical substance that is not on the confidential portion of the list published under section 8(b)(1) or subsequently added to the confidential portion of the list pursuant to this section shall not be eligible for protection from disclosure.

"(46) BAN OR PHASE-OUT.—If the Administrator promulgates a regulation pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—

"(A) except for information protected from disclosure under subsection (b), any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply;

"(B) for information protected from disclosure under subsection (b), and subject to subsection (g), the Administrator shall determine what of that information should remain protected from disclosure; and

"(CB) the Administrator promptly shall make public the information described in subparagraph (A), and the information described in subparagraph (B) that the Administrator has determined is not to be protected from disclosurepublic.

"(5) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1)(A)(i) that is not described in paragraph (1)(A)(ii), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under

Commented [SI_65]: This is true of all CBI; this suggests otherwise.

Commented [SI_66]: Same issues as above on this language. Plus this is not a full sentence.

Commented [SI_67]: This should probably say "subject to disclosure under this subsection". The purpose if this provision – at least in current TSCA -- is that the FOIA trade secrets protections cannot be invoked to shield information affirmatively made subject to disclosure in (c).

this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such regulations regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the ~~chemical identity~~information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law ~~in connection with 1 or more uses subject to this Act~~;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the conditions that—

"~~(i)~~ the generic name shall—

"(~~I~~i) conform with guidance prescribed by the Administrator under paragraph (3)(A) of this subsection; and

"(~~II~~ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(~~aa~~I) that are considered to be confidential; and

"(~~bb~~II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described ~~in paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the regulations promulgated and guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph

Commented [SI_68]: Another example of where guidance is used in an apparently binding way.

Commented [SI_69]: Another example of where guidance is used in an apparently binding way.

~~(2) and information that has been submitted is~~ true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) shall be disclosed if—

"(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of human health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) the Administrator determines that disclosure is necessary to protect human health or the environment;

"(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

~~"(A)~~ 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~; and~~

Commented [SI_70]: Again, binding guidance.

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State.~~

"(5) a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

Commented [SI_71]: Again, binding guidance.

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee;

"(9) the information is publicly available; or

Commented [SI_72]: We continue to think this is out of place, as it is a basis to reject a CBI claim, not a basis to disclose CBI.

"(10) the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION NOT SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information described in subsection (b) that meets the requirements of subsections (a) and (d), unless—

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(B) INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) an affected the person that asserted the claim notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any the actions described in required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

Commented [SI_73]: Should be B.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a request for extension statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

Commented [SI_74]: B

"(II) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in subparagraph (B) that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall, in accordance with subsection (g)(1)(C)—

"(aa) review the request the request submitted under subclause (I);

"(bb) make a determination regarding whether the claim information

for which the ~~request is made~~request was submitted continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the claim or request.

"(~~D~~C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (~~C~~B), if the Administrator determines that the ~~relevant statement~~request under subparagraph (~~C~~B)(ii)(I)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection of information against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and ~~substantiate or~~ resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating regulations pursuant to section 6(d) ~~, subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).~~

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information from disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and ~~substantiate or~~ resubstantiate the claim in accordance with this section—

"(i) as necessary to determine whether the information qualifies for an exemption from disclosure ~~comply with a request for information received by the Administrator~~ under section 552 of title 5, United States Code;

"(ii) ~~if information available to~~ if the Administrator ~~provides~~ has a reasonable a basis to believe that the information does not qualify for an exemption from disclosure under ~~requirements of~~ section 552(b)(4) of title 5, United States Code,

Commented [SI_75]: Should retain the stricken language but modified to say something like: "in connection with a request for information received by the Administrator". Otherwise, this provision will suggest that the standard for disclosure is section 552, not section 14. The point of our earlier comment re that language was not to delete reference to a FOIA request, but to drop the concept of "comply".

~~are no longer met~~; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and ~~substantiate or~~ resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator~~been denied by the Administrator on expiration of the period for appeal under subsection (g)(3), that has~~ expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

Commented [SI_76]: Need to insert "or" before "expired".

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) REASONS FOR D~~D~~ENIAL OR MODIFICATION.—

~~"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure~~

~~only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) REASONS FOR DENIAL OR MODIFICATION.—~~If the Administrator denies or modifies a claim or request under subparagraph (A), the Administrator shall provide to ~~a~~the person that ~~has~~ submitted ~~a~~the claim or request ~~described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim.

Commented [SI_77]: Should add "or request".

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims and requests under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim or request for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim or request for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim or request under paragraph (1), or intends to release information pursuant to subsection (e), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim or request of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

~~"(i) IN GENERAL.—~~Except as provided ~~in clause (ii)~~subparagraph (C), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(C) EXCEPTIONS.—

"(i) For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim or request receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to human health or the environment, in which case no prior notification shall be necessary.

"(ii) For information under paragraph (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) For information under paragraph (1), (2), (7), (9), or (10) of subsection (e), no notification shall be necessary.

"(iv) No notification shall be required for the disclosure of information for which a notice under subsection (f)(1)(C)(i) was received and for which no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to human health or the environment, in which case no prior notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), (9), or (10) of subsection (e), no prior notification shall be necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, in section 8, or under any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted~~ reported to or otherwise obtained by the Administrator under this Act before the date of enactment of the Chemical Safety Improvement Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) PRIOR-INITIATED ACTIONS.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such regulations applicable to those claims as the Administrator may promulgate after the date of enactment of the Chemical Safety Improvement Act.".

Commented [SI_78]: To avoid confusion with the issue of pre-CSIA claims (previous paragraph), suggest the following title:

ACTION PRIOR TO PROMULGATION OF REGULATIONS

SEC. 16. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any regulation promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any regulation promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any regulation promulgated or order issued pursuant to title II;".

SEC. 17. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) ~~by inserting "this Act or a regulation or order promulgated or issued pursuant to this Act, including" after "a provision of"; and~~

~~(ii)~~ by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

~~(B) by striking "section 15 or 409" and inserting "this Act";~~

(~~B~~C) by striking "$25,000" and inserting "$50,000"; and

(~~C~~D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY ~~INJURY~~HARM.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily ~~injury~~harm, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS ~~AND ENTITIES~~.—An [organization ~~or entity~~] that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

"(3) KNOWLEDGE OF IMMINENT DANGER OR ~~INJURY~~HARM.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily ~~injury~~harm—

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by an~~other~~ individual may not be attributed to the defendant.".

SEC. 18. ~~PREEMPTION~~ STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c) and (d) **and subject to paragraphs (2) and (3)**, no State or political subdivision of a State may establish or continue to enforce [any of the following:~~[Legis. Counsel note: this phrase and the colon have been inserted here and in subsection (b) to comply with formatting conventions regarding the use below of provisions with headers.]]~~

Commented [SI_79]: This should probably refer to "sections 2614 and 2689 of this Act", in conformance with the rest of section 16.

"(A) TESTING AND INFORMATION COLLECTION.—A statute or administrative action to require ~~for~~ the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) ~~for a substance~~ found to meet the safety standard and consistent with the scope of the determination made under section 6; ~~[or]~~

"(ii) ~~for a substance~~ found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) ~~EFFECTIVE DATE FOR~~ **SCOPE OF** CERTAIN PREEMPTION.—Under this subsection, Federal preemption **provided under paragraph (1)(B)** of State statutes and administrative actions applicable to specific substances shall ~~be consistent with the scope of the~~ **apply only to the uses or conditions of use of such substances that are included in the scope of the safety** determination made by the Administrator ~~and~~ **for the substance, and of any rule the Administrator promulgates pursuant to section 6(d).**

"(3) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the ~~date of the Administrator's determination that the substance meets the safety standard or until the date on which compliance with the rule issued under section 6(d) is required.~~ **effective date of the applicable action described in paragraph (1) taken by the Administrator.**

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish (after the date of enactment of the Chemical Safety Improvement Act) **a**~~[any of the following:]~~

~~"(1) High priority.—A~~ statute or administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance ~~identified~~ **designated** under section 4A, as of the date on which the Administrator commences a safety assessment under section 6.

~~"(2) Low priority.—A statute or administrative action prohibiting or restricting the~~

Commented [SI_80]: Or political subdivision, consistent with (a)(1)?

Commented [SI_81]: Shouldn't this be dropped? "Conditions of use" is used throughout.

Commented [SI_82]: Or political subdivision?

Commented [SI_83]: Note that this preemption is not delimited by the scope of the conditions of use EPA may have based its prioritization decision on or is assessing. Per earlier discussions, it's not clear if that was the intent (although the current formulation might make sense, since the scope may not clear at those junctures).

~~manufacture, processing, distribution in commerce or use of a chemical substance that is a low-priority substance identified under section 4A, as of the date on which the Administrator designates the substance as a low priority.~~

"(c) Exceptions.—

"(1) ~~[IN GENERAL]. SUBSECTIONS~~ **IN GENERAL.—Subsections** (a) and (b) shall not apply to a ~~requirement, prohibition, or restriction~~ **statute or administrative action** of a State or a political subdivision of a State ~~that —[Legis. Counsel note: Generic header was added here and in paragraph (3) to ensure consistency with paragraph (2), which was given a header in client specs]~~ **applicable to a specific chemical substance that—**

"(A) is adopted under the authority of**, or authorized to comply with**, any other Federal law;

"(B) implements a reporting, monitoring, or **other** information collection ~~requirement~~ **obligation for the chemical substance** not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal ~~that—~~**, unless the action taken by the State or political subdivision of a State—**

~~"(i) does not impose~~**"(i) imposes** a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) ~~is not otherwise required by or inconsistent with an~~ **(I) is already required by an action by the Administrator under section 5 or 6;**

"(II) is taken to address a human health or environmental concern that applies to the uses or conditions of use that are included in the scope of ~~is taken to address the same specific human health or environmental concern as an action taken~~ the safety determination made **by the Administrator** for the substance, and any rule the Administrator promulgates pursuant to section 6(d), or the scope of a significant new use rule the Administrator promulgates pursuant to section 5, ~~under section 5 or 6 but~~ but **is inconsistent with the action of the Administrator; or**

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, ~~requirement,~~ standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any regulation, ~~requirement,~~ standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **under the authority of,** or authorized to comply with**,** any other Federal law;

"(B) implements **a** reporting, monitoring, or **other** information collection ~~requirement~~ **obligation for the chemical substance** not otherwise required by the

Commented [SI_84]: This does not capture most federally authorized state requirements – eg, under the Clean Water Act and RCRA – because they are not authorized "to comply with" federal law.

Commented [SI_85]: Should probably be dropped.

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Commented [SI_86]: What does this mean? If a state seeks to regulate to protect water quality from a chemical that EPA has found safe, would that regulation be considered inconsistent with the EPA action? If so, then this seems likely to swallow the exception.

Commented [SI_87]: (2) seems like a slightly different version of (1). It seems like one of them should be deleted (and (2) seems like the best candidate for deletion, since the broader drafting could suggest that EPA actions under CSIA can have preemptive effect beyond that specified in 18 (a) and (b)).

Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal ~~that does not impose~~**, unless the~~at~~ action taken by the State or political subdivision of a State—**

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance ~~and is not otherwise required by or inconsistent with an~~ **; and**

"(ii)(I) is already required by an action by the Administrator under section 5 or 6;

"(II) is taken to address a human health or environmental concern that applies to the uses or conditions of use that are included in the scope of the safety determination~~is taken to address the same specific human health or environmental concern as an action taken~~ made **by the Administrator** for the substance, and any rule the Administrator promulgates pursuant to section 6(d), or the scope of a significant new use rule the Administrator promulgates pursuant to section 5, ~~under section 5 or 6 but~~ but **is inconsistent with the action of the Administrator; or**

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(3) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (d)—[~~RULE OF CONSTRUCTION~~]—~~NOTHING CONSTRUCTION.—N~~

"(A) nothing in this section shall be construed as ~~requiring the Administrator to modify or withdraw, any rule or order under section 5 or 6 of this Act, or as~~ modifying the effect under ~~of~~ this section, as in effect immediately ~~enacted~~ prior to [insert the effective date of the Chemical Safety Improvement Act], of ~~on~~ any rule or order promulgated or issued under this Act prior to [insert the effective date of the Chemical Safety Improvement Act]; and

"(B) with respect to a chemical substance or mixture for which for which any rule or order was promulgated or issued under section 6 prior to [insert the effective date of the Chemical Safety Improvement Act], this section as enacted prior to [insert the effective date of the Chemical Safety Improvement Act] shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after [insert the effective date of the Chemical Safety Improvement Act], unless such rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under section 4A(b) or (c) or as an additional priority for safety assessment and safety determination under section 4A(d).

"(d) Preservation of Certain State Law.—Nothing in this section shall be construed to preempt or otherwise affect any ~~warning requirement relating to consumer products or substances that is statute or administrative~~ **action** taken before January 1, 2015, under the authority of a State law, **that prohibits or** otherwise **restricts chemical manufacturing, processing, distribution in commerce,** ~~or~~ **use** or disposal of a chemical substance. This subsection does not affect the

Commented [SI_88]: Should be changed to "as in effect immediately".

Commented [T89]: Flag for discussion. It is not clear which reference to "rule or order" (line 11-12 or line 14-15) this applies to.

Commented [SI_90]: Per discussions, the reference is to the second rule or order.

Commented [SI_91]: Or political subdivision?

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relationship between state and federal law pursuant to any other federal law. established pursuant to State law that was in effect on August 31, 2003, unless a rule, consent agreement, or order is promulgated under section 6 imposing a warning requirement, which shall preempt a chemical specific State warning requirement consistent with the scope of the Administrator's determination under section 6. January 1, 2015.

"(e) State Waivers.—

"(1) IN GENERAL.—Upon application of a State or political subdivision of a State, the Administrator may provide a waiver **may—**

"(A) by rule, exempt from subsection (a) and subsection (b)(1), regarding**, under such conditions as may be prescribed in the rule,** a statute or administrative action of that State or political subdivision of the State that relates to the effects **of,** or exposure to any**, a** chemical substance under the intended or reasonably anticipated conditions of use **if** if—

"(A)(i) the State or political subdivision of the State determines it cannot wait until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and determination established under section 3A; and

"(ii) the Administrator determines that—

"(I)**"(i)** compelling State or local conditions warrant granting the waiver to protect human health or the environment;

"(II)**"(ii)** compliance with the proposed requirement of the State or political subdivision of the State will **would** not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(III)**"(iii)** compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(IV)**"(iv)** based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science; **or**"(B)(i) the Administrator finds a safety assessment or determination has been unreasonably delayed; and

"(ii) the State certifies that—**"(B) exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the** intended or reasonably intended **conditions of use if the Administrator determines that—**

"(I)**"(i)** the State has a compelling local interest **that warrants granting the waiver** to protect human health or the environment;

"(II)**"(ii)** compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

Commented [SI_92]: In general, the wording of A and B should be conformed, except where there is reason for it to be different. For example, is a B waiver not granted by rule, in contrast to A?

Commented [SI_93]: (A) says "effects of, or exposure to,".

Commented [SI_94]: Or political subdivision? Scrub for this throughout Why is the wording different from (A)?

Commented [SI_95]: Would, per A?

Commented [SI_96]: No consideration of foreign commerce here, as in (A)?

~~"(III)~~**"(iii)** compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

~~"(IV)~~**"(iv)** the proposed requirement is grounded in reasonable scientific concern~~; or~~

~~"(C)(i) the State has contracted with the National Academy of Sciences to assess the hazard, use and exposure, and risk of a chemical substance;~~

~~"(ii) the report complies with the requirements of the Federal Advisory Committee Act Amendments of 1997; and~~

~~"(iii) based on the best available evidence described in the report of the National Academy of Sciences, the State establishes a requirement relating to the effects of or exposure to a chemical substance~~.

"(2) APPROVAL OF A STATE WAIVER REQUEST.—The Administrator shall grant or deny a waiver application—

"(A) not later than 180 days after the date on which an application under paragraph (1)(A) is submitted; and

"(B) not later than 90 days after the date on which an application under paragraph (1)(B) is submitted.

"(3) NOTICE AND COMMENT.—The application of a State or political subdivision of the State shall be subject to public notice and comment.

"(4) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of the State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(5) DURATION OF WAIVERS.—A **waiver** ~~waiver—~~

~~"(A)~~ granted under paragraph **(1)(B)**~~(1)(A) shall remain in effect unless the waiver is found to be in conflict with a completed safety assessment and determination; and~~

~~"(B) granted under [subparagraph (B) or (C) of paragraph (2)]~~ shall remain in effect until **the later of**~~—~~

"(A) such time as the safety assessment and determination is completed**; and**~~.~~

~~"(6) Judicial review.—~~**"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.**

~~"(A) In general.—Not~~**"(6) JUDICIAL REVIEW.—Not** later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under **subparagraph (A) or (B) of** paragraph (1), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

~~"(B) Judicial review of prioritization screening decision.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(c) to designate a chemical substance as a low priority, the Governor of a State or a State~~

Commented [SI_97]: If the intent (as we understand it) is that (b) preemption applies only so long as the substance remains high priority, so that it is replaced by (a) preemption once a positive safety determination is completed or a control rule becomes effective, then this paragraph is unnecessary – the waiver becomes moot, because the preemptive effect of (b) has terminated.

Commented [SI_98]: If this paragraph is retained and the intent here is to say the waiver remains in effect until a positive safety determination or, in case of a negative safety determination, until the effective date of the rule, this doesn't say that.

Commented [SI_99]: It would be best to incorporate waiver decisions into section 19 and delete this pargraph.

~~agency with responsibility for protecting health and the environment that submitted the recommendation, as applicable, may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.~~

"(7) SAVINGS.—

"(A) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision in this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any state, maritime, or Federal common law or statutory theory.

"(C) NO EFFECT ON PRIVATE REMEDIES.—

"(i) Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(ii) This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 19. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d)~~(4)~~, 6~~(c)~~, 6(d), ~~6(g)~~, or 8 ~~of this title, or title II or IV of this chapter~~"; and

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "a~~n order issued under this title~~" ~~regulation promulgated pursuant to section 6(b)~~"; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

Commented [SI_100]: This seems to say the same things several different ways, and to be internally inconsistent at points.

Commented [SI_101]: There are no rules under 5(d) or 6(c). Section 5(d) merely alludes to rules under 5(b). Section 6(c) merely alludes to rules under 4(a).

Commented [SI_102]: Not currently included: Significant new use rules under 5(b)(2); procedural rules for safety determinations under 3A(h)(2); procedural rules for prioritization under 4A(a)(1); new chemical exemption rules under 5(h); rules regarding import certification for articles under 13(b); State preemption waiver rules under 18(e); Fee rules under 26(b). Consistent with (ii), consider just referencing all rules under this title to avoid missing anything. You could add "Except as otherwise provided in this Chapter" to the beginning, to ensure that nothing unintended is swept in.

Commented [SI_103]: Per previous comment, consider adding "Except as otherwise provided in this Chapter".

Commented [SI_104]: This change probably should not be made. It is not necessitated by any other changes to this section.

(C) by striking paragraph (3); and

(2) in subsection (c)(1)—

(A) in subparagraph (B)—

(i) in clause (i)—

(I) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), 5(d)~~(1)~~, ~~or~~ 6(d) ~~or 6(e)~~"; and

(II) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence ~~(including any matter)~~ in the rulemaking record, taken as a whole; and"; and

(ii) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the regulation, except as part of the rulemaking record, taken as a whole."; and

[(B) by striking subparagraph (C).]

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a ~~regulation~~ rule pursuant to section 4, 5~~(d)~~, 6~~(b), 6(e), 6(d)~~, or 8 or an order issued under section 4 or 5~~(d)~~, the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4, ~~4A, 5~~ or 6(d);

Commented [SI_105]: There are no rules under 5(d). Section 5(d) merely alludes to rules under 5(b).

Commented [SI_106]: Should be "rule".

Commented [SI_107]: Delete "issued"

Commented [SI_108]: (d) should be retained.

Commented [SI_109]: This makes no sense as drafted. Could say instead: "the information is needed for a purpose identified in section 4(a)". Note that, even with this corrected formulation, this would be an expansion of current section 21 as to testing. Current section 4 is a mandatory authority once the requisite findings are made, and current section 21 requires EPA to initiate a test rule if the section 4 triggers are met. CSIA section 21 is discretionary, and it arguably would make more sense to drop section 4 from section 21 entirely.

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule under section 8, there is a reasonable basis to conclude that the regulation is necessary to protect human health or the environment or ensure that the chemical substance meets the safety standard ~~from an unreasonable risk of harm to human health or the~~ environment.

Commented [SI_110]: This is not that different of a standard from what would trigger a high priority designation, and yet it could be the basis for any person to obtain a court order forcing EPA to proceed directly to the development of a 6(d) rule, skipping entirely over the prioritization process and any safety determination. It is also unclear whether there would be any preemption under 18(b) under this pathway.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to human health or the environment alleged by the petitioner is less than the extent of risks to human health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26 ~~(e) of the Toxic Substances Control Act (15 U.S.C. 2625(e)) is amended~~ **of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—**

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5;

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor

that—

"(i) is required to submits a notice pursuant to the rule promulgated under section 8(b)(4) identifying a chemical substance as active;

"(ii) is required to submits a notice pursuant to section 8(b)(5)(E)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

"(iv) manufactures or processes a chemical substance designated by the Administrator as a high-priority substance pursuant to section 4A(b).

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and make determinations for chemical substances under section 5(d)(1) and (3)e)(3) and impose any necessary restrictions under section 5(d)(4)e)(4);

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) insofar as possible, not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);

"(AB) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(BC) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray a portion of the costs of conducting the activities identified in that paragraph 2(A), not to exceed [__] percent of the cost of conducting the activities described in paragraph (2)(A);

"(CD) establish appropriate criteria for manufacturers or processors that

Commented [SI_111]: This should be "or"

Commented [SI_112]: This should also refer to substances designated for safety assessments and determinations per 4A(d), since, as drafted, those substances are not high priority substances.

results in a proportionate assessment of fees;

"(DE) for substances designated as additional priorities pursuant to section 4A(d), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6;

"(EF) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, shall accrueis applicable with respect to such meetings;

"(FG) beginning with the fiscal year that is 3 years after the date of enactment of the Chemical Safety Improvement Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

"(i) to ensure that funds deposited in the Fund are sufficient and not more than reasonably necessary to defray the portion of the costs specified in subparagraph (C) of conductingto conduct the activities identified in paragraph (2)(A) and the full costs of safety assessments and determinations pursuant to subparagraph (DE); and

"(ii) to account for inflation; and

"(iii) to minimize, to the maximum extent practicable, shortfalls in or an accumulation of unused amounts in the Fund established by paragraph (4)(A);

"(GH) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"(HI) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

Commented [SI_113]: If intent is to have these consultations not be subject to FACA or subchapter III, should say that.

Commented [SI_114]: garbled

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"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A)};

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this paragraph subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14,

including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead ~~allocation of costs~~ associated with the conduct of the activities described in paragraph (2)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is [10/15] years after the date of enactment of the Chemical Safety Improvement Act, unless otherwise reauthorized or modified by Congress."; and

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services", and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any ~~regulation~~rule or order promulgated or issued pursuant to this ~~section~~Act before the date of enactment of the Chemical Safety Improvement Act.".

Commented [SI_115]: This should say Act or Chapter. All this says now is that nothing in section 26 requires modification or withdrawal or rules or orders.

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SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METHODS.

Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking

paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a regulationrule, testing consent agreement, or order under section 4;".

SEC. 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended by striking "Except as provided in section 4(f), this" and inserting "This".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/24/2015 10:38:48 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: TSCA Reform TA - Fee Scenarios

Dimitri,
The approach we used is similar to how we calculate the percentage of the pesticides program paid by fees. We're not just adding 20%, 25%, or 30% to the base program, we are looking at the overall program and making the calculation from that. The denominator includes the appropriated dollars plus fees. The numerator is the fees. The result is then the percentage of the total resources paid by fees. One way to look at is to determine what you want the percentage to be and calculate the fees. Another way would be to assume how much people would be willing to pay and calculate from that. The size of the program and the number of chemicals assessed follow from that.

Here's the math to find how much it would cost for different fee levels where:
- Base + fees = new program total
- fees = a set percent of the new program total

Assume:
1. Base = $56M
2. x = fees generated
3. y = new total
4. z = 20% fee

Then:
1. 56 + x =y
2. x = y*z
3. x = y* 0.20= y/5
4. 56 + (y/5) = y
5. 56 = y- (y/5)
6. 56 = 4/5y
7. y = (56 * 5)/4
8. y = 280/4
9. y = $70M [program total at 20%]
10. x = 70-56 = $14M [fees generated at 20%]

You can substitute a different percentage (z) and get a new program total (y) and fees generated (x)

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, February 23, 2015 5:15 PM

To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

In further looking at this it seems like you all went about the calculations in a strange way. You cannot add the estimated fees to the current "base" then calculate the percentage. 20% of current $56 million would be $11.2 million. In order to get $14 million in fees you would have to have 25% fees from the baseline number.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 23, 2015 4:41 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

Dimitri and Jonathan,

We started with $56M as our current "base" for new and existing chemicals work. We then added fee amounts. The percentage was then calculated using the fees as a percentage of the new totals. We caveat that although there has been discussion of fees for new chemical submissions, those fees are not included here as either additional amounts or in the calculation of percentages.

At 20%, we estimate would raise $14M in fees, bringing the program total to $70M.

At 25%, we estimate would raise $19M in fees, bringing the program total to $75M.

At 30%, I calculated that we would raise $24M in fees, bringing the program total to $80M.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, February 20, 2015 1:21 PM
To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

Sven – quick follow up here. Can you give me an idea of what EPA expects to raise at each fee percentage? We had a somewhat confusing discussion about each percentage being a percentage of what (if that makes sense). If we could know what numbers EPA calculated it would raise at 20%, 25%, and 30%, it would let us know the total pot you all were working from.

Please let me know if that makes sense or if you want to follow up and thanks for your help with this.

Dimitri

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, February 18, 2015 12:07 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: TSCA Reform TA - Fee Scenarios

Jonathan and Dimitri,

In response to your request, please see attached technical assistance on fee scenarios. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/24/2015 2:06:16 PM
To: 'Hunt, Jasmine (Durbin)' [Jasmine_Hunt@durbin.senate.gov]
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke

Jasmine,
I'll send a scheduler – call in number & Personal Phone / Ex. 6 code Personal Phone / Ex. 6 Saw a BNA petcoke article this morning – any connection to your inquiry? Folks here were interested to know if there are any pet coke developments that stimulated your inquiry. Thanks,
Sven

Koch-Owned Facility to Cease Stockpiling
Petcoke in Chicago After Denial of Variance

By Michael Bologna
Feb. 23 — The city of Chicago won a major victory in its campaign to limit particulate matter emissions from energy and distribution companies handling petroleum coke and coal after KCBX Terminal Corp. announced plans to cease stockpiling such material within the city.
KCBX, controlled by billionaire industrialists Charles and David Koch, announced Feb. 19 it would cease operations at one of its two bulk storage locations in Chicago within five months. The announcement reflected the company's inability to comply with a recent city ordinance designed to limit emissions from bulk material piles.
KCBX also announced plans to draw down its petcoke storage activities at a second location over the next 16 months. Rather than store petcoke, KCBX said it would use the site to move product between railcars, cargo ships and barges. A company official said the new strategy would give KCBX additional time to evaluate its compliance options.
"We expect we'll have to make some adjustments in the services we provide our customers but we hope operating this way will allow us to remain in business and give us the time we need to determine whether we can proceed with the enclosure project,"said Dave Severson, KCBX's president, in a statement.
Variance Denied
The announcement came just days after the Chicago Department of Public Health denied KCBX's request for a variance from a city ordinance that would have required the company to completely enclose its extensive stockpiles of petcoke.
In a letter dated Feb. 13, Julie Morita, the department's acting commissioner, said KCBX had failed to provide an adequate justification for a 14-month variance from Chicago's bulk material storage rules. Morita said the company also had failed to explain how it would comply with the city's fire prevention, stormwater management and building code requirements. Moreover, Morita said KCBX had not developed a comprehensive strategy for controlling hazardous petcoke emissions.
"While the city's regulations allow KCBX to seek additional time to build the facility, they do not allow the company to keep exposing residents to harmful dust," Morita said in a statement. "The city needs to see more proof that KCBX understands the importance of protecting residents living in close proximity to its facilities while it builds the facility."
To contact the reporter on this story: Michael Bologna in Chicago at mbologna@bna.com
To contact the editor responsible for this story: Larry Pearl at lpearl@bna.com
For More Information
The Chicago Department of Public Health's variance denial is available at http://www.cityofchicago.org/content/dam/city/depts/cdph/environmental_health_and_food/CDPH_Response_KCBX_021315.pdf.

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Hunt, Jasmine (Durbin) [mailto:Jasmine_Hunt@durbin.senate.gov]
Sent: Monday, February 23, 2015 6:33 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke

I think I could swing 12:30p

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 23, 2015 11:20 AM
To: Hunt, Jasmine (Durbin)
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke

Jasmine,
Thanks for your patience. One of our key people on this is out until Weds. Do you have any availability on Weds, Feb 25 at 12:30, 2:30 or 3pm? Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Hunt, Jasmine (Durbin) [mailto:Jasmine_Hunt@durbin.senate.gov]
Sent: Sunday, February 22, 2015 4:29 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke

Hi Sven-Erik –

I wanted to circle back to see if you could find someone to briefly chat with me about the incomplete ata sets and non-hazrdous findings.

Thanks,
Jasmine

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, February 10, 2015 1:18 PM
To: Hunt, Jasmine (Durbin)
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke

Jasmine,
This responds to your request for information on the High Production Volume Challenge Program and petroleum coke. The HPV program challenged companies to submit basic hazard data for high production volume chemicals, i.e., in quantities greater than 1 million pounds per year produced or imported. Attached are several documents responding to your request: the CDR report for petroleum coke, CASRN 64743-05-1 (note highlighted total natl production of nearly 11 billion pds); HPV HC for the category; and a data report under TSCA section 8e. The information on petroleum coke is publicly available on ChemView by searching "coke, petroleum" or the two CAS numbers included in the Hazard Characterization: CASRNs 64741-79-3 and 64743-05-1. In particular, the Hazard Characterization document describes the tests that were conducted and the

results. Please take a look and let me know if any additional questions – I'll follow up on your questions about "incomplete data sets" and what does the "nonhazardous" finding mean. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
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Washington, DC 20460
202-566-2753

From: Hunt, Jasmine (Durbin) [mailto:Jasmine_Hunt@durbin.senate.gov]
Sent: Monday, February 09, 2015 3:14 PM
To: Kaiser, Sven-Erik
Subject: High Production Volume Challenge Program

Hi Sven:

Would someone be able to chat with me briefly about the framework of the program? Petroleum coke is characterized as non-hazardous and I'm hoping to understand more about the testing/analysis that was done

Thanks,
jasmine

Jasmine N. Hunt

Office of Senator Richard J. Durbin | Democratic Whip
711 Senate Hart Office Building | ☎ 202.224.2152 | 🖷 202.224.0400
✉ jasmine_hunt@durbin.senate.gov

Visit Senator Durbin's Website | Follow Senator Durbin:

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/23/2015 2:06:00 PM
To: 'Hunt, Jasmine (Durbin)' [Jasmine_Hunt@durbin.senate.gov]
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke

Jasmine,
What is your availability for a call today, Mon Feb 23 and tomorrow. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Hunt, Jasmine (Durbin) [mailto:Jasmine_Hunt@durbin.senate.gov]
Sent: Sunday, February 22, 2015 4:29 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke

Hi Sven-Erik –

I wanted to circle back to see if you could find someone to briefly chat with me about the incomplete ata sets and non-hazrdous findings.

Thanks,
Jasmine

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, February 10, 2015 1:18 PM
To: Hunt, Jasmine (Durbin)
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke

Jasmine,
This responds to your request for information on the High Production Volume Challenge Program and petroleum coke. The HPV program challenged companies to submit basic hazard data for high production volume chemicals, i.e., in quantities greater than 1 million pounds per year produced or imported. Attached are several documents responding to your request: the CDR report for petroleum coke, CASRN 64743-05-1 (note highlighted total natl production of nearly 11 billion pds); HPV HC for the category; and a data report under TSCA section 8e. The information on petroleum coke is publicly available on ChemView by searching "coke, petroleum" or the two CAS numbers included in the Hazard Characterization: CASRNs 64741-79-3 and 64743-05-1. In particular, the Hazard Characterization document describes the tests that were conducted and the results. Please take a look and let me know if any additional questions – I'll follow up on your questions about "incomplete data sets" and what does the "nonhazardous" finding mean. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460

202-566-2753

From: Hunt, Jasmine (Durbin) [mailto:Jasmine_Hunt@durbin.senate.gov]
Sent: Monday, February 09, 2015 3:14 PM
To: Kaiser, Sven-Erik
Subject: High Production Volume Challenge Program

Hi Sven:

Would someone be able to chat with me briefly about the framework of the program? Petroleum coke is characterized as non-hazardous and I'm hoping to understand more about the testing/analysis that was done

Thanks,
jasmine

Jasmine N. Hunt

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711 Senate Hart Office Building | ☎ 202.224.2152 | 🖷 202.224.0400
✉ jasmine_hunt@durbin.senate.gov

Visit Senator Durbin's Website | Follow Senator Durbin:

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/18/2016 12:50:33 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: RE: HEC Request on PMNs and Update Briefing

Jerry – I just found out Wendy is going to be out for two weeks after Tues. Do you want to try to squeeze something in tomorrow? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Friday, July 15, 2016 11:02 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: HEC Request on PMNs and Update Briefing

Probably later in the week.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Friday, July 15, 2016 11:01 AM
To: Couri, Jerry
Subject: HEC Request on PMNs and Update Briefing

Jerry – thanks for the request on PMNs. I'll get folks started on the request. Regarding periodic updates, perhaps we could set up an initial update briefing and see what frequency makes sense from there. Availability next week? Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Friday, July 15, 2016 10:55 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA process question

May I please get stats on PMN outcomes (i.e. Yearly run downs of how many PMNs were submitted to Agency, reviewed and action taken subject to 5(e) or 5(f), withdrawn, received notices of commencement) before enactment of reforms to TSCA title I (too long of a title to type out on BB).

Also, I would begin a discussion about setting up something so the Agency can update us periodically on section 5 and other implementation issues.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 3:04:50 PM
To: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]
Subject: Sen. Boxer TA Request on Asbestos Bill
Attachments: MCC16468.pdf

Jason,
This TA responds to the request on the draft asbestos bill.

EPA reviewed and does not have any technical or legal comment on the draft bill.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Albritton, Jason (EPW)" <Jason_Albritton@epw.senate.gov>
Date: May 24, 2016 at 6:37:57 PM EDT
To: "Distefano, Nichole" <DiStefano.Nichole@epa.gov>
Subject: FW: Asbestos Bill

Nichole,

Sen. Boxer plans to introduce a ban asbestos bill this week that would require EPA to implement restrictions on asbestos within a set period of time. The current draft is attached. Can we get EPA TA on the bill?

Jason

Jason Albritton
Senior Policy Advisor
Senate Committee on Environment and Public Works
Senator Barbara Boxer, Ranking Member
456 Dirksen Senate Office Building

Tel: 202-224-8832
Fax: 202-224-1273

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/7/2016 8:13:11 PM
To: 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]
CC: Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]; Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Subject: RE: Sen. Boxer TSCA TA Request on scientific standards in statement for the record

Okay - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Albritton, Jason (EPW) [mailto:Jason_Albritton@epw.senate.gov]
Sent: Tuesday, June 07, 2016 4:13 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Distefano, Nichole <DiStefano.Nichole@epa.gov>; Poirier, Bettina (EPW) <Bettina_Poirier@epw.senate.gov>
Subject: RE: Sen. Boxer TSCA TA Request on scientific standards in statement for the record

You can share with Adrian as well. He has these changes.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, June 07, 2016 4:11 PM
To: Albritton, Jason (EPW)
Cc: Distefano, Nichole; Poirier, Bettina (EPW)
Subject: Sen. Boxer TSCA TA Request on scientific standards in statement for the record

Jason -- Got it and adding it to the request. Does the response on these additional changes go to just you or include Adrian with Sen. Merkley's staff. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Albritton, Jason (EPW) [mailto:Jason_Albritton@epw.senate.gov]
Sent: Tuesday, June 07, 2016 4:08 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Distefano, Nichole <DiStefano.Nichole@epa.gov>; Poirier, Bettina (EPW) <Bettina_Poirier@epw.senate.gov>
Subject: TA

All,

We understand you are reviewing language from Merkley's office on scientific standards. We just suggested these additional changes below to this language. So, we wanted to make sure to get your feedback on our suggested changes as well. Please let us know if you have any comments ASAP.

Jason

Scientific Standards

Section 26(h) incorporates a number of principles of good scientific practice and directs EPA to "consider" these principles "as applicable." These principles are now reflected in the various guidelines and policies that EPA uses to review data and conduct risk evaluations and it is not expected that these guidelines and policies will need to be revised. In general, EPA retains broad scientific judgment to determine how to weigh the data and other information it considers in evaluating chemical risks and addressing issues of hazard and exposure that bear on determinations of unreasonable risk. Section 26(h) reinforces EPA's obligation to document its assumptions and judgments and explain the basis for its risk determinations consistent with good sciences principles but is not intended to micromanage or second-guess EPA's evaluations of risk.

Section 28(i) directs EPA to base decisions on the 'weight of the scientific evidence." The term ''weight of evidence'' refers to a systematic review method that ~~uses a pre-established protocol to~~ comprehensively, objectively, transparently, and consistently, identifies and evaluates each stream of evidence, including strengths, limitations, and relevance of each study and ~~to~~ that integrates evidence as necessary and appropriate to characterize hazards, exposures and risks based upon strengths, limitations, and relevance. This requirement is not intended to prevent the Agency from considering academic studies, or any other category of study that may provide relevant information. Nor is it intended to narrow EPA's scientific judgment in determining how much weight to place on different pieces of evidence. ~~We expect that when EPA makes a weight of the evidence decision it will fully describe its use and methods.~~

Jason Albritton
Senior Policy Advisor
Senate Committee on Environment and Public Works
Senator Barbara Boxer, Ranking Member
456 Dirksen Senate Office Building

Tel: 202-224-8832
Fax: 202-224-1273

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/9/2016 6:19:24 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Inquiry on TSCA Section 5 vs 6

Michal,
Thank you for the request on the interplay between sections 5 and 6. We'll work on the questions and provide a response. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, September 09, 2016 1:56 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 5 vs 6

Hi Sven

I have some questions about the interplay between sections 5 and 6.

1) If EPA initiates a risk evaluation on a chemical substance, can it legally decide that it no longer wishes to do one (for whatever reason) and stop doing so? Is the answer to this question different for a first 10 WP chemical as compared to a prioritized chemical?
2) If EPA a) initiates a risk evaluation on a chemical substance in order to find out whether the substance posed an unreasonable risk under the conditions of use, b) simultaneously or subsequently issues a SNUR requiring notification for all or some of the conditions of use of the substance, and c) receives a notification from a manufacturer subject to the SNUR, could EPA determine that the use intended by the manufacturer posed an unreasonable risk under section 5 before the risk evaluation under section 6 was completed? In other words, would EPA's authority under section 5 be limited by the existence of an incomplete section 6 risk evaluation?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/18/2016 2:13:14 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA Request on Problem with section 6 articles provision

Jonathan – we're going through HLC (5-16) and will provide TA as soon as possible. On the TA request on articles, we think that the Senate version is less susceptible to an interpretation that would raise the bar for making the finding.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, May 17, 2016 9:03 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Problem with section 6 articles provision
Importance: High

We're looking forward to any critical issues epa might flag with the current draft.

This appears to be one...

It requires that, for EPA to regulate an article, it has to find that the article presents an UR. Since most chemicals of concern are used in products, this will be a frequently encountered barrier to regulation of chemicals.

The Senate language would have required EPA to show that regulating the article was necessary to ensure the chemical does not present an UR.

This change was accomplished by putting the phrase the S asked be added back in, but putting it in a different place than was requested.

They did this:

"...only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture, so that the substance or mixture in the article or category of articles does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A)."

Instead of what was asked, which is this:

"...only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture in the article or category of articles, so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A)."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 2:52:24 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA leg history - chem ID

Michal,
Got it –checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, May 25, 2016 10:46 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: chem ID - pls review

1. Chemical Identity

Section 14(b)(2) of the bill retains TSCA's provision making clear that information from health and safety studies is not protected from disclosure. It also retains TSCA's two existing exceptions: for information where disclosure would disclose either how a chemical is made or the portion a chemical comprises in a mixture. A clarification has been added to the provision to note explicitly that the specific identity of a chemical is among the types of information that need not be disclosed, when disclosing health and safety information, if doing so would also disclose how a chemical is made or the portion a chemical comprises in a mixture. This clarification does not signal any Congressional intent to alter the meaning of the provision, only to clarify its intent.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
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202-224-2742

Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/15/2016 2:08:51 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Asbestos SNUR question

Michal,
This responds to your thoughts on dealing with asbestos concerns through section 5 SNUR authority.

As EPA begins implementation of the new TSCA statute, we recognize asbestos continues to be of concern and will be looking at how best to use the new tools TSCA provides us to address the risks from asbestos and the other Work Plan Chemicals. We will be looking at all of our authorities under TSCA, including Section 5. History has shown most manufacturers have moved away from asbestos already, but EPA will consider whether approaches such as a SNUR could achieve a similar outcome as would be achieved under Section 6.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, July 11, 2016 4:52 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: asbestos SNUR question

Hi Sven

On a whim I googled "SNUR abandoned" and found this below… it seems like exactly what I'm thinking about on the asbestos SNUR idea. What do you guys think?

EPA is proposing to stop resumption of manufacture, import and use of 15 currently discontinued nonyl phemol and nonyl phenol ethoxylates by using its TSCA Significant New Use Rule (SNUR) authority. Manufacturers have abandoned the chemicals voluntarily, but to make sure no one picks them back up anyone who intends to market them will first have to submit the PMN-like Significant New Use form 90 days before making or importing the chemicals. Hint: this is a de facto ban, so don't bother unless you have a very controlled process with no exposure like the 2 chemicals that whose use as intermediates or epoxy curing agents are not considered "new." The final SNUR will be retroactive to the date of Federal Register publication, expected next week).
For details see: http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/np-npe.html
If you are currently using any of these nonylphenols, contact EPA right away to refute their assumption they are no longer commercial. Comment period extended to Jan 15, 2015.
EPA has also added nonylphenols to the TRI list here for reporting in 2015.

M
https://www.gpo.gov/fdsys/pkg/FR-2014-10-01/html/2014-23253.htm

Michal Ilana Freedhoff, Ph.D.
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255 Dirksen Senate Office Building
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Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/23/2016 10:52:43 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA - redrafted section 5

Michal – do section 5 followups take higher priority than 6 and higher sections? Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 23, 2016 5:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA - redrafted section 5

For starters:

On the question of restrictions under section 5 – there is a desire by some to maintain the existing 697 list of restrictions rather than cross-referencing the 6(a) list, which as you point out is itself also more narrow than current authority. Can you point to times EPA has taken action related to a new chemical that it would not be able to take under S 697 as reported? What about under the 6(a)list?

michal

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202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, February 23, 2016 5:24 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA - redrafted section 5

Michal – the attached TA responds to your request, including the additional 5(d) question. We highlighted the more significant comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 22, 2016 3:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 5

Sven

I'm attaching a re-draft of section 5, with some streamlining and other more substantive changes. I'd appreciate your team's take, with a particular focus on the areas where we shifted away from a 'safety standard' and back to an 'unreasonable risk' construct, and to anything else you think could pose workability or other challenges.

I'd appreciate getting this back before 11 AM tomorrow and hope that is doable.

Thanks
Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 2:26:53 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]
Subject: Sen. Markey TSCA TA Request on leg history

Michal – got it – checking. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, May 25, 2016 10:26 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: leg history

I'd particularly like any additional edits to this section to ensure it says everything EPA OGC feels it should. Time may be short on this generally so I will send you pieces of it as I finish them. pls turn around as quickly as you can. not clear if vote is today or tomorrow but I want to get all Senate D negotiators on this document which means I need time.

1. **Unreasonable Risk**

TSCA as in effect before the date of enactment of TITLE authorized EPA to regulate chemical substances if it determined that the chemical substance "presents or will present an *unreasonable risk of injury* to health or the environment." In its decision in Corrosion Proof Fittings vs EPA[1], the U.S. Court of Appeals, 5th Circuit overturned EPA's proposed ban on asbestos, in part because it believed that

> "In evaluating what is "unreasonable," the EPA is required to consider the costs of any proposed actions and to "carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action." 15 U.S.C. § 2601(c).
>
> As the District of Columbia Circuit stated when evaluating similar language governing the Federal Hazardous Substances Act, "[t]he requirement that the risk be `unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." *Forester v. CPSC*, 559 F.2d 774, 789 (D.C.Cir.1977). We have quoted this language approvingly when evaluating other statutes using similar language. *See, e.g., Aqua Slide*, 569 F.2d at 839."

---

[1] **947 F.2d 1201 (1991)**

The TITLE clearly altered Congressional intent for what "unreasonable risk to health or the environment" means, by adding text that directs EPA to determine whether such risks exist "without consideration of costs or other nonrisk factors." In this manner, Congress has actively sought to ensure that when EPA evaluates a chemical to determine whether it poses an unreasonable risk to health or the environment , it does not consider the sort of "balancing test" described above.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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202-224-2742

Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/19/2015 1:50:16 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Articles

Michal,
This responds to your technical assistance request on articles.

EPA has some technical concerns with the formulation you suggest. We do not think it accomplishes your stated objective: to capture current practice without the additional affirmative finding of exposure. While it removes the word "affirmative", we do not think that word adds any significant meaning, and your formulation retains the requirement to make an exposure finding: that exposure considerations warrant notification for the particular article or category of articles. In addition, it links the imposition of articles notification with the section 5(b)(2) findings, which technically address a different issue, i.e., which uses are new and significant, as opposed to which activities should be subject to notification. If your intent is to retain a finding but to soften it, a better way to do it might be as follows (with redline from the bill):

> "(3) ARTICLE CONSIDERATION.—The Administrator may require the notification for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes a ~~an affirmative~~ finding in a rule under paragraph (2) that the ~~reasonable~~ potential for exposure to the chemical substance through ~~the article or category of~~ articles ~~subject to the rule~~ warrants such notification.";

In order of significance, the deletion of the finding for the specific article or category is the most significant change. The deletion of "affirmative" would have little or no impact. The deletion of "reasonable" would fall in the middle but also have little impact.

If there is a desire to eliminate any new finding but instead to require an EPA thought process, that could be accomplished as follows:

> "(3) ARTICLE CONSIDERATION.—~~If t~~The Administrator ~~may~~ requires the notification for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B), ~~if~~ the Administrator shall give [explicit] consideration ~~makes an affirmative finding~~ in a rule under paragraph (2) ~~that~~ to the ~~reasonable~~ potential for exposure to the chemical substance through the article or category of articles subject to the rule ~~warrants notification~~.";

The word "explicit" could be retained or not, at your discretion.

Also, during the last technical assistance call, we discussed the alternative possibility of adding a new subparagraph to (b)(2). On further reflection, we do not think that is a sound approach, for the reason stated above regarding the difference between the significant new use finding on one hand, and the scope of the notification requirement on the other.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA

Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, June 17, 2015 4:58 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey); Joseph, Avenel (Markey)
Subject: DRAFT LANGUAGE - ARTICLES

Sven – could you pls look at the following, and suggest alternative formulations that might work better as appropriate? Trying to capture existing practice without the additional affirmative finding of exposure.

Thanks

Michal

Proposed change from

"(3) ARTICLE CONSIDERATION.—The Administrator may require the notification for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.";

TO

"(3) ARTICLE CONSIDERATION.—The Administrator may require the notification for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes A finding in a rule under paragraph (2) THAT THE ADMINISTRATOR'S CONSIDERATIONS UNDER PARAGRAPH (2)(B) AND (2)(C) warrants SUCH notification.";

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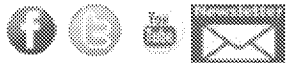
Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/21/2016 12:14:29 AM
To: 'Enderle, Emily (Whitehouse)' [Emily_Enderle@whitehouse.senate.gov]
Subject: Administration Views Letter on TSCA Reform Bills
Attachments: TSCA Reform Views.Boxer.pdf

Emily,
Please see attached and let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/8/2016 1:03:08 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on Senate edits to HLC 5-6

Ok - thanks- will pass along

On May 7, 2016, at 8:57 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

I think on 19 it was a question - do we need this given other changes in 19. Will try to get the rest to you when I can review paper.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Saturday, May 7, 2016 8:07 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall)
Subject: Sen. Markey TSCA TA request on Senate edits to HLC 5-6

Michal and Jonathan,
Thanks for sending over the Senate edits on HLC 5-6. We are working through the edits and have questions about a couple of comments. We are unable to locate:

- Section 6, Page 54, line 7
- Section 14, Page 105, lines 2-3

Also, we don't know how to handle the comment on "Section 19 Conforming changes." It's the last item on your list.

Please let me know if any additional questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: May 7, 2016 at 3:55:11 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Everything except 5

Again, no need to look at 18. Pls let us know of any concerns.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

<Senate Countoffer 5.7 - RLSO on HLC 5.6.docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/18/2016 2:43:14 AM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA request on Problem with section 6 articles provision

Jonathan- got it, Checking. Thanks,
Sven

On May 17, 2016, at 9:02 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

We're looking forward to any critical issues epa might flag with the current draft.

This appears to be one...

It requires that, for EPA to regulate an article, it has to find that the article presents an UR. Since most chemicals of concern are used in products, this will be a frequently encountered barrier to regulation of chemicals.

The Senate language would have required EPA to show that regulating the article was necessary to ensure the chemical does not present an UR.

This change was accomplished by putting the phrase the S asked be added back in, but putting it in a different place than was requested.

They did this:

"...only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture, so that the substance or mixture in the article or category of articles does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A)."

Instead of what was asked, which is this:

"...only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture in the article or category of articles, so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A)."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/23/2016 8:35:36 PM
To: 'Larkin, Brendan' [Brendan.Larkin@mail.house.gov]
Subject: Cong. Tonko TSCA TA Request on Byproducts Negotiated Rulemaking

Brendan,
This TA responds to the request on byproducts negotiated rulemaking provisions.

I wanted to see if EPA has provided any technical assistance on the following language:

(6) NEGOTIATED RULEMAKING.—(A) The Administrator shall enter into a negotiated rulemaking pursuant to subchapter III of chapter 5 of title 5, United States Code, to develop and publish, not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a proposed rule providing for limiting the reporting requirements, under this subsection, for manufacturers of any inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed.

Does EPA know the universe of inorganic byproducts that would be captured by this language?

EPA Response: EPA understands the particular reporting issues that would be the subject of the negotiated rulemaking. The key issue is whether the manufacture of inorganic byproducts needs to be reported under the Chemical Data Reporting rule (40 CFR Part 711), if the subsequent commercial purpose of those byproducts is simply to be recycled/reused/reprocessed. That said, the statutory language does not specifically exempt any particular inorganic byproducts from reporting; the actual scope of any such exemption would be the topic of the negotiation.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Larkin, Brendan [mailto:Brendan.Larkin@mail.house.gov]
Sent: Monday, May 23, 2016 2:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: TSCA Question

Hello Sven,

I wanted to follow up on this. Can you please provide any technical assistance EPA gave on this section as soon as possible?

Brendan

From: Larkin, Brendan
Sent: Wednesday, May 18, 2016 9:22 AM
To: 'Kaiser.Sven-Erik@epa.gov'
Subject: TSCA Question

Hello Sven,

I wanted to see if EPA has provided any technical assistance on the following language:

(6) NEGOTIATED RULEMAKING.—(A) The Administrator shall enter into a negotiated rulemaking pursuant to subchapter III of chapter 5 of title 5, United States Code, to develop and publish, not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a proposed rule providing for limiting the reporting requirements, under this subsection, for manufacturers of any inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed.

Does EPA know the universe of inorganic byproducts that would be captured by this language?

Thank you,
Brendan

Brendan W. Larkin
Office of Congressman Paul D. Tonko (NY-20)
2463 Rayburn House Office Building
Washington, DC 20515
brendan.larkin@mail.house.gov
(202) 225-5076

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/23/2016 10:23:58 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA - redrafted section 5
Attachments: Markey.TSCA TA.Section 5 text received on February 22.docx

Michal – the attached TA responds to your request, including the additional 5(d) question. We highlighted the more significant comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 22, 2016 3:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 5

Sven

I'm attaching a re-draft of section 5, with some streamlining and other more substantive changes. I'd appreciate your team's take, with a particular focus on the areas where we shifted away from a 'safety standard' and back to an 'unreasonable risk' construct, and to anything else you think could pose workability or other challenges.

I'd appreciate getting this back before 11 AM tomorrow and hope that is doable.

Thanks
Michal

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments

SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.MANUFACTURING AND PROCESSING NOTICES.

(a) DEFINITION.—For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

(ba)-NOTICESIN GENERAL.—(1) Except as provided in paragraph (3) and subsection (bg), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (c)(d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b).

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) ARTICLE CONSIDERATION.—The Administrator may require the notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.

Commented [A1]: EPA: "The" had been deleted from the senate draft.

(c) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—

Commented [A2]: All streamlining and conforming changes

(1) IN GENERAL.—The notice required by subsection (b) shall include, with respect to a chemical substance—

(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

(B) all known or reasonably ascertainable information regarding conditions of use and reasonably anticipated exposures.

(2) Subject to section 14, at the beginning of each month, the Administrator shall publish in the Federal Register—

ED_002117_00009950-00001

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments

(A) a list identifying, by generic class unless the Administrator determines that more specific information is required in the public interest, each chemical substance for which notice has been received under subsection (b), along with the conditions of use for each such substance, and for which the notification period prescribed by subsection (b) or (d) has not expired; and

(B) a list identifying each chemical substance for which such notification period has expired since the last publication of such list.

Commented [A3]: EPA: Add "identified in the notice"?

Commented [A4]: EPA: Probably makes more sense to substitute "the review period prescribed by subsection (d)", since it's the review period, not the notification period, that seems to govern completion of review.

Commented [A5]: EPA: Again, review period would probably be better.

~~(b) SUBMISSION OF TEST DATA.—(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 4 before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule at the time notice is submitted in accordance with subsection (a)(1).~~

~~(B) If—~~

~~(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and~~

~~(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule promulgated under section 4 before the submission of such notice,~~

~~such person may not, before the expiration of the 90-day period which begins on the date of the submission in accordance with such rule of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).~~

~~(2)(A) If a person—~~

~~(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and~~

~~(ii) is not required by a rule promulgated under section 4 before the submission of such notice to submit test data for such substance,~~

~~such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).~~

~~(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that—~~

~~(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or~~

~~(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.~~

~~(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14, for examination by interested persons.~~

~~(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator~~

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~~finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.~~

~~(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—~~

~~(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and~~

~~(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.~~

~~(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.~~

~~(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).~~

~~(c) EXTENSION OF NOTICE PERIOD.—The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.~~

(d) Review of Notice.—

(1) INITIAL REVIEW.—

(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall, following a review of the notice and any relevant information about the chemical substance available to the Administrator, including information about the potential for exposure to humans and the environment and any relevant information identified in subsection (c)(1), make a determination under paragraph (2).—

(B) EXTENSION.—Except as provided in paragraph (2)(C), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall not be more than 90 days.

(23) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and subject to section 18(g), the Administrator shall—

Commented [A6]: All streamlining

Commented [A7]: EPA: Should be "reasonably available"?

Commented [A8]: EPA: This is redundant, since this this information in the "notice", which is already referenced above.

Commented [A9]: EPA: In response to the specific TA request of 12:09pm, February 23, about reviewability in court:

The determination seems to meet the Bennet v. Spear test for a final agency action. It marks the culmination of a decision-making process established under § 5(d)(2) and legal consequences flow from the decision. This would be reviewable in court under the APA, subject to a 6-year statute of limitations. It is not covered under TSCA Section 19 (Judicial Review) but the main effect of that fact is to send judicial review to a U.S. District Court under the 6-year limit, not the Courts of Appeals under the TSCA 60-day limit.

Commented [A10]: Another option for review and discussion

Commented [A11]: EPA: It is confusing to say that EPA's determination is subject to the preemption provisions. Presumably the intent is to say something about the *effects* of an EPA determination (and even that would be confusing and unnecessary).

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A) determine, without a consideration of costs or other non-risk factors, that the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment under the conditions of use to the general population or to a potentially exposed or susceptible population identified by the Administrator, in which case the Administrator shall take applicable action under paragraph (3);

(B) determine that manufacture of the chemical substance or manufacture and processing of the chemical substance for the significant new use may commence, notwithstanding any remaining portion of the applicable period for review under subsection (b)(1); or

(C) determine that additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator—

(i) shall provide an opportunity for the submitter of the notice to submit the information, and may extend the review period for a reasonable amount of time by agreement with the submitter to allow the development and submission of the information;

(ii) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and

(iii) shall, on receipt of information the Administrator finds sufficient to support a determination under subparagraph (A) or (B), promptly make the determination, and take action under paragraph (3) as applicable.

(3) RESTRICTIONS.—

(A) DETERMINATION BY THE ADMINISTRATOR.—

(i) IN GENERAL.—If the Administrator makes a determination under paragraph (2)(A) with respect to a notice submitted under subsection (b)—

(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, such that the Administrator determines that compliance with such prohibition or restrictions are sufficient to ensure that there is no longer a reasonable basis to conclude that the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, and

(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

Commented [A12]: EPA: Note that, while EPA does not view this as a very high bar, there is some caselaw indicating that the standard requires EPA to find an overlap between levels of concern and actual exposure.

Commented [A13]: EPA: This contains no standard for the decision. Without clarification, this could lead to litigation about whether or not a (d)(2)(B) determination impliedly requires showing that a (d)(2)(A) determination is impossible. If that is the intended objective, you could say something like "determines that there is no [reasonable?] basis to determine that the chemical substance may present. . . "

Commented [A14]: EPA:

1. Nothing prevents manufacture in the meantime for these chemicals. Is that intentional? If the data comes back 2 years later showing that the chemical may present an unreasonable risk, it does not appear that a determination under (2)(A) or a restriction under (3) would be timely. Both provisions seem to assume that action is occurring within the ordinary review period of 90-180 days.

2. In line with the comment above as to the "may present" standard, "(C)" may indicate that EPA needs a fairly substantial amount of information to make the "may present" finding in "(A)". Under current TSCA, EPA can make the "may present" finding for new chemicals only where "information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects" of the chemical substance. In contrast, the drafting here suggests that lack of information would be a reason *not* to make a "may present" finding.

Commented [A15]: EPA: Distribution in commerce and use are reversed form usual order.

Commented [A16]: EPA: Should be "is"

Commented [A17]: EPA: Not part of the (2)(A) standard, but may be as good a formulation as any.

Commented [A18]: EPA: Note that this bars any person (not just the submitter) from activity that would be inconsistent with the order or agreement. In contrast, under TSCA currently, a section 5(e) order restricts only the recipient. The bill formulation calls into question the need for EPA to considering issuing a SNUR, as would be required by subparagraph (B), since the purpose of a SNUR following a 5(e) order is typically to apply the terms of the order to persons who are not parties to the order. This is an issue with the current Senate bill drafting that we had not picked up on before.

Commented [A19]: EPA: "such a" would be better

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(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the consent agreement or order, and, as applicable, initiate such a rulemaking, or publish a statement describing the reasons by the Administrator for not initiating such a rulemaking.

(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, any requirement or combination of requirements listed in section 6(a).

(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that there is no longer a reasonable basis to determine that the chemical substance may present an unreasonable risk to health and the environment, reduce potential exposure to the substance to the maximum extent practicable.

(E) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

(e) Notice of Commencement.—

(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

(A) the name of the manufacturer; and

(B) the initial date of nonexempt commercial manufacture.

(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

Commented [A20]: EPA: Should be "of"?

Commented [A21]: x-ref as discussed, but note that EPA says it doesn't need any list at all.

Commented [A22]: EPA: Note that the current 6(a) list is not comprehensive.

Commented [A23]: EPA: "Reasonable basis" is not in the standard (but again my not be a bad formulation).

Commented [A24]: EPA: Should add "of injury" after "risk"

Commented [A25]: EPA: Should be "or"

Commented [A26]: EPA: Makes no sense – how would a term displace common law? And the section generally uses "restriction" not "requirement" anyway.

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(f) Further evaluation.—The Administrator may review a chemical substance for which a notice of commencement has been submitted at any time, consistent with Section 6. .

~~(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—(1) The notice required by subsection (a) shall include—~~

~~(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and~~

~~(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and~~

~~(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.~~

~~Such a notice shall be made available, subject to section 14, for examination by interested persons.~~

~~(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of data under subsection (b), the Administrator shall publish in the Federal Register a notice which—~~

~~(A) identifies the chemical substance for which notice or data has been received;~~

~~(B) lists the uses or intended uses of such substance, and~~

~~(C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) or a rule under section 4.~~

~~A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.~~

~~(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.~~

~~(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—~~

~~(1)(A) If the Administrator determines that—~~

~~(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a), and~~

~~(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an~~

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~~unreasonable risk of injury to health or the environment, or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.~~

~~(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.~~

~~(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.~~

~~(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—~~

~~(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or~~

~~(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,~~

~~the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).~~

~~(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.~~

~~(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—~~

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~~(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a), and~~

~~(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or~~

~~(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.~~

~~(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.~~

~~(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.~~

~~(f) PROTECTION AGAINST UNREASONABLE RISKS. (1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a), or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 6 can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.~~

~~(2) The Administrator may issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)—~~

~~(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,~~

~~(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or~~

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~~(C) any combination of the requirements referred to in subparagraph (B).~~

~~Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.~~

~~(3)(A) The Administrator may—~~

~~(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or~~

~~(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.~~

~~A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.~~

~~(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.~~

~~(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A), and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).~~

~~(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.~~

~~(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the~~

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~~manufacturing or processing of the substance with respect to which the statement is to be published.~~

(g) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection ~~(a) or~~ (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, without taking into account cost or other non-risk factors, and

(B) under such restrictions as the Administrator considers appropriate.

~~(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—~~

~~(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b)(2), and~~

~~(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,~~

~~the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.~~

~~(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2) for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—~~

~~(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such data, and~~

~~(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.~~

~~In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide~~

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~~reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.~~

~~(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—~~

~~(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and~~

~~(ii) ending—~~

~~(I) five years after the date referred to in clause (i), or~~

~~(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,~~

~~whichever is later.~~

(2~~3~~) The requirements of subsections ~~(a) and~~ (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(3~~4~~) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines, without a consideration of costs and other non-risk factors, that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator. ~~A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).~~

(4~~5~~) The Administrator may, upon application, make the requirements of subsections ~~(a) and~~ (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(5~~6~~) Immediately upon receipt of an application under paragraph (1) or (4)~~(5)~~ the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The

Commented [A27]: EPA: Drop "a"

Commented [A28]: EPA: Should be "cost or", not "costs and".

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Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

~~(i) DEFINITION.—For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.~~
[15 U.S.C. 2604]

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/9/2016 2:20:56 PM
BCC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Jackson, Ryan (Inhofe [Ryan_Jackson@inhofe.senate.gov]; Fox, Thomas (EPW [Thomas_Fox@epw.senate.gov]; 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]; Poirier, Bettina (EPW [Bettina_Poirier@epw.senate.gov]; McCarthy, David [David.McCarthy@mail.house.gov]; Richards, Tina [Tina.Richards@mail.house.gov]; Couri, Jerry [JerryCouri@mail.house.gov]; 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]; Fruci, Jean [Jean.Fruci@mail.house.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Zipkin, Adam (Booker [Adam_Zipkin@booker.senate.gov]; Wojciechowski, Adrienne (Judiciary-Dem) [Adrienne_Wojciechowski@Judiciary-dem.senate.gov]; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]; Enderle, Emily (Whitehouse [Emily_Enderle@whitehouse.senate.gov]; Hunt, Jasmine (Durbin) [Jasmine_Hunt@durbin.senate.gov]; rick.kessler@mail.house.gov; tuley.wright@mail.house.gov; Bastian, Eleanor [Eleanor.Bastian@mail.house.gov]; Espinosa, Sergio [Sergio.Espinosa@mail.house.gov]; laura_gillam@carper.senate.gov; jordan_baugh@gillibrand.senate.gov; Parsons, Doug [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0a745542b2e4fa894e877ccf8b83957-Parsons, Doug]; Tharpe, Amanda (Rounds [Amanda_Tharpe@rounds.senate.gov]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]
Subject: EPA Notification: New TSCA Implementation FAQs Posted on PMNs

Heads up that EPA posted new FAQs on new chemical premanufacture notices (PMNs) - Q11 through 22. They are available at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-0.

EPA will continue to update the FAQs as we respond to stakeholder inquiries. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/8/2016 12:48:09 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on Senate edits to HLC 5-6

Thanks- we're plowing through. Will let you know if any other questions come up.

On May 7, 2016, at 8:41 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

I'm out of pocket for a bit yet. I will get back to you but don't wait on me!

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Saturday, May 7, 2016 8:07 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall)
Subject: Sen. Markey TSCA TA request on Senate edits to HLC 5-6

Michal and Jonathan,
Thanks for sending over the Senate edits on HLC 5-6. We are working through the edits and have questions about a couple of comments. We are unable to locate:

- Section 6, Page 54, line 7
- Section 14, Page 105, lines 2-3

Also, we don't know how to handle the comment on "Section 19 Conforming changes." It's the last item on your list.

Please let me know if any additional questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: May 7, 2016 at 3:55:11 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Everything except 5

Again, no need to look at 18. Pls let us know of any concerns.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

<Senate Countoffer 5.7 - RLSO on HLC 5.6.docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/10/2015 6:18:21 PM
To: 'Hunt, Jasmine (Durbin)' [Jasmine_Hunt@durbin.senate.gov]
Subject: RE: Sen. Durbin Inquiry on the HPV Challenge Program and Petcoke
Attachments: CDR 64743-05-1.pdf; HPV HC Category_Petroleum Coke_June_2011.pdf; 8e - 64743-05-1.pdf

Jasmine,
This responds to your request for information on the High Production Volume Challenge Program and petroleum coke. The HPV program challenged companies to submit basic hazard data for high production volume chemicals, i.e., in quantities greater than 1 million pounds per year produced or imported. Attached are several documents responding to your request: the CDR report for petroleum coke, CASRN 64743-05-1 (note highlighted total natl production of nearly 11 billion pds); HPV HC for the category; and a data report under TSCA section 8e. The information on petroleum coke is publicly available on ChemView by searching "coke, petroleum" or the two CAS numbers included in the Hazard Characterization: CASRNs 64741-79-3 and 64743-05-1. In particular, the Hazard Characterization document describes the tests that were conducted and the results. Please take a look and let me know if any additional questions – I'll follow up on your questions about "incomplete data sets" and what does the "nonhazardous" finding mean. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Hunt, Jasmine (Durbin) [mailto:Jasmine_Hunt@durbin.senate.gov]
Sent: Monday, February 09, 2015 3:14 PM
To: Kaiser, Sven-Erik
Subject: High Production Volume Challenge Program

Hi Sven:

Would someone be able to chat with me briefly about the framework of the program? Petroleum coke is characterized as non-hazardous and I'm hoping to understand more about the testing/analysis that was done

Thanks,
jasmine

Jasmine N. Hunt

Office of Senator Richard J. Durbin | Democratic Whip
711 Senate Hart Office Building | ☎ 202.224.2152 | 🖷 202.224.0400
✉ jasmine_hunt@durbin.senate.gov

Visit Senator Durbin's Website | Follow Senator Durbin:

280790

ConocoPhillips

411 South Keeler
Bartlesville, OK 74004

8EHQ-1104-15813

November 5, 2004

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Document Processing Officer (7407M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Attn: TSCA Section 8(e) Coordinator

ConocoPhillips Company ("ConocoPhillips") is writing to report the presence of low concentrations of coke particles having physical characteristics meeting the National Institute of Occupational Safety and Health (NIOSH) 7400 B criteria for "respirable fibers" in our calcined petroleum coke products. A ConocoPhillips occupational exposure assessment determined that, based on the physical characteristics of the fibers and the low concentrations observed through air sampling, their presence does not suggest a risk to ConocoPhillips' workers.

Calcining is a process in which green coke is converted to a dense, carbonaceous product used in the production of anodes, electrodes and other products. The green coke is heated at temperatures of 1000 to 1400 degrees C to remove moisture, drive off volatile matter, and increase the density of the coke structure. It is believed that the fibers, which were found in both bulk samples and in workplace air samples, are appropriately described by CASRN 64743-05-1, calcined coke. ConocoPhillips did not find coke fibers in green coke operations.

The respirable coke fibers (i.e. those with length ≥ 5 um, diameter ≤ 3 um, and aspect ratio > 5:1) found in ConocoPhillips' workplace air samples had median and mean diameters of 1.3 and 1.32 um, respectively. Median and mean lengths were 9.0 and 10.6 um, respectively. Approximately 94% of the respirable fibers were less than 20 um long, which is one of several length thresholds proposed to define potentially active fibers.

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Exposure monitoring was conducted at ConocoPhillips' calcining plants. Although consistently low, 8-hour TWA (time weighted average) concentrations varied with plant site and task. A total of 206 personal monitoring TWAs were calculated, none of which exceeded 0.300 f/ml. Approximately 98% of all TWAs calculated were less than 0.1 f/ml. Activities associated with the four TWAs that exceeded 0.1 f/ml involved sweeping, cleaning, loading or grinding petroleum coke. Workers conducting these activities

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generally wear respiratory protective equipment because the work environment is relatively dusty.

Presented below are the six highest exposure concentrations found in the workplace study. The findings were consistent at all locations.

Rank	Plant	Job	Activities	TWA (f/ml)
1	C	Operator at calcining facility	Loaded trucks with CPC[1] from an isolated booth using remotely operated equipment. (dumped vac truck of fines)	0.3000
2	A	Port operator	Swept and cleaned dock silo	0.2020
3	C	Operator at calcining facility	Worker was inside a calciner removing (chipping out) brick from the refractory lining of a kiln during turn around operation. Worker then loaded trucks with CPC.	0.1700
4	B	Lab technician	Made quality control tests on calcined or green product. Activity involves grinding both GPC[2] and CPC.	0.1107
5	A	Port operator	Swept and cleaned dock silo.	0.0958
6	B	Maintenance	Worker performed maintenance on a piece of equipment in the calcined coke storage building.	0.0838

Exposure limits have not been established for coke fibers. However, exposure guidelines offered in the scientific literature and in carbon fiber manufacturers' MSDSs range from 1 to 5 f/ml TWA. ConocoPhillips believes these guidelines are the best available benchmarks for workplace exposure levels of carbon fibers.

ConocoPhillips has no data or results from toxicological testing for coke fiber effects, and is not aware of any reported serious adverse effects from exposure to coke fibers. No published study indicates that exposure to carbon fibers (which might be similar to coke fibers) results in excess lung cancer or mesothelioma, and no regulatory or major advisory agency has concluded otherwise.

While coke fibers may be present at industrial locations other than our own, ConocoPhillips has no information upon which to base a conclusion that the characteristics and concentrations of such fibers at other locations differ (from those we observed) in ways that present a substantial risk of injury to health or the environment. We do not believe the information described here meets the reporting requirements of Section 8(e) of the Toxic Substances Control Act. However, to ensure transparency

[1] CPC – Calcined Petroleum Coke
[2] GPC – Green Petroleum Coke

ConocoPhillips is voluntarily submitting this information in a manner that is consistent with that section.

If you have further questions about the information, please contact me at (918) 661-3865.

Sincerely,

Jennifer Galvin, Ph.D.
Manager of Industrial Hygiene and Toxicology
918-661-3865

cc: C. R. Clark, TSCA Compliance Officer

Pollution Prevention and Toxics

Chemical Data Access Tool (CDAT)

Use this page to find a range of chemical-specific information submitted to EPA under the Toxic Substances Control Act. This information is part of EPA's ongoing effort to increase the public's access to chemical information held by the Agency and is intended for individuals learning more about chemicals that are manufactured or imported into the United States. Read more.

Highlights

New! April 9, 2014 – EPA has released 138 declassified documents under its Voluntary Declassification Challenge Program. Learn more.

EPA's newly developed database, ChemView, provides access to chemical information that the Agency receives and develops on chemicals. For more information, Go to ChemView.

Directions for Accessing Information:

1. Click on the tabs below to review what you will find in each database, e.g., the CDR tab contains the 2012 Chemical Data Reporting (CDR) information.
2. In the search box, type in a chemical name, CAS number, company name, or document number.
3. You can also click on the Advanced Options link which will allow you to do a more targeted search.
   Note: The chemical names are listed by their preferred Chemical Abstract Index names on the Substance Registry Service (SRS) and not by their synonyms.
4. Then select the tab that includes the information of interest to you. If the information is available in that particular tab, the results will be displayed.

You will need Adobe Reader to view some of the files on this page. See EPA's PDF page to learn more.

64743-05-1 Search

Advanced Options

CDR(34) eDoc(0) TSCATS(1) HPVIS(0) Declass(0) VDCP(0) HC(1)

CDR - This tab contains the 2012 Chemical Data Reporting (CDR) information on the production and use of chemicals manufactured or imported into the United States. Download the entire non-confidential CDR database (updated June 2014) .

Chemical/Generic Name: Coke (petroleum), calcined

CAS Number: 64743-05-1

Company: RAIN CII CARBON LLC

Site: Rain CII Carbon LLC, Chalmette Facility, 700 Coke Plant Road, Chalmette, LA, 70044

Manufactured: 388,655,126 lb/yr

Imported: 0 lb/yr

Is the chemical never physically at the import site? :

Volume used on the site : 0 lb/yr

Past Production Volume : 433,400,147 lb/yr

National Production Volume for Chemical : 10,822,660,064 lb/yr

Chemical/Generic Name: Coke (petroleum), calcined

CAS Number: 64743-05-1

Company: E I DU PONT DE NEMOURS & CO

Site: DUPONT JOHNSONVILLE PLANT, 1 DUPONT ROAD, NEW JOHNSONVILLE, TN, 371340219

Manufactured: CBI

Imported: 0 lb/yr

Is the chemical never physically at the import site? : CBI

Volume used on the site : CBI

Past Production Volume : CBI

National Production Volume for Chemical : 10,822,660,064 lb/yr

Chemical/Generic Name: Coke (petroleum), calcined

CAS Number: 64743-05-1

Company: GRAFTECH INTERNATIONAL LTD

Site: GRAFTECH INTERNATIONAL HOLDINGS INC, 791 SANTA FE PIKE, COLUMBIA, TN, 38401

Manufactured: 0 lb/yr

Imported: 1,409,825 lb/yr

Is the chemical never physically at the import site? : NO

Volume used on the site : 1,409,825 lb/yr

Past Production Volume : 0 lb/yr

National Production Volume for Chemical : 10,822,660,064 lb/yr

Chemical/Generic Name: Coke (petroleum), calcined

CAS Number: 64743-05-1

Company: RAIN CII CARBON LLC

Site: CII CARBON PURVIS FACILITY, BOX 349, HWY 11 NORTH, PURVIS, MS, 39475-0349

Manufactured: 60,829,947 lb/yr

Imported: 0 lb/yr

Is the chemical never physically at the import site? :

Volume used on the site : 0 lb/yr

Past Production Volume : 52,029,094 lb/yr

National Production Volume for Chemical : 10,822,660,064 lb/yr

34 results (0.055 seconds) 1 2 3 4

Last updated on Wednesday, July 23, 2014

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/21/2016 12:14:15 AM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Administration Views Letter on TSCA Reform Bills
Attachments: TSCA Reform Views.Boxer.pdf

Jonathan,
Please see attached and let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/27/2016 5:07:24 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Inquiry on conditions of use and preemption

Michal – Thanks for the request on conditions of use and preemption. I circulated it to the TSCA team. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, July 26, 2016 4:37 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: question on conditions of use and preemption

Sven

Something that I've been talking to a bunch of people about relates to the nature of EPA's obligation to assess all conditions of use associated with a chemical substance as part of a risk evaluation. It was this perceived obligation that led to the development of the partial RE language, so I understand EPA's general take – but I have some questions about how EPA interprets the final bill language, and how EPA would expect this to intersect with 18a preemption. While this isn't a time-sensitive request, it does bear directly on the RE and prioritization rulemakings, and I'm guessing your team is also asking itself these same questions. Thanks.

I'm pasting below some of the hey references to conditions of use in the bill and in caps, my read on these – first question – is EPA's read consistent with mine (and if not, what am I missing)?:

(4) The term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. IMPLIED – EPA SHOULD SURVEY/COLLECT THE KNOWN UNIVERSE OF USES FOR A SUBSTANCE

(i) HIGH-PRIORITY SUBSTANCES.—The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. MY READ – EPA CAN DEEM SOMETHING TO BE A HIGH PRIORITY CHEMICAL IF ANY USE MEETS THE "MAY PRESENT" THRESHOLD. LESS CLEAR TO ME - EPA COULD ALSO DETERMINE, AT THIS STAGE IN THE PROCESS, THAT SOME USES DO NOT MEET THIS THRESHOLD, BECAUSE OF THE HIGHLIGHTED LANGUAGE BELOW

(A) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

(4) RISK EVALUATION PROCESS AND DEADLINES.—

(i) (A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use. IMPLIED – EPA HAS TO DO A RISK EVALUATION ON ALL USES OF THE CHEMICAL. LESS CLEAR – COULD EPA ARGUE THAT IT ONLY HAS TO DO A FULL RISK EVALUATION ON ANY USE THAT MET THE "MAY PRESENT" THRESHOLD WHEN THE CHEMICAL WAS DESIGNATED A HIGH PRIORITY CHEMICAL?

(F) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and I

(v) describe the weight of the scientific evidence for the identified hazard and exposure. - IMPLIED – THIS LIST OF REQUIREMENTS APPLIES TO ALL USES OF THE CHEMICAL. LESS CLEAR – COULD EPA ARGUE THAT IT ONLY HAS TO DO A FULL RISK EVALUATION TO WHICH THESE REQUIREMENTS APPLYON ANY USE THAT MET THE "MAY PRESENT" THRESHOLD WHEN THE CHEMICAL WAS DESIGNATED A HIGH PRIORITY CHEMICAL?

"(D) SCOPE.—The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations **the Administrator expects to consider** …" THIS LANGUAGE SEEMS TO STATE THAT EPA DOES HAVE THE DISCRETION TO ONLY LOOK AT SOME OF THESE CONSIDERATIONS, INCLUDING CONDITIONS OF USE, AS PART OF A FULL RISK EVALUATION.

So the rest of my questions are as follows:

1) Does EPA believe it has to do a full risk evaluation on all conditions of use? In that case, would any use that EPA did not find posed an unreasonable risk be part of a "no unreasonable risk determination" for that chemical, and would those also be subject to 18a preemption?
2) Does EPA believe it has to CONSIDER all conditions of use, decide when it is prioritizing the chemical which uses meet the threshold for an RE and which do not, and document that as part of prioritization? In that case, would the uses that did not meet the threshold for an RE need to be deemed "low priority chemical conditions of use" or otherwise just not be in the RE, not subject to any final agency action (and thus not subject to any preemption)?
3) Does EPA believe it has to CONSIDER all conditions of use as part of scoping the RE, and that it also has to note which ones are getting a full RE in the scope and describe the reasons why it is not giving a full RE to some uses? In that case, for the uses that are not getting a full RE, would EPA be able to make a "no unreasonable risk" determination (and thus subject these uses to 18a preemption) even though EPA chose not to fully review them, or could these uses just receive no final agency action regulatory treatment and thus not be subject to 18a preemption?
4) Are there other alternatives that I haven't considered that better describe EPA's interpretation of the language?

18(a)(1) (B) CHEMICAL SUBSTANCES FOUND NOT TO PRESENT AN UNREASONABLE RISK OR RESTRICTED.—A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) for which the determination described in section 6(i)(1) is made, consistent with the scope of the risk evaluation under section (6)(b)(4)(D); or

(ii) for which a final rule is promulgated under section 6(a), after the effective date of the rule issued under section 6(a) for the chemical substance, consistent with the scope of the risk evaluation under section (6)(b)(4)(D).

c) SCOPE OF PREEMPTION.—Federal preemption under subsections (a) and (b) of statutes, criminal penalties, and administrative actions applicable to specific chemical substances shall apply only to—

(1) with respect to subsection (a)(1)(A), the chemical substances or category of chemical substances subject to a rule, order, or consent agreement under section 4, 5, or 6;

(2) with respect to subsection (b), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D);

(3) with respect to subsection (a)(1)(B), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 6(a) or 6(i)(1); or

(4) with respect to subsection (a)(1)(C), the uses of such chemical substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/7/2016 8:54:40 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
CC: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: TSCA 5 - HLC 5-6 with Senate proposed additions

Jonathan,
Got it - checking. Thanks,
Sven

On May 7, 2016, at 4:53 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Sven, we'd like some review of these proposed changes.

The attached shows TSCA Section 5 as amended by the latest House language, with additional proposed changes highlighted in green for EPA review.

We want to make sure these changes do not pose any problems. And we want to make sure that an affirmative decision is made, and if an order is issued that commencement can only occur in compliance with the order.

Also... do the formulations in (a)(3)(C) and (g) work to ensure an affirmative finding?

<TSCA 5 - HLC 5-6 with Senate proposed additions.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/8/2016 6:17:23 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Followup Inquiry on New TSCA Implementation FAQs Posted on CBI and PBTs

Michal,
This responds to the questions on PBT FAQs. There are 4 (not 3) that were excluded due to actions underway and EPA removed Pigment Yellow because it was erroneously identified as PBT. Please see the updated chart below and let me know if any followup questions. Thanks,
Sven

Chemicals on 2014 TSCA Work Plan that received a PB Score of 3

Chemical Name	*Applicability of section 6(h)*
Butanamide, 2,2'-[(3,3'-dichloro[1,1'- biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5 -dimethoxyphenyl)-3-oxo- (Pigment Yellow 83)	No; error in the T scoring
Cadmium & Cadmium Compounds	Excluded; Metal or metal compound
Chromium & Chromium Compounds	Excluded; Metal or metal compound
Cobalt & Cobalt Compounds	Excluded; Metal or metal compound
Decabromodiphenyl ethers (DecaBDE)	Yes
Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl)-	Yes
Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)- (note: same name as above, but different CAS number)	Yes
Hexabromocyclododecane (HBCD)	Excluded; Problem formulation released
Hexachlorobutadiene	Yes
Lead and Lead Compounds	Excluded; Metal or metal compound
Long-chain chlorinated paraffins (C18-20)	Excluded; Review under Sec 5
Medium-chain chlorinated paraffins (C14-17)	Excluded; Review under Sec 5
Molybdenum and Molybdenum Compounds	Excluded; Metal or metal compound
Octamethylcyclotetra-siloxane (D4)	Excluded; Consent agreement under Sec. 4
Pentachlorothio-phenol	Yes
Phenol, isopropylated, phosphate (3:1) (iPTPP)	Yes
Antimony & Antimony Compounds	Excluded; Metal or metal compound
2,4,6-Tris(-tert-butyl)phenol	Yes

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, September 06, 2016 11:59 AM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: EPA Notification: New TSCA Implementation FAQs Posted on CBI and PBTs

Question for you:

- There are 18 high PBTs on the WP.
- 6 are metals/compounds as I recall
- 3 fell into the categories that were excluded (various forms of being worked on by epa already)
- Where are the other 2? I see 7 on that list below.

Thanks
michal

PBT Chemicals Subject to Section 6(h)
Decabromodiphenyl ethers (DecaBDE) (CASRN 1163-19-5)
Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl)- (CASRN 54464-59-4)
Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)- (CASRN 54464-57-2)
Hexachlorobutadiene (CASRN 87-68-3)
Pentachlorothio-phenol (CASRN 133-49-3)
Phenol, isopropylated, phosphate (3:1) (iPTPP) (CASRN 68937-41-7)
2,4,6-Tris(-tert-butyl)phenol (CASRN 732-26-3)

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, September 06, 2016 10:59 AM
Subject: EPA Notification: New TSCA Implementation FAQs Posted on CBI and PBTs

Heads up that EPA posted new FAQs on CBI and PBTs. They are available at:
https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-0

EPA will continue to update the FAQs as we respond to stakeholder inquiries. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/26/2016 10:01:59 PM
To: JerryCouri@mail.house.gov
Subject: Fwd: HEC Inquiry on New Chemicals Data
Attachments: New Chem Stats July 25 2016 revised.docx; ATT00001.htm

Jerry - check the second page of the attachment for the additional info. Thanks,
Sven

Begin forwarded message:

From: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Date: July 26, 2016 at 5:00:05 PM EDT
To: "'Couri, Jerry'" <JerryCouri@mail.house.gov>
Subject: HEC Inquiry on New Chemicals Data

Jerry, please see the attached PMN data that responds to the request. Talk to you tomorrow, Weds, July 27 at 9am – 8 Personal Phone / Ex. 6 code Personal Phone / Ex. 6 Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Friday, July 15, 2016 10:55 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA process question

May I please get stats on PMN outcomes (i.e. Yearly run downs of how many PMNs were submitted to Agency, reviewed and action taken subject to 5(e) or 5(f), withdrawn, received notices of commencement) before enactment of reforms to TSCA title I (too long of a title to type out on BB).

Also, I would begin a discussion about setting up something so the Agency can update us periodically on section 5 and other implementation issues.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

TSCA New Chemicals Program Statistics FY2012 through FY2015

Number of Valid Submissions Received:

Used July 21, 2016 PMN Lotus Notes Annual Report

Notice or Action	FY 2012	FY 2013	FY 2014	FY 2015
Premanufacture Notice (PMN)	516	637	657	589
Low Volume Exemption (LVE)[1]	454	399	434	399
Low Release & Low Exposure Exemption (LOREX)[1]	8	7	6	2
Significant New Use Notice (SNUN)	6	7	13	5
Test Market Exemption (TME)	12	24	4	15
Microbial Commercial Activity Notice (MCAN)	7	14	21	34
Withdrawal Notice	31	66	52	53

[1]The number of TSCA Section 5(h)(4) exemptions (i.e., LVE and LOREX) includes Modifications (LOREXM & LVM).

TSCA New Chemicals Program Statistics FY2012 through FY2015

Number of Valid Submissions Received:

Using CCD Consent Order Database and ICB Databases

Notice or Action	FY 2012	FY 2013	FY 2014	FY 2015
Notice of Commencement (NOC)[1]	395	403	395	267
5(e) or 5(f) Order[2]	33	30	20	48

[1]The number of NOCs received during the FY
[2]Number of Consent Orders from CCD Database by FY signed

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/17/2016 2:43:04 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Nomenclature savings clauses (HLC 5-6)

Michal,
This TA responds to the request on nomenclature provisions in HLC (5-6).

We don't anticipate that these provisions will raise significant implementation problems along the lines you outlined. As we did not see any technical issues, we did not supply earlier TA on these provisions when you circulated the May 6 HLC draft to us for review.

With respect to the first savings clause in 8(b)(3)(C), it appears that you may be reading this as providing that any chemical substance that is not separately listed on the Inventory would be treated as a new chemical substance, post enactment, irrespective of whether it is covered under a statutory listing. But the actual text of the savings clause is that any chemical substance that is "manufactured for the first time after the date of enactment of [FRL21]" would be treated as a new chemical substance, irrespective of whether it is covered under a statutory listing, until it goes through new chemical review. Whether a particular chemical substance was manufactured for the first time before or after FRL21 was enacted is a factual inquiry that wouldn't be settled simply by arguing about the scope of a statutory mixture listing and whether the substance is therefore already on the Inventory. In effect, this would mean that every chemical substance that has been manufactured within the scope of a statutory mixture listing, up until now, is "grandfathered in" under the listing, whereas any further chemical substances cannot rely on the listing and must have separate PMN review. While this is a different sort of grandfathering than the ordinary distinction between new and existing chemical substances, we do not see it as raising significant implementation problems.

With respect to the second savings clause in 8(b)(3)(C), it appears that this savings clause is intended to close off a third pathway for getting a new chemical onto the Inventory, beyond the two you list (being grandfathered in from the outset or passing through the new chemicals program). The third pathway would be for EPA to alter the definition of an existing chemical substance to make the definition more capacious. The savings clause seems intended to address a concern that EPA would merge one or more particular Inventory entries, on the theory that they are all, more or less, referring to the same chemical substance, when viewed from a less granular perspective. To guard against the possibility that a directive to remove duplicate entries from the Inventory would be construed as a directive to consolidate similar entries on the Inventory, this savings clause provides that any such consolidation would be inoperative for purposes of determining which chemicals need new chemicals review. The consolidation would be inoperative for such purpose because it would be an "action of the Administrator pursuant to subparagraph (B)." We don't see this provision as raising the reverse implication concerns you do, because it appears to be targeted at addressing a particular concern: arguments that EPA should construe 8(b)(2) as a directive for EPA to make Inventory listings less precise than they currently are. Concerns about the possible reverse implication could be further ameliorated by an explanation of the purpose of the savings clause, in the legislative history.

While these savings clauses seem unlikely to raise implementation problems, we think that omitting them would be similarly unlikely to raise implementation problems. The nomenclature provisions are already sufficiently clear, and already afford sufficient discretion to EPA, so that EPA can implement them without compromising the new chemicals review process.

Consequently, while EPA does not see the savings clauses as necessary, neither does it see them, as they are now drafted, as posing implementation issues of concern.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical

assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, May 16, 2016 5:00 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Nomenclature savings clauses

What am I getting wrong below?

The first savings clause basically invalidates EPA's statutory mixture authority, and would require EPA to review PMNS for thousands of components of statutory mixtures/categories that EPA can treat as being part of the statutory mixture (EPA treats all of these as having substantially equivalent risks to health and the environment, and they tend to be for things like ceramics, frits, etc.). None of the individual components of these categories would currently show up on the TSCA inventory solely by virtue of being part of a statutory mixture/category and somehow bypass Section 5 – EPA only puts the MIXTURES/CATEGORIES, not any individual byproducts associated with creating the mixtures/categories, on the inventory. This savings clause would reverse EPA's current practice.

- The second savings clause says that nothing that EPA does to recognize multiple substances on the inventory as being the same chemical can be used as a basis to conclude that the chemical is not a new chemical. This savings clause is silly at best – since the only way a chemical can get on the inventory in the first place is to either be grandfathered into TSCA or be considered a new chemical under Section 5. But at worst, this savings clause could create some sort of implication that there IS some different way to get onto the TSCA inventory besides the only 2 ways that are currently available, and this obviously would be a problem for everyone.?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/18/2015 6:56:24 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA Reform TA on "sound" science

Michal,
We're working on it along with the articles language that came over last night. Expect to have something for you shortly. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, June 18, 2015 2:53 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey)
Subject: FW: "sound" science - this is from the Safe Drinking Water Act

Sven - forgot this follow-up to see if there are other examples like this you guys flagged on the call yesterday, and whether the language below has been subject to litigation?

Thanks
Michal

(3) RISK ASSESSMENT, MANAGEMENT, AND COMMUNICATION.—
(A) USE OF SCIENCE IN DECISIONMAKING.—In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—
(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and
(ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/7/2016 7:39:03 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on conditions of use and Mercury

Michal- does what I sent answer the mercury question? Thanks,
Sven

On May 7, 2016, at 3:36 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks - yes, I meant section 12 of tsca not section 12 of house proposal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Saturday, May 7, 2016 3:35 PM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall)
Subject: Sen. Markey TSCA TA request on conditions of use and Mercury

Michal,
This TA responds to the request on conditions of use and mercury.

Conditions of use: other than page 32, where else do we need to look at? We don't think the problem exists in 6(g), they didn't seem to make this change in 6(a). A solution to this for p 32 may be to insert the entire definition of conditions of use EXCEPT for the as ID'd by the Admin part.

RESPONSE:
The issue with "conditions of use" appears in several places -- some created by the latest HLC additions, some by pre-existing uses of the phrase. Following is a list of the places we have identified where we think it would make most sense to drop "condition of" or "conditions of" and just use "use"or "uses"; we have identified whether the usage is newly created by the latest HLC edits or pre-existing. We do not think it makes sense to import the definition of conditions of use into p 32 as modified, as you suggest, both because it is not the only place we see an issue and because we do not think the issue is significant enough to warrant such a change. Although we have identified this usage issue as a point of consistency within TSCA as a whole, we are not bothered by leaving the current discrepancy between "use" and "condition of use".

p. 32 lines 8-9 (new)
p. 49 line 23 (new)
p. 55 line 11 (pre-existing)
p. 55 lines 13 and 23 (new)
p. 95 lines 1, 8-9, and 25 (pre-existing)
p. 96 lines 7-8, 12 (pre-existing)

Hg - I seem to recall that the SWDA/RCRA components of the language used to be outside TSCA and not in section 12. Doesn't that make more sense?

RESPONSE:
We interpret your question a referring to sections 10(b) and 10(c) of the bill. These provision amend the Mercury Export Ban Act but do not amend TSCA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

On May 7, 2016, at 1:54 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Conditions of use: other than page 32, where else do we need to look at? We don't think the problem exists in 6(g), they didn't seem to make this change in 6(a). A solution to this for p 32 may be to insert the entire definition of conditions of use EXCEPT for the as ID'd by the Admin part.

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Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/23/2016 9:18:20 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Se. Markey TSCA TA Request on Section 8

Michal – got it – thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 23, 2016 4:15 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 8

Sven

Attached is a redline of Senate section 8 with a few changes from the reported text. Could you have your team take a look and address any issues? This can be at the back of the current queue.

Thanks
Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/7/2016 6:07:59 PM
To: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Merkley TSCA TA Request on statment for the record

Adrian,
Got it - checking. Thanks,
Sven

On Jun 7, 2016, at 2:01 PM, Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov> wrote:

Hi Sven
Can you run the traps on this language for the stmt for the record?

Scientific Standards
The term ''weight of evidence'' refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance. This requirement is not intended to prevent the Agency from considering academic studies, or any other category of study. We expect that when EPA makes a weight of the evidence decision it will fully describe its use and methods.

Industry Requested Chemicals
Sec. 6(b)(4)(E) sets the percentage of risk evaluations that the Administrator shall conduct at industry's request at between 25 percent (if enough requests are submitted) and 50 percent. The Administrator should set up a system to ensure that those percentages are met and not exceeded in each fiscal year. An informal effort that simply takes requests as they come in and hopes that the percentages will work out does not meet the requirement that the Administrator "ensure" that the percentages be met. Also, clause (E)(ii) makes clear that industry requests for risk evaluations "shall be" subject to fees. Therefore, if at any point the fees imposed by the Frank Lautenberg Act (which are subject to a termination in section 26(b)(6)) are allowed to lapse, industry's opportunity to seek risk evaluations will also lapse and the minimum 25 percent requirement will not apply.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/26/2016 9:46:14 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: RE: HEC Inquiry on New Chemicals Data

Jerry - Checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Tuesday, July 26, 2016 5:44 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC Inquiry on New Chemicals Data

These numbers are great, thanks! One thing that I perhaps did not mention: could I -- for each of these years – get the number of 40 CFR § 720.102 notices received by the Agency signaling commencement of manufacture or import?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, July 26, 2016 5:00 PM
To: Couri, Jerry
Subject: HEC Inquiry on New Chemicals Data

Jerry, please see the attached PMN data that responds to the request. Talk to you tomorrow, Weds, July 27 at 9am – Personal Phone / Ex. 6 code Personal Phone / Ex. 6 Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
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Washington, DC 20460
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From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
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To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
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May I please get stats on PMN outcomes (i.e. Yearly run downs of how many PMNs were submitted to Agency, reviewed and action taken subject to 5(e) or 5(f), withdrawn, received notices of commencement) before enactment of reforms to TSCA title I (too long of a title to type out on BB).

Also, I would begin a discussion about setting up something so the Agency can update us periodically on section 5 and other implementation issues.

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/7/2016 7:35:08 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Markey TSCA TA request on conditions of use and Mercury

Michal,
This TA responds to the request on conditions of use and mercury.

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RESPONSE:
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Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA

Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

On May 7, 2016, at 1:54 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Conditions of use: other than page 32, where else do we need to look at? We don't think the problem exists in 6(g), they didn't seem to make this change in 6(a). A solution to this for p 32 may be to insert the entire definition of conditions of use EXCEPT for the as ID'd by the Admin part.

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Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/16/2016 9:00:00 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Nomenclature savings clauses

Got it - checking

On May 16, 2016, at 4:59 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

What am I getting wrong below?

The first savings clause basically invalidates EPA's statutory mixture authority, and would require EPA to review PMNS for thousands of components of statutory mixtures/categories that EPA can treat as being part of the statutory mixture (EPA treats all of these as having substantially equivalent risks to health and the environment, and they tend to be for things like ceramics, frits, etc.). None of the individual components of these categories would currently show up on the TSCA inventory solely by virtue of being part of a statutory mixture/category and somehow bypass Section 5 – EPA only puts the MIXTURES/CATEGORIES, not any individual byproducts associated with creating the mixtures/categories, on the inventory. This savings clause would reverse EPA's current practice.

- The second savings clause says that nothing that EPA does to recognize multiple substances on the inventory as being the same chemical can be used as a basis to conclude that the chemical is not a new chemical. This savings clause is silly at best – since the only way a chemical can get on the inventory in the first place is to either be grandfathered into TSCA or be considered a new chemical under Section 5. But at worst, this savings clause could create some sort of implication that there IS some different way to get onto the TSCA inventory besides the only 2 ways that are currently available, and this obviously would be a problem for everyone.?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/21/2016 12:13:55 AM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: Administration Views Letter on TSCA Reform Bills
Attachments: TSCA Reform Views.Upton.pdf

Jerry,
Please see attached for Mr. Shimkus and let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/18/2015 6:19:22 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: HEC TSCA TA Request on FY15 Budget

Jerry,
Thank you for the request on the TSCA Budget levels. Below is the FY15 for the existing and new chemicals programs. Please let me know if any additional questions. Thanks,
Sven

OCSPP Chemical Risk Review and Reduction total*:	$58M
New Chemicals	$17.7M
Existing Chemicals – Data Collection	$12.5M
Existing Chemicals – Risk Assessment	$16.2M
Existing Chemicals – Risk Management	$11.6M

*varies from year to year, funding represents FY15 and only OCSPP TSCA (excluding Lead program) related programs.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Thursday, June 18, 2015 1:06 PM
To: Kaiser, Sven-Erik
Subject: RE: Technical Assistance Request

What is the current appropriated amount for TSCA?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/7/2016 5:57:17 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Markey TSCA TA on conditions of use and Mercury

Michal,
Got it- checking. Thanks,
Sven

On May 7, 2016, at 1:54 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Conditions of use: other than page 32, where else do we need to look at? We don't think the problem exists in 6(g), they didn't seem to make this change in 6(a). A solution to this for p 32 may be to insert the entire definition of conditions of use EXCEPT for the as ID'd by the Admin part.

Hg - I seem to recall that the SWDA/RCRA components of the language used to be outside TSCA and not in section 12. Doesn't that make more sense?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/13/2015 3:09:55 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA on Imports

Jonathan,
I'm cleaning up loose ends. Please let me know if you're interested in a call on the issues raised in the blog.
Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, September 16, 2015 5:50 PM
To: Kaiser, Sven-Erik
Subject: RE: Imports, FYI...

I'd like to have a call on this issue in the near-future. Thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, September 16, 2015 5:48 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Imports, FYI...

thanks

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U.S. EPA
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From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, September 16, 2015 5:45 PM
To: Jones, Jim; Kaiser, Sven-Erik
Subject: Imports, FYI...

Daniel Rosenberg's Blog

What They Are Not Telling You: The Senate TSCA Bill Would Weaken EPA's Ability to Stop Importation of Products with Unsafe Chemicals

Print this page

Posted September 16, 2015

Tags:

cancer, carcinogens, chemcials, publichealth, righttoknow, saferchemicalshealthyfamilies, takeouttoxics, toxicchemicals, TSCA

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The Senate is poised to take up a bill to amend the Toxic Substances Control Act (TSCA), perhaps as early as next week. Supporters of the bill continue to overstate (see also here) the benefits of the legislation, while downplaying or ignoring its flaws - flaws that have led almost the entire environmental community to withhold its support, including more than 400 organizations that are part of the Safer Chemicals Healthy Families coalition. (NRDC is a member.) Supporters of the Senate bill generically claim that it will "protect America's families, especially children, from harmful chemicals that are present in everyday consumer products." But one key provision of the bill will actually make it *harder* for EPA to identify uses of chemicals of concern in everyday products, and to prevent their importation from overseas. And industry is pushing this precisely because EPA is finally starting to act to protect the public against imported products that contain toxic chemicals.

Those who recall the Senate mark-up of the bill may be surprised to hear this. At the mark-up, industry-written (or supported) language that weakened EPA's current import authority was removed from the bill, which was an important improvement. But as part of that deal, new language was added that weakens EPA's current authority under a different part of the law, but is designed to have a similar, and arguably worse, effect.

The current provision creates additional legal hurdles before EPA can require notification about products that contain toxic chemicals the agency believes could harm public health or the environment. The new provision is directed at EPA's authority to issue Significant New Use Rules (or "SNURs"). These are rules EPA issues when the agency wants advance notice about the new use of a chemical that could have potential to harm human health or the environment.

Under current law, one of the few effective steps EPA can take to protect the public is to require notice before a new use of a chemical is adopted, which EPA does by issuing a SNUR. A SNUR requires EPA to be notified at least 90 days before a significant new use of the identified chemical (or group of chemicals) begins. This gives EPA an opportunity to obtain more information if necessary and make a decision whether limitations should be imposed on the production or use of the chemical to protect public health or the environment. This kind of assessment cannot typically be done up-front, because EPA does not at that point have the information about the potential use, or the full universe of potential uses, to sufficiently analyze the hazards and exposures attendant to that new use. If EPA does not act within 90 days of receiving the notice, then the entity that submitted the notice is free to use the chemical as proposed.

EPA has issued about 2,000 Significant New Use Rules since TSCA became law. EPA estimates that it receives only about seven Significant New Use Notices (SNUNs) proposing new uses of those chemicals of concern, each year, and that after EPA evaluates information on the potential exposures resulting from the specific proposed use, many of these Notices expire without any restrictions being imposed on the proposed use of the chemical.

Although SNURs are deeply in the weeds of TSCA policy, they are an important means of informing the agency and protecting the public. They ensure that EPA has an opportunity to address the potential use of a chemical of concern *before* it causes problems to human health or the environment. Most SNURs are issued because EPA is concerned about the toxicity of a chemical and the potential harm to health and the environment that it may cause. SNURs can also serve as an important signal to the marketplace to move toward use of safer chemicals. Even if you never know it is there, the Significant New Use Program is operating to protect the public from greater exposure to unsafe chemicals.

So why are companies like Honda, Intel, and GE trying to weaken the program?

When EPA initially adopted its rules for how to implement the Significant New Use program in the early 1980s during the Reagan Administration, it adopted a default exemption for chemicals that were imported in "articles" (without going further down a legal and policy rabbit hole, an "article" essentially means a formulated item or product). The exemption was adopted on an extremely thin and flimsy rationale - literally one sentence -- which would not hold up to scrutiny if it was offered today: "This decision was made in response to a comment received on this issue and because the identified risks from uses of these substances in articles are not likely to occur." (49 FR 35017, September 5, 1984) Unsurprisingly, the one comment received promoting the default exemption for articles came from the Chemical Manufacturers' Association, which later rebranded itself as the American Chemistry Council. (Forget it, Jake, it was the Ann Burford era). As a result, for the vast majority of Significant New Use Rules issued by EPA, entities interested in importing a chemical of concern for a new use in an article have not been required to notify EPA in advance. In fact, until last year, out of some 2,000 Significant New Use Rules, EPA had only lifted the articles exemption for *two chemicals*: mercury and erionite fibers - a fiber with properties and health effects similar to asbestos.

However, despite the agency's default policy of excluding imported articles from reporting requirements for significant new uses, the agency has always retained its existing authority to lift the exemption "if EPA decides that review under a SNUR is warranted for specific substances...in articles." (79 FR 77897 ellipsis in original)

In recent years, it has become clearer to everyone - industry, EPA, state regulators and legislators, public health professionals, environmental groups, and academics and researchers of various types - that we are frequently exposed to chemicals of concern from many types of products (or "articles"), including those that we have in our homes, our workplaces, our schools, and in our modes of transportation. The scientific and popular literature is replete with examples of sources of human and/or environmental exposure including toys, carpets, clothes, seat cushions, furniture, cleaning supplies, computers, building materials and auto parts. These products have all been identified as potential sources of exposure to one or more problematic chemicals, including brominated flame retardants, formaldehyde, phthalates, non-stick and non-stain chemicals (perfluorinated), mercury, cadmium and a host of other substances.

In short, our understanding of how we are typically exposed to chemicals has expanded since the 1980s - and EPA has begun to shift its approach accordingly. The agency is starting to look more carefully at instances when the default exemption from Significant New Use Notification requirements for chemicals imported in articles should be lifted.

In December, EPA finalized a Significant New Use Rule for of benzidine dyes - these dyes have been found to break down into their component chemical, benzidine, which is classified as a *known human carcinogen*. "[T]he primary human health concern for consumers is exposure to the benzidine-based chemical substances through

oral, dermal, or inhalation routes. Evidence from animal studies suggests that there is early life susceptibility to benzidine carcinogenesis. Cancer potency for benzidine was substantially increased when the dose was given in early life as compared to adults." (77 Fed. Reg. 18756, March 28, 2012)

Because of concern about the toxicity of the chemical EPA opted to "lift" the articles exemption, so that any proposed new uses of the benzidine dyes - including importing articles containing benzidine dyes -- will need EPA review and approval via a Significant New Use Notice.

"Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use." (77 Fed. Reg. 18758)

It is in reaction (and opposition) to these recent steps by EPA that industry is now pressuring Congress to revise TSCA and make it harder for EPA to require reporting of potential new uses of chemicals of concern imported in products. A lobbying entity called the Chemical Users Coalition, which comprises nine major corporations, has been lobbying to weaken EPA's authority under existing TSCA. The other member companies of the Chemical Users Coalition are: Procter & Gamble, Lockheed Martin, PPG, Hewlett Packard, IBM, and Boeing.

Under current law, EPA is authorized to designate a use of a chemical as a significant new use requiring notification after it has considered all relevant factors including:

- The projected volume of manufacturing and processing of the chemical;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical;
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of chemical.

These are all factors related to the form and substance of a chemical, the potential life cycle use of the chemical, and the potential for increased exposure from a new use of a chemical. The law does not now require a particular determination about the likelihood of exposure from a particular source, or product, or class of products.

The new provision goes well beyond these general factors for consideration, and imposes a new limitation on EPA - that it cannot impose a significant new use reporting requirement on an article being imported or processed in the U.S. unless the Administrator makes "an affirmative finding" that "the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification."

Thus, under the new language in the Senate bill, EPA would now have to make a specified finding on a case-by-case basis on the "reasonable potential for exposure" before requiring notice of a new use of a chemical in an article or category of articles. This is a substantial shift in the burden of proof the agency must meet before obtaining simple notice about a potential new use of a chemical in an article. The new language gives the industry a stronger legal basis to challenge a significant new use requirement in court and raises the bar as to what the agency would have to show about the potential for exposure to a substance, prior to having any concrete information about the potential new use. In essence, the provision requires EPA to evaluate something

before the agency even knows what it is. It also gives ammunition to EPA's frequent opponents in the inter-agency process, including OMB and the Small Business Administration Advocacy Office.

Currently, if EPA has a concern about the toxicity (health or environmental effects) of a chemical, and therefore a generalized concern about increased human or environmental exposure, it can adopt a new use notice requirement, including for new use in an article to be imported into the U.S. It may be that industry could successfully sue to overturn a significant new use requirement under the current language of TSCA, but it hasn't happened yet and there is no question that the new language raises the legal bar on EPA. Industry is seeking this language for a reason.

Some supporters of the Senate bill have argued that, while the new provision does change current law, it will have no practical effect on how EPA currently administers its SNUR program. This is incorrect. EPA would have a more difficult time adopting new use notice requirements under the new language in the Senate bill for the substances for which it has previously required notice of potential new use of a chemical in articles. For example, in its proposal to require notice for any new use of erionite fibers, EPA focused almost exclusively on the serious toxicity of the fibers ("In inhalation or injection studies in the rat and mouse, erionite fibers are more potent than crocidolite or chrysotile asbestos in inducing malignant mesothelioma." 56 FR 2890). EPA noted that there were no current known uses of the fibers in the U.S. and that, because of the serious health concerns the fibers raised, any new use, including importing in an article, would pose a risk of exposure and a potential health threat that warranted agency notice. EPA finalized a significant new use rule that applied to any new use, and "lifted" the articles exemption making the notice requirement applicable to imported articles. As a result, the public has been protected from any exposure to these cancer-causing fibers.

Under the new Senate language, EPA would now have to affirmatively identify any potential use of erionite fibers and then make a determination -- subject to legal challenge and judicial review if it made it through the OMB gauntlet --regarding the reasonable potential of exposure to the fibers from any article or category of articles before it could require notification of its potential new use in an imported article. If EPA neglected to correctly predict one or more potential uses of erinonite fibers -using crystal ball gazing technology for the 21st Century -- it could not then impose a new use notification requirement for those uses. Failure to imagine in advance *every potential use* would leave the public vulnerable to importation of new articles that the Administrator did not anticipate or predict.

Or consider EPA's recent significant new use rule for benzidine dyes, finalized last December. EPA identified the breakdown products of benzidine dyes as known human carcinogens, and referenced evidence of potential exposure from the dyes in clothes and textile-related uses. Based on the available information EPA had regarding the chemical's toxicity, and the potential for exposure from clothing, footwear and textiles, EPA imposed a new use notice requirement for any new use of benzidine dyes, and lifted the articles exemption, making the notice requirement applicable to potential new uses of benzidine dyes in articles (products) to be imported into the U.S.

Under the new Senate language, EPA *might* be able to issue the same notice requirement for use of benzidine dyes in clothes, footwear and textiles - as long as it could clear the new hurdle of demonstrating satisfactorily (to a court reviewing EPA's action in a legal challenge brought by industry) that it had identified a reasonable potential for exposure to benzidine dyes from each of those types of articles. But for any other articles, or category or articles for which EPA could not as easily identify a "reasonable potential for exposure" from the chemical -- for example, other categories of articles for which EPA did not already have some exposure information -- a court might rule that EPA did not have the authority to extend notice requirements to those uses, despite the agency's concerns about the chemicals' potential harm to health or the environment. Relying on the argument that EPA *might* prevail in such a lawsuit as an excuse for not flatly rejecting the proposed weakening of current law is simply irresponsible. The new Senate language in fact makes it more likely that articles containing chemicals of concern to EPA will be imported into the U.S. It is also directly contrary to what the drafters of the original TSCA intended.

In the Committee report filed when TSCA was originally passed in 1976, the Senate Commerce Committee (which handled TSCA then) noted the heightened concern about chemicals causing cancer, birth defects and other harms to health and the environment and the limited scope of other existing laws that touched in various ways on the problem of chemical pollution including the Clean Air Act, Clean Water Act, Occupational Safety and Health Act and the Consumer Product Safety Act: "None of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances. Under these other statutes, the Government regulator's only response to chemical dangers is to impose restrictions after manufacture begins. The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest....If hazards are to be discovered and prevented prior to the manufacture of new chemical substances or prior to the imposition of significant new uses of existing substances, premarket notification is an essential provision... the pre-market notification provisions of the committee bill forms [sic] the backbone of the preventive aspects of health protection sought by this legislation."

EPA is currently working on several other Significant New Use Rules, for which it also has proposed to lift the default regulatory exemption for new uses of the chemical in articles to be imported into the U.S. These include new use notice requirements for:

- (take a deep breath before you say this one) Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (LCPFACs) - a group of substances that are persistent, bioaccumulative and toxic (PBTs);
- Toluene Diisocyanates (TDI) and related compounds - that are dermal and inhalation sensitizers that can cause asthma and lung damage;
- Hexabromocyclododecane (HBCD) - a flame retardant ingredient linked to hormone disruption, aquatic toxicity and a possible reproductive toxin that is already subject to authorization (meaning likely phase out) under the European Union's REACH regulation and a global phase-out under the Persistent Organic Pollutants (POPs) treaty;
- Polybrominated Diphenyl Ethers (PBDEs) - another group of flame retardants that are persistent, bioaccumulative and toxic.

In short, EPA is proposing to be notified before new uses of these chemicals - some of the "worst of the worst" that EPA has identified through its existing prioritization process - are introduced into the United States, including in the use of articles imported from China and other countries, to *prevent* people or the environment from being harmed by these toxic substances -- *exactly what the agency should be doing under TSCA*. EPA cannot possibly predict all the potential uses of these substances in advance -- or fully evaluate the hazards and risk of those that it can predict - without the information that the agency would receive in a significant new use notice from an entity seeking to use the chemical.

Efforts to limit EPA's ability to obtain information about potential new uses of chemicals of concern in products before they reach the market, are swimming against the tide of chemical regulation around the world, as well as consumer satisfaction and acceptance. Public demand (and therefore retailer demand) to know what chemicals are used in products is not going away. Contrary to the hopes of many in industry who are salivating for passage of the Udall/Vitter bill, flawed TSCA reform legislation will not stem that tide. EPA's existing authority to obtain information about potential new uses of chemicals of concern before they are imported into the U.S. in products is a modest and effective method of ensuring some degree of protection for the public. Constraining EPA's authority to target articles for significant new use notification is the industry's over-reaction to EPA's exercising its authority in a handful of instances. But increasing the burden on EPA and limiting its ability to take these steps will be met with its own reaction - more action at the state level, and in the marketplace - something these same industries should seriously contemplate before taking a step that could easily backfire.

Members of Congress who consider themselves supporters and protectors of EPA's role in protecting public health and the environment should carefully consider (or reconsider) their support for legislation containing this

very problematic provision. If the Senate does not have the fortitude to tell these companies that this special interest provision to weaken current TSCA is an early Christmas gift that they cannot have, then the White House should make clear that it needs to come out of the bill before TSCA reform legislation reaches the President's desk.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/7/2016 12:51:07 AM
To: jason_albritton@epw.senate.gov; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]; Bettina_Poirier@epw.senate.gov
Subject: Sen. Boxer TSCA TA on Updated Statement for the Record - section 18(f)(2)(B)

Jason,

This TA responds to the request on section 18(f)(2)(B). Please note that there are highlights and strikeouts that might not show up on a phone.

We think that the addition of "12-" before "18" is confusing, because it could suggest a window for states to act, rather than a deadline, and because it makes the end of the sentence ("and before EPA publishes the scope of the risk evaluation for the chemical substance") redundant, since that limitation is what establishes the 12-month end of the range.

Thus, we think the language we had suggested earlier is accurate without any edits. That said, if there is a desire to be clear that the deadline will never be shorter than 12 months, that could be accomplished in one of these two ways:

". . . provided these actions occur during the 18 month period after EPA initiates the prioritization process and before EPA publishes the scope of the risk evaluation for the chemical substance (which cannot be less than 12 months after EPA initiates the prioritization process)."

Or:

". . . provided these actions occur ~~during~~ within the first 12-18 months ~~period~~ after EPA initiates the prioritization process ~~and before EPA publishes the scope of the risk evaluation for the chemical substance~~."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

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Washington, DC 20460

202-566-2753

From: Albritton, Jason (EPW) [mailto:Jason_Albritton@epw.senate.gov]
Sent: Monday, June 06, 2016 1:30 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Poirier, Bettina (EPW) <Bettina_Poirier@epw.senate.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: RE: Sen. Boxer TSCA TA on Updated Statement for the Record_EPW edits 5.26.16.docx

Thanks. One follow up question.

On the language related to the 18(f)(2)(B) waiver, is EPA ok with the highlighted change below?

In particular, Subsection 18(f)(2)(B) specifies that, where requested, EPA shall grant a waiver from preemption under subsection (b) upon the enactment of any statute, or the proposal or completion of a preliminary administrative action, with the intent of prohibiting or otherwise regulating a chemical substance or mixture, provided these actions occur during the 12 - 18-month period after EPA initiates the prioritization process and before EPA publishes the scope of the risk evaluation for the chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/7/2016 7:26:10 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA Inquiry on Section 26 and Initial 10 Chemicals

Michal – thanks for the request on the use of TSCA section 26 and the first 10 workplan chemicals. I'll check with folks and get back to you with a response. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, July 07, 2016 3:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA question followup

HI Sven

In the call we had a couple weeks ago, it sounded like OGC hadn't yet made a determination about whether you can use the section 26 category authority for the first 10 WPs (ie, group flame retardants or pigments even though they are not necessarily grouped on the WP itself). Has that been figured out yet?

I'm getting increasing numbers of requests for EJM to weigh in on various chemicals and am trying to sort out whether it makes any sense for him to do so.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/16/2016 8:45:19 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: HEC min TSCA TA request on House section 8(a)(6) negotiated rulemaking

Jacqueline,
This TA responds to the request on negotiated rulemaking provisions in House bill section 8(a)(6).

I am wondering if the negotiated rulemaking requirement included in the recent versions of the House TSCA bill could limit EPA's authority to promulgate and implement the fracking data collection rule that was subject to the recent ANPRM? I know that the ANPRM mentioned data collection on byproducts from fracking. We would greatly appreciate an answer today if possible.

EPA Response: Section 8(a)(6) of the bill wouldn't limit EPA's authority to promulgate and implement reporting on any inorganic byproducts related to hydraulic fracturing.

Section 8(a)(6) requires EPA to enter into a negotiated rulemaking to develop and publish, not later than 3 years after the date of enactment, a proposed rule providing for limiting 8(a) reporting requirements for manufacturers of inorganic byproducts, when those byproducts are recycled, reused, or reprocessed. But the bill does not bar EPA from establishing or maintaining reporting requirements for the manufacturers of inorganic byproducts prior to the proposal. And if EPA required TSCA 8(a) reporting on the manufacture of any inorganic byproducts related to hydraulic fracturing prior to issuing the section 8(a)(6) proposal, the bill would not obligate EPA to include the withdrawal of those requirements in the section 8(a)(6) proposal. This is because the substantive content of the proposal is not specified by the bill – the bill does not specify any particular reporting requirement that EPA must propose to eliminate or disallow.

Similarly, EPA would not be required to undertake a second negotiated rulemaking process if EPA first issued the proposal under 8(a)(6) then later wished to establish further reporting requirements for manufacturers of any inorganic byproducts related to hydraulic fracturing. Ordinary rulemaking procedures would suffice because the bill does not establish that all rules pertaining to section 8(a) reporting of inorganic byproduct manufacture must be based on a negotiated rulemaking process.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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On May 16, 2016, at 10:28 AM, Cohen, Jacqueline <jackie.cohen@mail.house.gov> wrote:

Sven,

I am wondering if the negotiated rulemaking requirement included in the recent versions of the House TSCA bill could limit EPA's authority to promulgate and implement the fracking data collection rule that was subject to the recent ANPRM? I know that the ANPRM mentioned data collection on byproducts from fracking. We would greatly appreciate an answer today if possible.

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff
U.S. House of Representatives
jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/16/2016 6:51:09 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: HEC Min TSCA TA followup request on section 18(d)(2)(B) preemption (Senate 5-9)

Jacqueline,
Thanks for the followup TA request. I'm checking on the question and will get back promptly with a response. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Monday, May 16, 2016 2:28 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC Min TSCA TA request on section 18(d)(2)(B) preemption (Senate 5-9)

To follow up – wouldn't any new rules on the other chemicals you listed be done pursuant to 6(b)(1)(B)(i), 6(b)(2)(A), or 6(b)(4)(E)(iii)(II) (the list at the end of subparagraph (B))? So new rules on those chemicals would fall under the new preemption scheme. Only new rules on PCB's would be done outside of those sections I think, under 6(e), meaning only PCB's would be subject to the old preemption regime even when new rules are promulgated. Is that right?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, May 16, 2016 2:22 PM
To: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: HEC Min TSCA TA request on section 18(d)(2)(B) preemption (Senate 5-9)

Jacqueline,
This responds to the TA request on section 18(d)(2)(B) preemption (Senate 5-9 version).

PCBs are chemical substances for which rules have been issued under section 6 prior to the effective date of FRL21. Accordingly, they would fall within the scope of 18(d)(2)(B). Metalworking fluids (40 CFR Part 747), hexavalent chromium-based water treatment chemicals in cooling systems (40 CFR Part 749), and asbestos (40 CFR Part 763) are other chemical substances for which rules have been issued under section 6 prior to the effective date of FRL21. Accordingly, these also would fall within the scope of 18(d)(2)(B).

In conclusion, 18(d)(2)(B) does not result in treating PCBs differently from all other chemical substances.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

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202-566-2753

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Monday, May 16, 2016 10:36 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC Min TSCA TA request on section 18 preemption (Senate 5-9)

One additional question on this language – the "Applicability to Certain Rules or Orders" paragraph on 8-10 appears to say that the old preemption regime will continue to apply to new rules on chemicals that have previously been regulated under TSCA unless they go through the general section 6 process. Does that language have the effect of singling PCB's out for special preemption treatment? Are there any other chemicals that would fall under subparagraph (B)?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, May 11, 2016 10:24 AM
To: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: HEC Min TSCA TA request on section 18 preemption (Senate 5-9)

Jacqueline,
This TA responds to the request on Senate section 18 preemption language (5-9).

- Without a reference to criminal penalties in section 18(b)(2)(A) [p. 4, line 12], there is an implication that pause preemption applies even to state criminal penalties established *prior to* EPA's scoping of the risk evaluation.

- Section 18(b)(2)(B) [p. 4, lines 16-22] addressing pause preemption appears unnecessary, and could be read to prevent a state from enforcing any new requirement established after EPA publishes the scope of a risk evaluation, rather than a simply providing that a state cannot enforce such a requirement during the period between scoping and completion of the risk evaluation.

- The reference in section 18(c)(1) to "rule, order or consent agreement under section 4" [p. 5, line 6] is inconsistent with the EPA actions identified in section 18(a)(1)(A) as giving rise to preemption, which references "sections 4, 5 or 6" [p. 1, line 17].

- Section 18(c)(2) [p. 5, lines 7-15] describes the scope of preemption under 18(a)(1)(B) and (b) as follows: "the hazards, exposures, risks, and uses or conditions of use of such substances that are identified by the Administrator as subject to review in a risk evaluation and included in the scope of the risk evaluation published by the Administrator for the chemical substance under section 6(b)(4)(D), or of any rule the Administrator promulgates pursuant to section 6(c)". In contrast, section 18(a)(1)(B) provides that the scope of preemption under (B) is "the scope of the risk evaluation under section 6(b)(4)(D)." This drafting could be clarified. To avoid a conflict between the two, EPA would presumably interpret (c)(2) as providing for preemption of any requirements addressing hazards identified or included in *any* of the sources listed there (note that, although (c)(2) on its face lists three sources, the first two – chemicals subject to risk evaluation and chemicals identified in scoping under 6(b)(4)(D) – appear to say the same thing). Assuming the reference to a rule is retained in (c)(2), the citation should be to 6(a), not 6(c).

- The direction in section 18(f)(2)(B) [p. 13, lines 11-23] as to when the window for a state to enact a requirement to qualify for the new pause preemption waiver ends could be read to say that the opportunity ends 18 months after initiation of prioritization or *18 months after* the scope of the risk evaluation is published, whichever is sooner. The former will always occur sooner, so the effect is that states will always have an 18 month window. Although the intent appears clear that the opportunity should end 18 months after initiation of prioritization, or when the scope of the risk evaluation is published, whichever is sooner, we suggest the

following clarification to ensure that intent is effectuated: on p. 13, line 11, by inserting "either the date that is" before "18 months".

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

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From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Monday, May 09, 2016 10:55 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request

Sven,

Can the TSCA team provide technical assistance on the attached language? We have not requested TA on preemption language before, so we would appreciate all TA, not just TA on changes in this version. Thank you!

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff
U.S. House of Representatives
jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/7/2016 5:31:03 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: RE: Sen. Udall TSCA TA Request on HLC (5-6)
Attachments: Udall.TSCA TA.HLC (5-6).docx

Resending in case first send doesn't download properly. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Saturday, May 07, 2016 1:19 PM
To: 'Black, Jonathan (Tom Udall)' <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Sen. Udall TSCA TA Request on HLC (5-6)

Jonathan,
The attached TA responds to the request to review the House counteroffer (HLC 5-6). Yellow highlighting indicates EPA TA that was provided to the House on the HLC 5-4 version, but that may not have been received with enough time to consider and incorporate before the House finalized and transmitted the HLC 5-6 version.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, May 06, 2016 5:03 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Jones, Jim <Jones.Jim@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Fw: House TSCA draft

Please take a look...

This is the current hlc draft, but not yet reviewed or approved by senate team.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Friday, May 6, 2016 5:00 PM
To: Jackson, Ryan (Inhofe)
Cc: Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey); Larkin, Brendan; Deveny, Adrian (Merkley); Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick; Fruci, Jean
Subject: House TSCA draft

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

[DISCUSSION DRAFT]

114TH CONGRESS
2D SESSION

H. R. ||

To modernize the Toxic Substances Control Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ml. |||||introduced the following bill; which was referred to the Committee on
|||||||||||||

A BILL

To modernize the Toxic Substances Control Act, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 "Frank R. Lautenberg Chemical Safety for the 21st Cen-
6 tury Act".

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings, policy, and intent.
Sec. 3. Definitions.

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Sec. 4. Testing of chemical substances and mixtures.
Sec. 5. Manufacturing and processing notices.
Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.
Sec. 7. Imminent hazards.
Sec. 8. Reporting and retention of information.
Sec. 9. Relationship to other Federal laws.
Sec. 10. Exports of elemental mercury.
Sec. 11. Confidential information.
Sec. 12. Penalties.
Sec. 13. State-Federal relationship.
Sec. 14. Judicial review.
Sec. 15. Citizens' civil actions.
Sec. 16. Studies.
Sec. 17. Administration of the Act.
Sec. 18. State programs.
Sec. 19. Conforming amendments.
Sec. 20. No retroactivity.
Sec. 21. Trevor's Law.

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended by striking "proposes to take" and inserting "proposes as provided".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4) through (14) as paragraphs (5), (6), (8), (9), (10), (11), (13), (14), (15), (16), and (17), respectively;

(2) by inserting after paragraph (3) the following:

"(4) The term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reason-

1 ably foreseen to be manufactured, processed, distributed
2 in commerce, used, or disposed of.";
3 (3) by inserting after paragraph (6), as so re-
4 designated, the following:
5 "(7) The term 'guidance' means any significant writ-
6 ten guidance of general applicability prepared by the Ad-
7 ministrator."; and
8 (4) by inserting after paragraph (11), as so re-
9 designated, the following:
10 "(12) The term 'potentially exposed or susceptible
11 subpopulation' means a group of individuals within the
12 general population identified by the Administrator who,
13 due to either greater susceptibility or greater exposure,
14 may be at greater risk than the general population of ad-
15 verse health effects from exposure to a chemical substance
16 or mixture, such as infants, children, pregnant women,
17 workers, or the elderly.".

18 **SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIX-**
19 **TURES.**

20 Section 4 of the Toxic Substances Control Act (15
21 U.S.C. 2603) is amended—
22 (1) by striking "standards" each place it ap-
23 pears and inserting "protocols and methodologies";
24 (2) in subsection (a)—

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1 (A) by striking "If the Administrator
2 finds" and inserting "(1) If the Administrator
3 finds";
4 (B) in paragraph (1), as so designated—
5 (i) by striking "(1)(A)(i)" and insert-
6 ing "(A)(i)(I)";
7 (ii) by striking "(ii)" each place it ap-
8 pears and inserting "(II)";
9 (iii) by striking "are insufficient data"
10 and inserting "is insufficient information"
11 each place it appears;
12 (iv) by striking "(iii)" each place it
13 appears and inserting "(III)";
14 (v) by striking "such data" and in-
15 serting "such information" each place it
16 appears;
17 (vi) by striking "(B)(i)" and inserting
18 "(ii)(I)";
19 (vii) by striking "(I)" and inserting
20 "(aa)";
21 (viii) by striking "(II)" and inserting
22 "(bb)";
23 (ix) by striking "(2)" and inserting
24 "(B)"; and

1 (x) in the matter following subpara-
2 graph (B), as so redesignated—
3 (I) by inserting ", or, in the case
4 of a chemical substance or mixture
5 described in subparagraph (A)(i), by
6 rule, order, or consent agreement,"
7 after "rule";
8 (II) by striking "data" each place
9 it appears and inserting "informa-
10 tion"; and
11 (III) by striking "and which are
12 relevant" and inserting "and which is
13 relevant"; and
14 (C) by adding at the end the following:
15 "(2) ADDITIONAL TESTING AUTHORITY.—In
16 addition to the authority provided under paragraph
17 (1), the Administrator may, by rule, order, or con-
18 sent agreement—
19 "(A) require the development of new infor-
20 mation relating to a chemical substance or mix-
21 ture if the Administrator determines that the
22 information is necessary—
23 "(i) to review a notice under section 5
24 or to perform a risk evaluation under sec-
25 tion 6(b);

Commented [A1]: Note that this gives EPA authority to act by order or consent agreement if EPA acts based on a "may present" finding, but not if EPA acts based on a substantial production/release/exposure finding. Is that intentional? If not, the insert you make could be changed to simply read: ", order or consent agreement".

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1 "(ii) to implement a requirement im-
2 posed in a rule, order, or consent agree-
3 ment under subsection (e) or (f) of section
4 5 or in a rule promulgated under section
5 6(a);
6 "(iii) at the request of a Federal im-
7 plementing authority under another Fed-
8 eral law, to meet the regulatory testing
9 needs of that authority with regard to tox-
10 icity and exposure; or
11 "(iv) pursuant to section 12(a)(2);
12 and
13 "(B) require the development of new infor-
14 mation for the purposes of prioritizing a chem-
15 ical substance under section 6(b) only if the Ad-
16 ministrator determines that such information is
17 necessary to establish the priority of the sub-
18 stance, subject to the limitations that—
19 "(i) not later than 90 days after the
20 date of receipt of information regarding a
21 chemical substance complying with a rule,
22 order, or consent agreement under this
23 subparagraph, the Administrator shall des-
24 ignate the chemical substance as a high-

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1 priority substance or a low-priority sub-
2 stance; and
3 "(ii) information required by the Ad-
4 ministrator under this subparagraph shall
5 not be required for the purposes of estab-
6 lishing or implementing a minimum infor-
7 mation requirement of broader applica-
8 bility.
9 "(3) STATEMENT OF NEED.—When requiring
10 the development of new information relating to a
11 chemical substance or mixture under paragraph (2),
12 the Administrator shall identify the need for the new
13 information, describe how information reasonably
14 available to the Administrator was used to inform
15 the decision to require new information, explain the
16 basis for any decision that requires the use of
17 vertebrate animals, and, as applicable, explain why
18 issuance of an order is warranted instead of promul-
19 gating a rule or entering into a consent agreement.
20 "(4) TIERED TESTING.—When requiring the
21 development of new information under this sub-
22 section, the Administrator shall consider employing
23 a tiered screening and testing process, under which
24 the results of screening-level tests or assessments of
25 available information inform the decision as to

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1 whether 1 or more additional tests are necessary,
2 unless information available to the Administrator
3 justifies more advanced testing of potential health or
4 environmental effects or potential exposure without
5 first considering conducting screening-level testing.";
6 (3) in subsection (b)—
7 (A) in paragraph (1)—
8 (i) in subparagraph (B), by striking
9 "test data" and inserting "information";
10 (ii) in subparagraph (C), by striking
11 "data" and inserting "information"; and
12 (iii) in the matter following subpara-
13 graph (C), by striking "data" and insert-
14 ing "information";
15 (B) in paragraph (2)—
16 (i) in subparagraph (A)—
17 (I) by striking "test data" and
18 inserting "information";
19 (II) by inserting "Protocols and
20 methodologies for the development of
21 information may also be prescribed
22 for the assessment of exposure or ex-
23 posure potential to humans or the en-
24 vironment." after the first sentence;
25 and

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1 (III) by striking "hierarchical
2 tests" and inserting "tiered testing";
3 and
4 (ii) in subparagraph (B), by striking
5 "data" and inserting "information";
6 (C) in paragraph (3)—
7 (i) by striking "data" each place it
8 appears and inserting "information";
9 (ii) in subparagraph (A), by inserting
10 "or (C), as applicable," after "subpara-
11 graph (B)";
12 (iii) by striking "(a)(1)(A)(ii) or
13 (a)(1)(B)(ii)" each place it appears in sub-
14 paragraph (B) and inserting
15 "(a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II)";
16 (iv) in subparagraph (B), in the mat-
17 ter before clause (i), by striking "sub-
18 section (a)" and inserting "subsection
19 (a)(1)"; and
20 (v) by adding at the end the following:
21 "(C) A rule or order under paragraph (1) or (2) of
22 subsection (a) may require the development of information
23 by any person who manufactures or processes, or intends
24 to manufacture or process, a chemical substance or mix-
25 ture subject to the rule or order.";

Commented [A2]: This should read: "A rule or order under paragraph (2) of subsection (a), or an order under paragraph (1) of subsection (a), may require. . . ."

As drafted, it gives conflicting direction for rules under (a)(1).

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1 (D) in paragraph (4)—
2 (i) by striking "of data" each place it
3 appears and inserting "of information";
4 and
5 (ii) by striking "test data" each place
6 it appears and inserting "information";
7 and
8 (E) by striking paragraph (5);
9 (4) in subsection (c)—
10 (A) in paragraph (1), by striking "data"
11 and inserting "information";
12 (B) in paragraph (2), by striking "data"
13 each place it appears and inserting "informa-
14 tion";
15 (C) in paragraph (3)—
16 (i) by striking "test data" each place
17 it appears and inserting "information";
18 and
19 (ii) by striking "such data" each place
20 it appears and inserting "such informa-
21 tion"; and
22 (D) in paragraph (4) by striking "test
23 data" each place it appears and inserting "in-
24 formation";
25 (5) in subsection (d)—

1 (A) by striking "test data" each place it
2 appears and inserting "information";
3 (B) by striking "such data" each place it
4 appears and inserting "such information"; and
5 (C) by striking "for which data have" and
6 inserting "for which information has";
7 (6) in subsection (e)—
8 (A) in paragraph (1)—
9 (i) in subparagraph (A)—
10 (I) by striking "promulgation of
11 a rule" and inserting "development of
12 information"; and
13 (II) by striking "data" each place
14 it appears and inserting "informa-
15 tion"; and
16 (ii) in subparagraph (B), by striking
17 "either initiate a rulemaking proceeding
18 under subsection (a) or if such a pro-
19 ceeding is not initiated within such period,
20 publish in the Federal Register the Admin-
21 istrator's reason for not initiating such a
22 proceeding" and insert "issue an order,
23 enter into a consent agreement, or initiate
24 a rulemaking proceeding under subsection
25 (a), or, if such an order or consent agree-

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1 ment is not issued or such a proceeding is
2 not initiated within such period, publish in
3 the Federal Register the Administrator's
4 reason for not issuing such an order, en-
5 tering into such a consent agreement, or
6 initiating such a proceeding"; and
7 (B) in paragraph (2)(A)—
8 (i) by striking "eight members" and
9 inserting "ten members"; and
10 (ii) by adding at the end the fol-
11 lowing:
12 "(ix) One member appointed by the Chairman
13 of the Consumer Product Safety Commission from
14 Commissioners or employees of the Commission.
15 "(x) One member appointed by the Commis-
16 sioner of Food and Drugs from employees of the
17 Food and Drug Administration.";
18 (7) in subsection (f)—
19 (A) in paragraph (1), by striking "test
20 data" and inserting "information"; and
21 (B) in the matter following paragraph
22 (2)—
23 (i) by striking "from cancer, gene
24 mutations, or birth defects";
25 (ii) by striking "data or";

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1 (iii) by striking "appropriate" and in-
2 serting "applicable"; and
3 (iv) by inserting ", made without con-
4 sideration of costs or other nonrisk fac-
5 tors," after "publish in the Federal Reg-
6 ister a finding";
7 (8) in subsection (g)—
8 (A) by amending the subsection heading to
9 read as follows:"PETITION FOR PROTOCOLS
10 AND METHODOLOGIES FOR THE DEVELOPMENT
11 OF INFORMATION";
12 (B) by striking "test data" each place it
13 appears and inserting "information"; and
14 (C) by striking "submit data" and insert-
15 ing "submit information"; and
16 (9) by adding at the end the following:
17 "(h) REDUCTION OF TESTING ON VERTEBRATES.—
18 "(1) IN GENERAL.—The Administrator shall re-
19 duce, to the extent practicable, scientifically justi-
20 fied, and consistent with the policies of this title, the
21 use of vertebrate animals in the testing of chemical
22 substances or mixtures under this title by—
23 "(A) when making a request or adopting a
24 requirement for testing using vertebrate ani-
25 mals, and in accordance with subsection (a)(3),

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1 taking into consideration, as appropriate and to
2 the extent practicable and scientifically justi-
3 fied, reasonably available existing information,
4 including—
5 "(i) toxicity information;
6 "(ii) computational toxicology and
7 bioinformatics; and
8 "(iii) high-throughput screening meth-
9 ods and the prediction models of those
10 methods; and
11 "(B) encouraging and facilitating—
12 "(i) the use of scientifically valid test
13 methods and strategies that reduce the use
14 of vertebrate animals while providing infor-
15 mation of equivalent or better scientific
16 quality and relevance that will support reg-
17 ulatory decisions under this title;
18 "(ii) the grouping of 2 or more chem-
19 ical substances into scientifically appro-
20 priate categories in cases in which testing
21 of a chemical substance would provide sci-
22 entifically valid and useful information on
23 other chemical substances in the category;
24 and

1 "(iii) the formation of industry con-
2 sortia to jointly conduct testing to avoid
3 unnecessary duplication of tests, provided
4 that such consortia make all information
5 from such testing available to the Adminis-
6 trator.
7 "(2) IMPLEMENTATION OF ALTERNATIVE TEST-
8 ING METHODS.—To promote the development and
9 timely incorporation of new scientifically valid test
10 methods and strategies that are not based on
11 vertebrate animals, the Administrator shall—
12 "(A) not later than 2 years after the date
13 of enactment of the Frank R. Lautenberg
14 Chemical Safety for the 21st Century Act, de-
15 velop a strategic plan to promote the develop-
16 ment and implementation of alternative test
17 methods and strategies to reduce, refine, or re-
18 place vertebrate animal testing and provide in-
19 formation of equivalent or better scientific qual-
20 ity and relevance for assessing risks of injury to
21 health or the environment of chemical sub-
22 stances or mixtures through, for example—
23 "(i) computational toxicology and
24 bioinformatics;

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1 "(ii) high-throughput screening meth-
2 ods;
3 "(iii) testing of categories of chemical
4 substances;
5 "(iv) tiered testing methods;
6 "(v) in vitro studies;
7 "(vi) systems biology;
8 "(vii) new or revised methods identi-
9 fied by validation bodies such as the Inter-
10 agency Coordinating Committee on the
11 Validation of Alternative Methods or the
12 Organization for Economic Co-operation
13 and Development; or
14 "(viii) industry consortia that develop
15 information submitted under this title;
16 "(B) as practicable, ensure that the stra-
17 tegic plan developed under subparagraph (A) is
18 reflected in the development of requirements for
19 testing under this section;
20 "(C) include in the strategic plan devel-
21 oped under subparagraph (A) a list, which the
22 Administrator shall update on a regular basis,
23 of particular alternative test methods or strate-
24 gies the Administrator has identified that do
25 not require new vertebrate animal testing and

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1 are scientifically reliable, relevant, and capable
2 of providing information of equivalent or better
3 scientific reliability and quality to that which
4 would be obtained from vertebrate animal test-
5 ing for specific health and environmental
6 endpoints;
7 "(D) provide an opportunity for public no-
8 tice and comment on the contents of the plan
9 developed under subparagraph (A), including
10 the criteria for considering scientific relevance
11 and value for risk assessment purposes of the
12 test methods and strategies that may be identi-
13 fied pursuant to subparagraph (C);
14 "(E) beginning on the date that is 5 years
15 after the date of enactment of the Frank R.
16 Lautenberg Chemical Safety for the 21st Cen-
17 tury Act, and every 5 years thereafter, submit
18 to Congress a report that describes the progress
19 made in implementing the plan developed under
20 subparagraph (A) and goals for future alter-
21 native test methods and strategies implementa-
22 tion; and
23 "(F) prioritize and, to the extent con-
24 sistent with available resources and the Admin-
25 istrator's other responsibilities under this title,

1 carry out performance assessment, validation,
2 and translational studies to accelerate the devel-
3 opment of scientifically valid test methods and
4 strategies that reduce, refine, or replace the use
5 of vertebrate animals, including minimizing du-
6 plication, in any testing under this title.".

7 **SEC. 5. MANUFACTURING AND PROCESSING NOTICES.**

8 Section 5 of the Toxic Substances Control Act (15
9 U.S.C. 2604) is amended—
10 (1) in subsection (a)—
11 (A) in paragraph (1)—
12 (i) by striking "Except as provided
13 in" and inserting "(A) Except as provided
14 in subparagraph (B) of this paragraph
15 and";
16 (ii) by redesignating subparagraphs
17 (A) and (B) as clauses (i) and (ii), respec-
18 tively;
19 (iii) by striking all that follows "sig-
20 nificant new use" and inserting a period;
21 and
22 (iv) by adding at the end the fol-
23 lowing:
24 "(B) A person may take the actions described
25 in subparagraph (A) if—

1 "(i) such person submits to the Adminis-
2 trator, at least 90 days before such manufac-
3 ture or processing, a notice, in accordance with
4 subsection (d), of such person's intention to
5 manufacture or process such substance and
6 such person complies with any applicable re-
7 quirement imposed under subsection (b); and
8 "(ii) the Administrator—
9 "(I) conducts a review of the notice;
10 and
11 "(II) makes a determination under
12 subparagraph (A), (B), (C), or (D) of
13 paragraph (3) and takes the actions re-
14 quired in association with that determina-
15 tion under such subparagraph within the
16 applicable review period."; and
17 (B) by adding at the end the following new
18 paragraphs:
19 "(3) REVIEW AND DETERMINATION.—Within
20 the applicable review period, subject to section 18,
21 the Administrator shall review such notice and de-
22 termine—
23 "(A) that the relevant chemical substance
24 or significant new use presents or will present
25 an unreasonable risk of injury to health or the

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1 environment, without consideration of costs or
2 other nonrisk factors, including an unreason-
3 able risk to a potentially exposed or susceptible
4 subpopulation identified as relevant by the Ad-
5 ministrator under the conditions of use, in
6 which case the Administrator shall take the ac-
7 tions required under subsection (f);
8 "(B) that—
9 "(i) the information available to the
10 Administrator is insufficient to permit a
11 reasoned evaluation of the health and envi-
12 ronmental effects of the relevant chemical
13 substance or significant new use; and
14 "(ii)(I) in the absence of sufficient in-
15 formation to permit the Administrator to
16 make such an evaluation, the manufacture,
17 processing, distribution in commerce, use,
18 or disposal of such substance, or any com-
19 bination of such activities, may present an
20 unreasonable risk of injury to health or the
21 environment, without consideration of costs
22 or other nonrisk factors, including an un-
23 reasonable risk to a potentially exposed or
24 susceptible subpopulation identified as rel-
25 evant by the Administrator; or

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1 "(II) such substance is or will be pro-
2 duced in substantial quantities, and such
3 substance either enters or may reasonably
4 be anticipated to enter the environment in
5 substantial quantities or there is or may be
6 significant or substantial human exposure
7 to the substance,
8 in which case the Administrator shall take the actions re-
9 quired under subsection (e);
10 "(C) that the relevant chemical substance
11 or significant new use is likely not to present an
12 unreasonable risk of injury to health or the en-
13 vironment, without consideration of costs or
14 other nonrisk factors, including an unreason-
15 able risk to a potentially exposed or susceptible
16 subpopulation identified as relevant by the Ad-
17 ministrator under the conditions of use, in
18 which case the submitter of the notice may
19 commence manufacture of the chemical sub-
20 stance or manufacture or processing for a sig-
21 nificant new use; or
22 "(D) that the relevant chemical substance
23 is a low-hazard substance, in which case the
24 submitter of the notice may commence manu-
25 facture of the chemical substance or manufac-

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1 ture or processing of the chemical substance for
2 a significant new use.
3 "(4) FAILURE TO RENDER DETERMINATION.—
4 "(A) FAILURE TO RENDER DETERMINA-
5 TION.—If the Administrator fails to make a de-
6 termination on a notice under paragraph (3) by
7 the end of the applicable review period and the
8 notice has not been withdrawn by the sub-
9 mitter, the Administrator shall refund to the
10 submitter all applicable fees charged to the sub-
11 mitter for review of the notice pursuant to sec-
12 tion 26(b)(1), and the Administrator shall not
13 be relieved of any requirement to make such de-
14 termination.
15 "(B) LIMITATIONS.—(i) A refund of appli-
16 cable fees under subparagraph (A) shall not be
17 made if the Administrator certifies that the
18 submitter has not provided information required
19 under subsection (b) or has otherwise unduly
20 delayed the process such that the Administrator
21 is unable to render a determination within the
22 applicable review period.
23 "(ii) A failure of the Administrator to
24 render a decision shall not be deemed to con-
25 stitute a withdrawal of the notice.

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1 "(iii) Nothing in this paragraph shall be
2 construed as relieving the Administrator or the
3 submitter of the notice from any requirement of
4 this section.
5 "(5) ARTICLE CONSIDERATION.—In promul-
6 gating a rule under paragraph (2), the Adminis-
7 trator may consider whether there is a likely poten-
8 tial for exposure to a chemical substance through an
9 article or category of articles, and if the Adminis-
10 trator finds such a likely potential, the Adminis-
11 trator shall require notification under this section
12 for the import or processing of a chemical substance
13 as part of the article or category of articles.";
14 (2) in subsection (b)—
15 (A) in the subsection heading, by striking
16 "TEST DATA" and inserting "INFORMATION";
17 (B) in paragraph (1)—
18 (i) in subparagraph (A)—
19 (I) by striking "test data" and
20 inserting "information"; and
21 (II) by striking "such data" and
22 inserting "such information"; and
23 (ii) in subparagraph (B)—
24 (I) by striking "test data" and
25 inserting "information";

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1 (II) by striking "subsection
2 (a)(1)(A)" and inserting "subsection
3 (a)(1)(A)(i)"; and
4 (III) by striking "subsection
5 (a)(1)(B)" and inserting "subsection
6 (a)(1)(A)(ii)";
7 (C) in paragraph (2)—
8 (i) in subparagraph (A)—
9 (I) by striking "test data" in
10 clause (ii) and inserting "informa-
11 tion";
12 (II) by striking "shall" and in-
13 serting "may"; and
14 (III) by striking "data pre-
15 scribed" and inserting "information
16 prescribed"; and
17 (ii) in subparagraph (B)—
18 (I) by striking "Data" and in-
19 serting "Information";
20 (II) by striking "data" both
21 places it appears and inserting "infor-
22 mation";
23 (III) by striking "show" and in-
24 serting "shows";

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1 (IV) by striking "subsection
2 (a)(1)(A)" in clause (i) and inserting
3 "subsection (a)(1)(A)(i)"; and
4 (V) by striking "subsection
5 (a)(1)(B)" in clause (ii) and inserting
6 "subsection (a)(1)(A)(ii)";
7 (D) in paragraph (3)—
8 (i) by striking "Data" and inserting
9 "Information"; and
10 (ii) by striking "paragraph (1) or (2)"
11 and inserting "paragraph (1) or (2) of this
12 subsection or under subsection (e)"; and
13 (E) in paragraph (4)—
14 (i) in subparagraph (A)(i), by insert-
15 ing ", without consideration of costs or
16 other nonrisk factors" after "health or the
17 environment"; and
18 (ii) in subparagraph (C), by striking
19 ", except that" and all that follows
20 through "subparagraph (A)";
21 (3) in subsection (c)—
22 (A) in the subsection heading, by striking
23 "NOTICE" inserting "REVIEW"; and
24 (B) by striking "before which" and all that
25 follows through "subsection may begin";

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1 (4) in subsection (d)—
2 (A) by striking "test data" in paragraph
3 (1)(B) and inserting "information";
4 (B) by striking "data" each place it ap-
5 pears in paragraph (1)(C) and paragraph (2)
6 and inserting "information";
7 (C) in paragraph (2)(B), by striking "uses
8 or intended uses of such substance" and insert-
9 ing "uses of such substance identified in the no-
10 tice"; and
11 (D) in paragraph (3)—
12 (i) by striking "for which the notifica-
13 tion period prescribed by subsection (a),
14 (b), or (c)" and inserting "for which the
15 applicable review period"; and
16 (ii) by striking "such notification pe-
17 riod" and inserting "such period";
18 (5) in subsection (e)—
19 (A) in paragraph (1)(A)—
20 (i) in clause (ii)(I), by inserting "with-
21 out consideration of costs or other nonrisk
22 factors, including an unreasonable risk to
23 a potentially exposed subpopulation identi-
24 fied as relevant by the Administrator

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1 under the conditions of use;" after "health
2 or the environment,"; and
3 (ii) in the matter after clause
4 (ii)(II)—
5 (I) by striking "may issue a pro-
6 posed order" and inserting "shall
7 issue an order"; and
8 (II) by striking "notification pe-
9 riod applicable to the manufacturing
10 or processing of such substance under
11 subsection (a), (b), (c)" and inserting
12 "applicable review period";
13 (B) in paragraph (1)(B)—
14 (i) by striking "A proposed order"
15 and inserting "An order";
16 (ii) by striking "notification period
17 applicable to the manufacture or proc-
18 essing of such substance under subsection
19 (a), (b), (c)" and inserting "applicable re-
20 view period"; and
21 (iii) by striking "of the proposed
22 order" and inserting "of the order";
23 (C) by striking paragraph (1)(C); and
24 (D) by striking paragraph (2);
25 (6) in subsection (f)—

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1 (A) in paragraph (1)—
2 (i) by striking "finds that there is a
3 reasonable basis to conclude that the man-
4 ufacture, processing, distribution in com-
5 merce, use, or disposal of a chemical sub-
6 stance with" and inserting "determines
7 that a chemical substance or significant
8 new use with";
9 (ii) by striking ", or that any com-
10 bination of such activities,";
11 (iii) by striking "before a rule promul-
12 gated under section 6 can protect against
13 such risk," and inserting ", without con-
14 sideration of costs or other nonrisk factors,
15 including an unreasonable risk to a poten-
16 tially exposed subpopulation identified as
17 relevant by the Administrator under the
18 conditions of use,"; and
19 (iv) by striking "notification period
20 applicable under subsection (a), (b), or (c)
21 to the manufacturing or processing of such
22 substance" and inserting "applicable re-
23 view period";
24 (B) in paragraph (2), the matter following
25 subparagraph (C), by striking "Section

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1 6(d)(2)(B)" and inserting "Section
2 6(d)(3)(B)";
3 (C) in paragraph (3)—
4 (i) in subparagraph (A)—
5 (I) by striking "Administrator
6 may" and all that follows through
7 "issue a proposed order to prohibit
8 the" and inserting "Administrator
9 may issue an order to prohibit or limit
10 the"; and
11 (II) by striking "under para-
12 graph (1)" and all that follows
13 through "processing of such sub-
14 stance." and inserting "under para-
15 graph (1). Such order shall take effect
16 on the expiration of the applicable re-
17 view period.";
18 (ii) by striking subparagraph (B) and
19 redesignating subparagraph (C) as sub-
20 paragraph (B);
21 (iii) in subparagraph (B), as so redes-
22 ignated—
23 (I) by striking "subparagraphs
24 (B) and (C)" and inserting "subpara-
25 graph (B)";

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1 (II) by striking "clause (i) of";
2 and
3 (III) by striking "; and the provi-
4 sions of subparagraph (C) of sub-
5 section (e)(2) shall apply with respect
6 to an injunction issued under sub-
7 paragraph (B)"; and
8 (iv) by striking subparagraph (D);
9 and

10 (D) by adding at the end the following:
11 "(4) TREATMENT OF NONCONFORMING USES.—
12 Not later than 90 days after taking an action under
13 paragraph (2) or (3) or issuing an order under sub-
14 section (e) relating to a chemical substance with re-
15 spect to which the Administrator has made a deter-
16 mination under subsection (a)(3)(A) or (B), the Ad-
17 ministrator shall consider whether to promulgate a
18 rule pursuant to subsection (a)(2) that identifies as
19 a significant new use any manufacturing, processing,
20 use, distribution in commerce, or disposal of the
21 chemical substance that does not conform to the re-
22 strictions imposed by the action or order, and, as ap-
23 plicable, initiate such a rulemaking or publish a
24 statement describing the reasons of the Adminis-

25 trator for not initiating such a rulemaking.

1 "(5) WORKPLACE EXPOSURES.—To the extent
2 practicable, the Administrator shall consult with the
3 Assistant Secretary of Labor for Occupational Safe-
4 ty and Health prior to adopting any prohibition or
5 other restriction relating to a chemical substance
6 with respect to which the Administrator has made a
7 determination under subsection (a)(3)(A) or (B) to
8 address workplace exposures.";
9 (7) by amending subsection (g) to read as fol-
10 lows:
11 "(g) STATEMENT ON ADMINISTRATOR FINDING.—If
12 the Administrator finds in accordance with subsection
13 (a)(3)(C) that a chemical substance or significant new use
14 is likely not to present an unreasonable risk of injury to
15 health or the environment, or in accordance with sub-
16 section (a)(3)(D) that the chemical substance is a low-haz-
17 ard substance, then notwithstanding any remaining por-
18 tion of the applicable review period, the submitter of the
19 notice may commence manufacture of the chemical sub-
20 stance or manufacture or processing for the significant
21 new use, and the Administrator shall make public a state-
22 ment of the Administrator's finding. Such a statement
23 shall be submitted for publication in the Federal Register
24 as soon as is practicable before the expiration of such pe-
25 riod. Publication of such statement in accordance with the

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1 preceding sentence is not a prerequisite to the manufac-
2 turing or processing of the substance with respect to which
3 the statement is to be published.";
4 (8) in subsection (h)—
5 (A) in paragraph (1)(A), by inserting ",
6 including an unreasonable risk to a potentially
7 exposed or susceptible subpopulation identified
8 by the Administrator for the specific conditions
9 of use identified in the application" after
10 "health or the environment";
11 (B) in paragraph (2), by striking "data"
12 each place it appears and inserting "informa-
13 tion"; and
14 (C) in paragraph (4), by striking ". A rule
15 promulgated" and all that follows through "sec-
16 tion 6(c)" and inserting ", including an unrea-
17 sonable risk to a potentially exposed or suscep-
18 tible subpopulation identified by the Adminis-
19 trator under the conditions of use"; and
20 (9) by amending subsection (i) to read as fol-
21 lows:
22 "(i) DEFINITIONS.—(1) For purposes of this section,
23 the terms 'manufacture' and 'process' mean manufac-
24 turing or processing for commercial purposes.

Commented [A3]: A global comment about "use" v "conditions of use". Both the senate and house bills, as we read them, previously differentiated between these terms, using "conditions of use" to describe the suite of current and foreseeable uses EPA must consider when evaluating and regulating chemical substances, and "use" to refer to individual uses. HLC has changed a number of reference to "use" to "conditions of use", where it appears the intent is to refer to individual uses. This appears to result in inconsistency in TSCA, because the statute – including unamended portions – uses "use" throughout. For example, the menu of regulatory options in 6(a) refers to "use" – eg, 6(a)(2)(A)(i) authorizes EPA to prohibit manufacture, etc., for "a particular use."

1 "(2) For purposes of this Act, the term 'requirement'
2 as used in this section shall not displace any statutory or
3 common law.
4 "(3) For purposes of this section, the term 'applicable
5 review period' means the period starting on the date the
6 Administrator receives a notice under subsection (a)(1)
7 and ending 90 days after that date, or on such date as
8 is provided for in subsection (b)(1) or (c).".

9 **SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULA-**
10 **TION OF CHEMICAL SUBSTANCES AND MIX-**
11 **TURES.**

12 Section 6 of the Toxic Substances Control Act (15
13 U.S.C. 2605) is amended—
14 (1) by striking the section heading and insert-
15 ing "**PRIORITIZATION, RISK EVALUATION, AND**
16 **REGULATION OF CHEMICAL SUBSTANCES AND**
17 **MIXTURES**";
18 (2) in subsection (a)—
19 (A) by striking "finds that there is a rea-
20 sonable basis to conclude" and inserting "deter-
21 mines in accordance with subsection (b)(4)(A)";
22 (B) by inserting "and subject to section
23 18, and in accordance with subsection (c)(2),"
24 after "shall by rule";

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1 (C) by striking "to protect adequately
2 against such risk using the least burdensome
3 requirements" and inserting "so that the chem-
4 ical substance or mixture no longer presents
5 such risk";
6 (D) by inserting "or otherwise restricting"
7 after "prohibiting" in paragraphs (1)(A) and
8 (2)(A);
9 (E) by inserting "minimum" before "warn-
10 ings" both places it appears in paragraph (3);
11 (F) by striking "and monitor or conduct
12 tests" and inserting "or monitor or conduct
13 tests" in paragraph (4); and
14 (G) in paragraph (7)—
15 (i) by striking "such unreasonable
16 risk of injury" and inserting "such deter-
17 mination"; and
18 (ii) by striking "such risk of injury"
19 and inserting "such determination";
20 (3) by amending subsection (b) to read as fol-
21 lows:
22 "(b) RISK EVALUATIONS.—
23 "(1) PRIORITIZATION FOR RISK EVALUA-
24 TIONS.—
25 "(A) ESTABLISHMENT OF PROCESS.—

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1 "(i) IN GENERAL.—Not later than 1
2 year after the date of enactment of the
3 Frank R. Lautenberg Chemical Safety for
4 the 21st Century Act, the Administrator
5 shall establish, by rule, a risk-based
6 screening process, including criteria for
7 designating chemical substances as high-
8 priority substances for risk evaluations or
9 low-priority substances for which risk eval-
10 uations are not warranted at the time. The
11 process to designate the priority of chem-
12 ical substances, which shall not take longer
13 than one year, shall include a consideration
14 of the hazard and exposure potential of a
15 chemical substance or a category of chem-
16 ical substances (including consideration of
17 persistence and bioaccumulation, poten-
18 tially exposed or susceptible subpopulations
19 and storage near significant sources of
20 drinking water), the conditions of use or
21 significant changes in the conditions of use
22 of the chemical substance, and the volume
23 or significant changes in the volume of the
24 chemical substance manufactured or proc-
25 essed.

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1 "(ii) PUBLIC NOTICE AND COM-
2 MENT.—The process established under
3 clause (i) shall require the Administrator
4 to notify the public when prioritization be-
5 gins and allow for notice and comment
6 which shall be completed along with the
7 rest of the process within the one year
8 deadline.
9 "(B) IDENTIFICATION OF PRIORITIES FOR
10 RISK EVALUATION.—
11 "(i) HIGH-PRIORITY SUBSTANCES.—
12 The Administrator shall designate as a
13 high-priority substance a chemical sub-
14 stance that the Administrator concludes,
15 without consideration of costs or other
16 nonrisk factors, may present an unreason-
17 able risk of injury to health or the environ-
18 ment because of potential hazard and a po-
19 tential route of exposure under the condi-
20 tions of use, including an unreasonable
21 risk to a potentially exposed or susceptible
22 subpopulation identified as relevant by the
23 Administrator.
24 "(ii) LOW-PRIORITY SUBSTANCES.—
25 Except as provided in clause (iii), the Ad-

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1 ministrator shall designate a chemical sub-
2 stance as a low-priority substance if the
3 Administrator concludes, based on infor-
4 mation sufficient to establish, without con-
5 sideration of costs or other nonrisk factors,
6 that such substance does not meet the
7 standard identified in clause (i) for desig-
8 nating a chemical substance a high-priority
9 substance.
10 "(iii) LOW-HAZARD SUBSTANCES.—
11 The Administrator may designate a chem-
12 ical substance as a low-hazard substance if
13 the Administrator concludes, based on in-
14 formation sufficient to establish, without
15 consideration of costs or other nonrisk fac-
16 tors or exposure, that the chemical sub-
17 stance—
18 "(I) poses no or low hazard to
19 health or the environment, including
20 any hazard to a potentially exposed or
21 susceptible subpopulation identified as
22 relevant by the Administrator; and
23 "(II) does not meet the standard
24 identified in clause (i) for designating

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1 a chemical substance a high-priority
2 substance.
3 "(C) EXTENSION OF DEADLINE.—The Ad-
4 ministrator shall, in the rulemaking required
5 under subparagraph (A), provide for a process
6 to extend the one year deadline under subpara-
7 graph (A) for up to six months in order to re-
8 ceive or evaluate information required to be
9 submitted in accordance with section
10 4(a)(2)(B), subject to the limitation that if the
11 information available to the Administrator at
12 the end of such an extension remains insuffi-
13 cient to enable the designation of the chemical
14 substance as a low-priority substance, the Ad-
15 ministrator shall designate the substance as
16 high-priority substance.
17 "(2) INITIAL RISK EVALUATIONS AND SUBSE-
18 QUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY
19 SUBSTANCES.—
20 "(A) INITIAL RISK EVALUATIONS.—Not
21 later than 180 days after the date of enactment
22 of the Frank R. Lautenberg Chemical Safety
23 for the 21st Century Act, the Administrator
24 shall ensure that risk evaluations are being con-
25 ducted on at least 10 chemical substances

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1 drawn from the 2014 update of the TSCA
2 Work Plan for Chemical Assessments.
3 "(B) ADDITIONAL RISK EVALUATIONS.—
4 Not later than three and one half years after
5 the date of enactment of the Frank R. Lauten-
6 berg Chemical Safety for the 21st Century Act,
7 the Administrator shall ensure that risk evalua-
8 tions are being conducted on at least 20 high-
9 priority substances and that at least 20 chem-
10 ical substances have been designated as low-pri-
11 ority or low-hazard substances, subject to the
12 limitation that at least 50 percent of all chem-
13 ical substances on which risk evaluations are
14 being conducted by the Administrator are
15 drawn from the 2014 update of the TSCA
16 Work Plan for Chemical Assessments.
17 "(C) CONTINUING DESIGNATIONS AND
18 RISK EVALUATIONS.—The Administrator shall
19 continue to designate priority substances and
20 conduct risk evaluations in accordance with this
21 subsection.
22 "(D) PREFERENCE.—In designating high-
23 priority substances, the Administrator shall give
24 preference to—

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1 "(i) chemical substances that are list-
2 ed in the 2014 update of the TSCA Work
3 Plan for Chemical Assessments as having a
4 Persistence and Bioaccumulation Score of
5 3; and
6 "(ii) chemical substances that are list-
7 ed in the 2014 update of the TSCA Work
8 Plan for Chemical Assessments that are
9 known human carcinogens and have high
10 acute and chronic toxicity.
11 "(E) METALS AND METAL COMPOUNDS.—
12 In identifying priorities for risk evaluation and
13 conducting risk evaluations of metals and metal
14 compounds, the Administrator shall use the
15 Framework for Metals Risk Assessment of the
16 Office of the Science Advisor, Risk Assessment
17 Forum, and dated March 2007, or a successor
18 document that addresses metals risk assessment
19 and is peer reviewed by the Science Advisory
20 Board.
21 "(3) INITIATION OF RISK EVALUATIONS; DES-
22 IGNATIONS.—
23 "(A) RISK EVALUATION INITIATION.—
24 Upon designating a chemical substance as a

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