1 order is not supported by substantial evidence
2 in the record taken as a whole; and"; and
3 (III) by striking clauses (ii) and
4 (iii) and the matter after clause (iii)
5 and inserting the following:
6 "(ii) the court may not review the contents and
7 adequacy of any statement of basis and purpose re-
8 quired by section 553(c) of title 5, United States
9 Code, to be incorporated in the rule or order, except
10 as part of the record, taken as a whole."; and
11 (iii) by striking subparagraph (C);
12 and
13 (B) in paragraph (2), by striking "any
14 rule" and inserting "any rule or order".
15 (n) SECTION 20.—Section 20(a)(1) of the Toxic Sub-
16 stances Control Act (15 U.S.C. 2619(a)(1)) is amended
17 by striking "order issued under section 5" and inserting
18 "order issued under section 4 or 5".
19 (o) SECTION 21.—Section 21 of the Toxic Substances
20 Control Act (15 U.S.C. 2620) is amended—
21 (1) in subsection (a), by striking "order under
22 section 5(e) or (6)(b)(2)" and inserting "order
23 under section 4 or 5(e) or (f)"; and
24 (2) in subsection (b)—

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1 (A) in paragraph (1), by striking "order
2 under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)"
3 and inserting "order under section 4 or 5(e)";
4 and
5 (B) in paragraph (4)(B)—
6 (i) in the matter preceding clause (i),
7 by striking "order under section 5(e) or
8 6(b)(2)" and inserting "order under sec-
9 tion 4 or 5(e)";
10 (ii) in clause (i), by striking "order
11 under section 5(e)" and inserting "order
12 under section 4 or 5(e)"; and
13 (iii) in clause (ii), by striking "or an
14 order under section 6(b)(2)".
15 (p) SECTION 24.—Section 24(b)(2)(B) of the Toxic
16 Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is
17 amended—
18 (1) by inserting "and" at the end of clause (i);
19 (2) by striking clause (ii); and
20 (3) by redesignating clause (iii) as clause (ii).
21 (q) SECTION 26.—Section 26 of the Toxic Substances
22 Control Act (15 U.S.C. 2625) is amended—
23 (1) in subsection (e), by striking "Health, Edu-
24 cation, and Welfare" each place it appears and in-
25 serting "Health and Human Services"; and

1 (2) in subsection (g)(1), by striking "data" and
2 inserting "information".
3 (r) SECTION 27.—Section 27(a) of the Toxic Sub-
4 stances Control Act (15 U.S.C. 2626(a)) is amended—
5 (1) by striking "Health, Education, and Wel-
6 fare" and inserting "Health and Human Services";
7 (2) by striking "test data" both places it ap-
8 pears and inserting "information";
9 (3) by striking "rules promulgated" and insert-
10 ing "rules, orders, or consent agreements"; and
11 (4) by striking "standards" and inserting "pro-
12 tocols and methodologies".
13 (s) SECTION 30.—Section 30(2) of the Toxic Sub-
14 stances Control Act (15 U.S.C. 2629(2)) is amended by
15 striking "rule" and inserting "rule, order, or consent
16 agreement".
17 **SEC. 20. NO RETROACTIVITY.**
18 Nothing in sections 1 through 19, or the amendments
19 made by sections 1 through 19, shall be interpreted to
20 apply retroactively to any State, Federal, or maritime legal
21 action filed before the date of enactment of this Act.
22 **SEC. 21. TREVOR'S LAW.**
23 (a) PURPOSES.—The purposes of this section are—

1 (1) to provide the appropriate Federal agencies
2 with the authority to help conduct investigations into
3 potential cancer clusters;
4 (2) to ensure that Federal agencies have the
5 authority to undertake actions to help address can-
6 cer clusters and factors that may contribute to the
7 creation of potential cancer clusters; and
8 (3) to enable Federal agencies to coordinate
9 with other Federal, State, and local agencies, insti-
10 tutes of higher education, and the public in inves-
11 tigating and addressing cancer clusters.
12 (b) DESIGNATION AND INVESTIGATION OF POTEN-
13 TIAL CANCER CLUSTERS.—Part P of title III of the Pub-
14 lic Health Service Act (42 U.S.C. 280g et seq.) is amended
15 by adding at the end the following:
16 **"SEC. 399V–6. DESIGNATION AND INVESTIGATION OF PO-**
17 **TENTIAL CANCER CLUSTERS.**
18 "(a) DEFINITIONS.—In this section:
19 "(1) CANCER CLUSTER.—The term 'cancer
20 cluster' means the incidence of a particular cancer
21 within a population group, a geographical area, and
22 a period of time that is greater than expected for
23 such group, area, and period.
24 "(2) PARTICULAR CANCER.—The term 'par-
25 ticular cancer' means one specific type of cancer or

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1 a type of cancers scientifically proven to have the
2 same cause.
3 "(3) POPULATION GROUP.—The term 'popu-
4 lation group' means a group, for purposes of calcu-
5 lating cancer rates, defined by factors such as race,
6 ethnicity, age, or gender.
7 "(b) CRITERIA FOR DESIGNATION OF POTENTIAL
8 CANCER CLUSTERS.—
9 "(1) DEVELOPMENT OF CRITERIA.—The Sec-
10 retary shall develop criteria for the designation of
11 potential cancer clusters.
12 "(2) REQUIREMENTS.—The criteria developed
13 under paragraph (1) shall consider, as appropriate—
14 "(A) a standard for cancer cluster identi-
15 fication and reporting protocols used to deter-
16 mine when cancer incidence is greater than
17 would be typically observed;
18 "(B) scientific screening standards that
19 ensure that a cluster of a particular cancer in-
20 volves the same type of cancer, or types of can-
21 cers;
22 "(C) the population in which the cluster of
23 a particular cancer occurs by factors such as
24 race, ethnicity, age, and gender, for purposes of
25 calculating cancer rates;

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1 "(D) the boundaries of a geographic area
2 in which a cluster of a particular cancer occurs
3 so as not to create or obscure a potential clus-
4 ter by selection of a specific area; and
5 "(E) the time period over which the num-
6 ber of cases of a particular cancer, or the cal-
7 culation of an expected number of cases, occurs.
8 "(c) GUIDELINES FOR INVESTIGATION OF POTEN-
9 TIAL CANCER CLUSTERS.—The Secretary, in consultation
10 with the Council of State and Territorial Epidemiologists
11 and representatives of State and local health departments,
12 shall develop, publish, and periodically update guidelines
13 for investigating potential cancer clusters. The guidelines
14 shall—
15 "(1) recommend that investigations of cancer
16 clusters—
17 "(A) use the criteria developed under sub-
18 section (b);
19 "(B) use the best available science; and
20 "(C) rely on a weight of the scientific evi-
21 dence;
22 "(2) provide standardized methods of reviewing
23 and categorizing data, including from health surveil-
24 lance systems and reports of potential cancer clus-
25 ters; and

1 "(3) provide guidance for using appropriate epi-
2 demiological and other approaches for investigations.
3 "(d) INVESTIGATION OF CANCER CLUSTERS.—
4 "(1) SECRETARY DISCRETION.—The Sec-
5 retary—
6 "(A) in consultation with representatives of
7 the relevant State and local health departments,
8 shall consider whether it is appropriate to con-
9 duct an investigation of a potential cancer clus-
10 ter; and
11 "(B) in conducting investigations shall
12 have the discretion to prioritize certain poten-
13 tial cancer clusters, based on the availability of
14 resources.
15 "(2) COORDINATION.—In investigating poten-
16 tial cancer clusters, the Secretary shall coordinate
17 with agencies within the Department of Health and
18 Human Services and other Federal agencies, such as
19 the Environmental Protection Agency.
20 "(3) BIOMONITORING.—In investigating poten-
21 tial cancer clusters, the Secretary shall rely on all
22 appropriate biomonitoring information collected
23 under other Federal programs, such as the National
24 Health and Nutrition Examination Survey. The Sec-

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1 retary may provide technical assistance for relevant
2 biomonitoring studies of other Federal agencies.
3 "(e) DUTIES.—The Secretary shall—
4 "(1) ensure that appropriate staff of agencies
5 within the Department of Health and Human Serv-
6 ices are prepared to provide timely assistance, to the
7 extent practicable, upon receiving a request to inves-
8 tigate a potential cancer cluster from a State or
9 local health authority;
10 "(2) maintain staff expertise in epidemiology,
11 toxicology, data analysis, environmental health and
12 cancer surveillance, exposure assessment, pediatric
13 health, pollution control, community outreach, health
14 education, laboratory sampling and analysis, spatial
15 mapping, and informatics;
16 "(3) consult with community members as inves-
17 tigations into potential cancer clusters are con-
18 ducted, as the Secretary determines appropriate;
19 "(4) collect, store, and disseminate reports on
20 investigations of potential cancer clusters, the pos-
21 sible causes of such clusters, and the actions taken
22 to address such clusters; and
23 "(5) provide technical assistance for inves-
24 tigating cancer clusters to State and local health de-
25 partments through existing programs, such as the

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1 Epi-Aids program of the Centers for Disease Control
2 and Prevention and the Assessments of Chemical
3 Exposures Program of the Agency for Toxic Sub-
4 stances and Disease Registry.".

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/22/2015 7:58:12 PM
BCC: 'dimitri_Karakitsos@epw.senate.gov' [dimitri_Karakitsos@epw.senate.gov]; 'Fox, Thomas (EPW)' [Thomas_Fox@epw.senate.gov]; 'jason_albritton@epw.senate.gov' [jason_albritton@epw.senate.gov]; 'Fruci, Jean' [Jean.Fruci@mail.house.gov]; 'Couri, Jerry' [JerryCouri@mail.house.gov]; 'Miller, Jonathan (Brown)' [Jonathan_Miller@brown.senate.gov]; 'McCracken, Jonathan (Brown)' [Jonathan_McCracken@brown.senate.gov]; 'Wilson, Jeanne (Brown)' [Jeanne_Wilson@brown.senate.gov]; 'Lalonde, Marianne (Brown)' [Marianne_Lalonde@brown.senate.gov]; 'Sachs, Adam' [Adam.Sachs@mail.house.gov]; 'ryan.seiger@mail.house.gov' [ryan.seiger@mail.house.gov]; 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; 'Enderle, Emily (Whitehouse)' [Emily_Enderle@whitehouse.senate.gov]; 'Adam_Zipkin@booker.senate.gov' [Adam_Zipkin@booker.senate.gov]; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: Notification: EPA Issuing a Federal Register Notice Requesting Information on Chlorinated Paraffins

As part of EPA's review of medium and long-chain chlorinated paraffins, the agency is providing stakeholders and the public with an opportunity to submit new information on Pre-Manufacture Notices submitted under the Toxic Substances Control Act (TSCA) Section 5 New Chemicals Program. Chlorinated paraffins are used primarily in metal working fluids and sealants, resins, and coatings. EPA is currently reviewing these new chemical notices and is requesting new available data on a range of environmental releases. This information will inform the risk assessments for chlorinated paraffins submitted as TSCA new chemical notices.

A pre-publication copy of the Federal Register Notice, along with links to the New Chemicals Program standard review risk assessments, can be found at www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chlorinated-paraffin-premanufacture.

EPA will accept this new data for 60 days following the date of publication in the Federal Register. Additional information on EPA's New Chemicals program can be found at http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.

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: 6/1/2016 11:24:27 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on PCBs

Michal,
This TA responds to the TA request on PCBs.

Are EPA's PCB disposal regulations under 6(e) or 6(a)(6)? If the former, was there any reference to (a)(6) in the (e) regulations?

EPA Response: The authority for EPA's PCB regulations arises under TSCA Section 6(e), not 6(a)(6). The PCB disposal regulations do not themselves reference 6(a)(6) but EPA has discussed the relationship to 6(a)(6) in preamble text. See 59 FR 62832 (1994). EPA interprets the preemption exception at 18(a)(2)(B) as applying to PCB disposal regulations, even though they are not issued under 6(a)(6), because they are still the kind of "requirement described in subsection (a)(6) [of section 6]."

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 27, 2016, at 9:38 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Are EPA's PCB disposal regulations under 6(e) or 6(a)(6)? If the former, was there any reference to (a)(6) in the (e) regulations?

Ty – would also be interested in any edits to the table of enviro votes you might have time to provide now that we have a bit more time (unfortunately).

m

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
<image001.png><image002.png><image003.png><image004.jpg>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/22/2016 4:07:27 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Proposed Bipartisan Technical Managers Amendment for TSCA

Flag: Flag for follow up

Michal,
This TA responds to the request to look at the proposed bipartisan managers amendment.

Our only comment concerns the first proposed bipartisan technical managers amendment (and associated discussion of it in the first remaining Senate request). The proposed change is on page 62, lines 5-7, and is to strike the phrase "that meets the criteria prescribed by the Administrator in the rule promulgated under subsection (b)(4)(B)". The rationale appears to be that leaving the 90 day window as a window from the date of enactment means that the window will close before the EPA prescribes the criteria for requests since that rule is not due until one-year after enactment. However, striking the requirement that the request meet the criteria we prescribe and leaving the window at 90 days after enactment creates another apparent incongruity in the bill as section 6(b)((4)(C)(ii) requires manufacturer requests for risk evaluations to be made in a "form and manner and using the criteria prescribed by the Administrator" in the section 6(b)(4)(B) rule. We are not sure how such requests would be evaluated if there are no criteria to which they are subject. If the intent is that any request for a risk evaluation of a PBT made in the first 90 days after enactment--even a one-sentence letter-- be enough to exempt a PBT from the requirements of the subsection, then the section 6(b)(4)(C)(ii) language would also need to be modified to exempt PBT requests under section 6(h)(5). Unless that is the intended result, however, it would seem that the window needs to occur after the promulgation of the rule establishing the criteria as it would under the proposed Senate change.

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

On May 22, 2016, at 9:35 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Pls take a look and flag any issues asap. This is House list not Senate. Senate list has yet to be transmitted.

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

Begin forwarded message:

From: "Andres, Gary" <Gary.Andres@mail.house.gov>
Date: May 22, 2016 at 7:11:19 AM EDT
To: "Repko, Mary Frances" <Mary.Frances.Repko@mail.house.gov>, "DeGraff, Kenneth" <kenneth.degraff@mail.house.gov>, "Carroll, Jeff" <Jeff.Carroll@mail.house.gov>, "Brown, Maryam" <Maryam.Brown@mail.house.gov>, Ryan Jackson <ryan_jackson@inhofe.senate.gov>, "Bettina_Poirier@epw.senate.gov" <Bettina_Poirier@epw.senate.gov>, "Andres, Gary" <Gary.Andres@mail.house.gov>
Cc: "McCarthy, David" <David.McCarthy@mail.house.gov>, "Richards, Tina" <Tina.Richards@mail.house.gov>, "Couri, Jerry" <JerryCouri@mail.house.gov>, "Sarley, Chris" <Chris.Sarley@mail.house.gov>, "Bloomquist, Mike" <Mike.Bloomquist@mail.house.gov>, "Kielty, Peter" <Peter.Kielty@mail.house.gov>, "Christian, Karen" <Karen.Christian@mail.house.gov>
Subject: Proposed Bipartisan Technical Managers Amendment for TSCA

Good morning everyone and thanks again for all your hard work and cooperation in finalizing this process. In order to expedite the completion of the legislation, we prepared the document pasted below. Thankfully, the list of remaining requests and outstanding items is relatively short, so we should be able to wrap this up maybe through exchanging emails today. However, after reviewing the document, if the group believes we need to do a call, I would proposed 3 pm today and I can circulate our Committee's Conference Call information.

The first part of the document lists instructions to legislative counsel for the preparation of the Bipartisan Technical Managers Amendment. I believe everything on this list is pretty straightforward and non-controversial.

The second section of the document summarizes all the requests that have been made from either the Senate, the House or the Administration (EPA) and a suggested disposition. Most of these, as you can see, have been deemed "non-technical" by either the House or the Senate, so we would recommend NOT including them in the Managers amendment. (There are also a couple where we either suggest a resolution or they are duplicates and have already been included in the proposed Managers amendment).

The final section of the document reflects the TA we received yesterday from EPA after they had a chance to review the Rules Committee Print. We would propose accepting 7 of the 8 EPA recommendations and suggest adding them to the Managers amendment if the rest of the group agrees.

Please reply all w/ any feedback or questions. And if you could let me know by around 2 pm if you think we need to do a call I will be glad to circulate a number for us to use. I would like to get final instructions for the preparation of the Managers amendment to legislative counsel by late this afternoon in order to meet our 10 am deadline on Monday.

Thanks again.

Best

Gary

* all page/line #s are to Rules Committee Print
** See explanation below regarding suggested edits not included

PROPOSED Bipartisan Technical Managers Amendment: **

p. 62, lines 5-7 - strike "that meets the criteria prescribed by the Administrator in the rule promulgated under subsection (b)(4)(B)," **[Senate ask w/ House suggestion]**

p. 109, after line 6 - insert "(9) ***[need to fix this to fit with the lead in]*** nothing in this title prohibits the disclosure of any information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or state law." [also, p. 109, line 3 - strike "and" p. 109, line 6 - strike "of Federal law." and insert "of Federal law; and"] — **[House Ds]**

p.129, line 21 - insert "section" before "6(b)(1)(B)(i)" — **[EPA]**

p. 130, line 16 - strike "section 4" and insert "sections 4, 5, or 6" — **[Senate/House Ds/EPA]**

p. 130, strike lines 17 – 21, and insert the following: — **[House Ds]**
"(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"

p. 130, line 22, strike "(3)" and replace with "(4)" — **[House Ds]**

p. 157, line 19 - strike "section 6(b)(4)(A)(ii)" and insert "6(b)(4)(C)(ii)" — **[EPA]**

p. 157, line 13 - strike "and (ii)" — **[EPA]**

p.173, strike lines 4-7 and replace with "(iii) in clause (ii), by striking "section 6 or 8" and all that follows through the end of the clause and inserting "section 6(a) or 8 or an order under section 5(f), the chemical substance or mixture to be subject to such rule or order presents or will present 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, under the conditions of use" — **[EPA]**

p. 173, line 3 - strike "or (f)" — **[EPA]**

To Be Discussed:

Effective Date — **[EPA]**

Summary of Technical/Conforming Change Requests:

Remaining Senate Requests:

1. p. 62, line 1- strike "date of enactment…" and insert "after the Administrator publishes a rule under 6(b)(4)(B)" — **CHANGE IS NOT TECHNICAL/CONFORMING**

NOTE: there is an incongruity in the text because if a manufacturer requests a risk evaluation on a PBT within 90 days of the date of enactment (in order to be exempted from the requirements of the subsection) the manufacturer would be required to do so in accordance with the 6(b)(4)(B) rule which EPA has up to a year from the date of enactment to promulgate.

HOUSE R's PROPOSED COMPROMISE TECHNICAL CORRECTION]: p. 62, lines 5-7 - strike "that meets the criteria prescribed by the Administrator in the rule promulgated under subsection (b)(4)(B),"

NOTE: This would keep the policy of a 90 day window for manufacturers to request a risk evaluation on a PBT and fix the incongruity by removing the requirement that such request comply with the 6(b)(4)(B) rule.

2. p. 130, line 16 - add section 5 and 6 — **[duplicates House D & EPA suggested edit]**

Remaining House D Requests:

1. p. 109, line 17 - add new (9) — **YES ON OPTION 1 (with change "act" to "title" and fix new (9) so it fits with the lead in)**
   OR
   p. 97, line 7 - add new (C)

2. p. 130, line 4 - insert "criminal penalty" after "statute enacted" — **CHANGE IS NOT TECHNICAL/CONFORMING**

3. p. 130, line 16 - strike "section 4" and insert "sections 4, 5, or 6" — **YES [duplicates Senate & EPA suggested edit]**

4. p. 130, strike lines 17 – 21, and insert the following: — **CHANGE IS NOT TECHNICAL/CONFORMING but YES (if Senate agrees)**

"(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"

p. 130, line 22, strike "(3)" and replace with "(4)" **(part of #4)**

5. p. 131, line 17 - insert "occupation safety and health: after "air quality" — **CHANGE IS NOT TECHNICAL/CONFORMING**

6. p. 132, line 4 - insert "approved" after "adopted" — **CHANGE IS NOT TECHNICAL/CONFORMING**

House R Requests:

None.

EPA TA Requests:

1. p.129, line 21 - insert "section" before "6(b)(1)(B)(i)" — **YES**

2. p. 130, line 16 - strike "section 4" and insert "sections 4, 5 or 6" - to conform with section 18(a)(1)(A) —**YES**

3. p. 130, line 21 - insert "section" before "6(b)(4)(D)" — **YES**

4. p. 157, line 19 - to section 6(b)(4)(A)(ii) should be replaced by a cross reference to section 6(b)(4)(C)(ii) — **YES**

5. p. 157, line 13 - to delete the words "and (ii)" since that appears to duplicate in part the corrected cross reference on page 157, line 19 — **YES**

6. p.173, strike lines 4-7 and replace with "(iii) in clause (ii), by striking "section 6 or 8" and all that follows through the end of the clause and inserting "section 6(a) or 8 or an order under section 5(f), the chemical substance or mixture to be subject to such rule or order presents or will present 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, under the conditions of use" — **YES**

7. p. 173, line 3 - strike "or (f)" — **YES**

8. A brief period of time between enactment and the effective date would be helpful in order for EPA to ensure that appropriate mechanisms are in place to implement our new responsibilities, particularly those contemplated in Sections 5

and 14. We suggest an effective date of the new law to be 30 days after enactment. — **CHANGE IS NOT TECHNICAL/CONFORMING but GROUP should DISCUSS**

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/22/2016 10:00:17 PM
To: Michal Freedhoff [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - risk finding to initiate risk evaluations under section 6

Michal,
Alternative 2 is the higher bar. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 11, 2016 at 12:00:32 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: TA request - risk finding to initiate risk evaluations under section 6

Sven

I'd like EPA's view on which formulation represents a higher bar to initiating a risk evaluation, and why. Thanks.

Michal

Alternative 1:

A) In general.—Not later than 6 months after the receipt of information under paragraph (3) for a chemical substance, the Administrator shall determine, using the process developed under paragraph (6);

"(i) whether the chemical substance may present an unreasonable risk of injury to human health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use, and shall identify such substances as high-priority substance for risk evaluation. The Administrator shall publish for public notice and comment the scope of the risk evaluation to be conducted for any such chemical substance; or

Alternative 2:

"(A) In general.—Not later than 6 months after the receipt of information under paragraph (3) for a chemical substance, the Administrator shall determine, using the process developed under paragraph (6);

"(i) whether there exists the potential that the chemical substance presents or will present an unreasonable risk of injury to human health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use, and shall identify such substances as high-priority substance for risk evaluation. The Administrator shall publish for public notice and comment the scope of the risk evaluation to be conducted for any such chemical substance;

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: 5/13/2016 5:47:06 PM
To: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: TA request on entry to market

Got it- checking

On May 13, 2016, at 1:45 PM, Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov> wrote:

FYI here are the 3 additions to now include (5)(f):

In 5(e)(1)(A), insert the language in red:

> "; the Administrator shall issue an order, to take effect on the expiration of the applicable review period, 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 to the extent necessary to protect against 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 by the Administrator under the conditions of use, and, the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, only in compliance with the order."

In 5(f)(2), insert the language in red:

"Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(3)(B) shall apply with respect to such rule, and, the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, only in compliance with the final rule."

And in 5(f)(3)(A), insert the language in red:

"(3)(A) The Administrator may issue an order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), and, the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, only in compliance with the order."

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, May 13, 2016 1:36 PM
To: Black, Jonathan (Tom Udall)
Cc: Deveny, Adrian (Merkley)
Subject: Re: TA request on entry to market

Great - let me know if any additional requests. Thanks,
Sven

On May 13, 2016, at 1:34 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Thank you!

Unnecessary, but no technical issue is exactly what we want!!!

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, May 13, 2016 1:30 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request on entry to market

Jonathan,
This responds to the TA request on entry to market.

We believe the language added in Adrian's 1:02:48 PM email is unnecessary but that it also creates no technical issues within 5(e). Note, though, that if comparable language is not added to 5(f), it could create the implication either that manufacture and processing may not proceed under an (f) order, or that they may proceed out of compliance with the terms of an (f) order.

From: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Date: May 13, 2016 at 1:18:49 PM EDT
To: "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>, "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: need something

Sven, this is the new urgent email:

Please let us know if this creates any problem, or presumption of entry into market.

From: Black, Jonathan (Tom Udall)
Sent: Friday, May 13, 2016 1:03 PM
To: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: need something

Sorry, we're adding one thing: "the submitter"

the Administrator shall issue an order, to take effect on the expiration of the applicable review period, 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 to the extent necessary to protect against 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 by the Administrator under the conditions of use, and, the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, only in compliance with the order.

From: Deveny, Adrian (Merkley)
Sent: Friday, May 13, 2016 1:02 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: need something

Please let us know if this creates any problem, or presumption of entry into market.

From: Black, Jonathan (Tom Udall)
Sent: Friday, May 13, 2016 1:01 PM
To: Kaiser, Sven-Erik
Cc: Deveny, Adrian (Merkley)
Subject: RE: need something

We're thinking about this:

the Administrator shall issue an order, to take effect on the expiration of the applicable review period, 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 to the extent necessary to protect against 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 by the Administrator under the conditions of use, and, may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, only in compliance with the order.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, May 13, 2016 12:52 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Re: need something

Close

On May 13, 2016, at 12:50 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Almost done?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/22/2015 2:52:30 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: FW: Sen. Markey TSCA TA Request on SNURs
Attachments: Carpet SNUR Final.pdf; Bundle SNUR for TA.pdf

Michal – Resending July SNUR TA in case you need 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: Kaiser, Sven-Erik
Sent: Tuesday, July 07, 2015 9:08 AM
To: 'Freedhoff, Michal (Markey)' <Michal_Freedhoff@markey.senate.gov>; Joseph, Avenel (Markey) <Avenel_Joseph@markey.senate.gov>
Subject: Sen. Markey TSCA TA Request on SNURs

Michal,
This responds to your technical assistance request on SNURs. Attached are two final SNURs that describe the section 5 considerations and discuss the rationale for lifting the articles exemption.

1) PFCs in Carpets: the relevant portions start in section III on p. 62445 and continue through section IV on p. 62447.

2) Benzidine Dyes (and other chemicals): the relevant portions for the benzidine dyes can be found in section III on p. 77893 and section IV on p. 77894

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: Thursday, June 25, 2015 3:56 PM
To: Kaiser, Sven-Erik
Cc: Joseph, Avenel (Markey)
Subject: TA request - SNURs

Hi Sven

I'm looking for a couple of illustrative examples of SNURs that show how the section 5 considerations are typically described. It would be great to get one that describes the basis for removing the exemption for articles too.

Thanks
michal

(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.

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: 5/22/2016 1:42:34 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Proposed Bipartisan Technical Managers Amendment for TSCA

Michal- Got it, checking. Thanks,
Sven

On May 22, 2016, at 9:35 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Pls take a look and flag any issues asap. This is House list not Senate. Senate list has yet to be transmitted.

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

Begin forwarded message:

From: "Andres, Gary" <Gary.Andres@mail.house.gov>
Date: May 22, 2016 at 7:11:19 AM EDT
To: "Repko, Mary Frances" <Mary.Frances.Repko@mail.house.gov>, "DeGraff, Kenneth" <kenneth.degraff@mail.house.gov>, "Carroll, Jeff" <Jeff.Carroll@mail.house.gov>, "Brown, Maryam" <Maryam.Brown@mail.house.gov>, Ryan Jackson <ryan_jackson@inhofe.senate.gov>, "Bettina_Poirier@epw.senate.gov" <Bettina_Poirier@epw.senate.gov>, "Andres, Gary" <Gary.Andres@mail.house.gov>
Cc: "McCarthy, David" <David.McCarthy@mail.house.gov>, "Richards, Tina" <Tina.Richards@mail.house.gov>, "Couri, Jerry" <JerryCouri@mail.house.gov>, "Sarley, Chris" <Chris.Sarley@mail.house.gov>, "Bloomquist, Mike" <Mike.Bloomquist@mail.house.gov>, "Kielty, Peter" <Peter.Kielty@mail.house.gov>, "Christian, Karen" <Karen.Christian@mail.house.gov>
Subject: Proposed Bipartisan Technical Managers Amendment for TSCA

Good morning everyone and thanks again for all your hard work and cooperation in finalizing this process. In order to expedite the completion of the legislation, we prepared the document pasted below. Thankfully, the list of remaining requests and outstanding items is relatively short, so we should be able to wrap this up maybe through exchanging emails today. However, after reviewing the document, if the group believes we need to do a call, I would proposed 3 pm today and I can circulate our Committee's Conference Call information.

The first part of the document lists instructions to legislative counsel for the preparation of the Bipartisan Technical Managers Amendment. I believe everything on this list is pretty straightforward and non-controversial.

The second section of the document summarizes all the requests that have been made from either the Senate, the House or the Administration (EPA) and a suggested disposition. Most of these, as you can see, have been deemed "non-technical" by either the House or the Senate, so we would recommend NOT including them in the Managers amendment. (There are also a couple where we either suggest a resolution or they are duplicates and have already been included in the proposed Managers amendment).

The final section of the document reflects the TA we received yesterday from EPA after they had a chance to review the Rules Committee Print. We would propose accepting 7 of the 8 EPA recommendations and suggest adding them to the Managers amendment if the rest of the group agrees.

Please reply all w/ any feedback or questions. And if you could let me know by around 2 pm if you think we need to do a call I will be glad to circulate a number for us to use. I would like to get final instructions for the preparation of the Managers amendment to legislative counsel by late this afternoon in order to meet our 10 am deadline on Monday.

Thanks again.

Best

Gary

* all page/line #s are to Rules Committee Print
** See explanation below regarding suggested edits not included

PROPOSED Bipartisan Technical Managers Amendment: **

p. 62, lines 5-7 - strike "that meets the criteria prescribed by the Administrator in the rule promulgated under subsection (b)(4)(B)," **[Senate ask w/ House suggestion]**

p. 109, after line 6 - insert "(9) ***[need to fix this to fit with the lead in]*** nothing in this title prohibits the disclosure of any information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or state law." [also, p. 109, line 3 - strike "and" p. 109, line 6 - strike "of Federal law." and insert "of Federal law; and"] — **[House Ds]**

p.129, line 21 - insert "section" before "6(b)(1)(B)(i)" — **[EPA]**

p. 130, line 16 - strike "section 4" and insert "sections 4, 5, or 6" — **[Senate/House Ds/EPA]**

p. 130, strike lines 17 – 21, and insert the following: — **[House Ds]**
"(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"

p. 130, line 22, strike "(3)" and replace with "(4)" — **[House Ds]**

p. 157, line 19 - strike "section 6(b)(4)(A)(ii)" and insert "6(b)(4)(C)(ii)" — **[EPA]**

p. 157, line 13 - strike "and (ii)" — **[EPA]**

p.173, strike lines 4-7 and replace with "(iii) in clause (ii), by striking "section 6 or 8" and all that follows through the end of the clause and inserting "section 6(a) or 8 or an order under section 5(f), the chemical substance or mixture to be subject to such rule or order presents or will present 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, under the conditions of use" — **[EPA]**

p. 173, line 3 - strike "or (f)" — **[EPA]**

To Be Discussed:

Effective Date — **[EPA]**

Summary of Technical/Conforming Change Requests:

Remaining Senate Requests:

1. p. 62, line 1- strike "date of enactment…" and insert "after the Administrator publishes a rule under 6(b)(4)(B)" — **CHANGE IS NOT TECHNICAL/CONFORMING**

NOTE: there is an incongruity in the text because if a manufacturer requests a risk evaluation on a PBT within 90 days of the date of enactment (in order to be exempted from the requirements of the subsection) the manufacturer would be required to do so in accordance with the 6(b)(4)(B) rule which EPA has up to a year from the date of enactment to promulgate.

HOUSE R's PROPOSED COMPROMISE TECHNICAL CORRECTION]: p. 62, lines 5-7 - strike "that meets the criteria prescribed by the Administrator in the rule promulgated under subsection (b)(4)(B),"

NOTE: This would keep the policy of a 90 day window for manufacturers to request a risk evaluation on a PBT and fix the incongruity by removing the requirement that such request comply with the 6(b)(4)(B) rule.

2. p. 130, line 16 - add section 5 and 6 — **[duplicates House D & EPA suggested edit]**

Remaining House D Requests:

1. p. 109, line 17 - add new (9) — **YES ON OPTION 1 (with change "act" to "title" and fix new (9) so it fits with the lead in)**
   OR
   p. 97, line 7 - add new (C)

2. p. 130, line 4 - insert "criminal penalty" after "statute enacted" — **CHANGE IS NOT TECHNICAL/CONFORMING**

3. p. 130, line 16 - strike "section 4" and insert "sections 4, 5, or 6" — **YES [duplicates Senate & EPA suggested edit]**

4. p. 130, strike lines 17 – 21, and insert the following: — **CHANGE IS NOT TECHNICAL/CONFORMING but YES (if Senate agrees)**

"(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"

p. 130, line 22, strike "(3)" and replace with "(4)" **(part of #4)**

5. p. 131, line 17 - insert "occupation safety and health: after "air quality" — **CHANGE IS NOT TECHNICAL/CONFORMING**

6. p. 132, line 4 - insert "approved" after "adopted" — **CHANGE IS NOT TECHNICAL/CONFORMING**

House R Requests:

None.

EPA TA Requests:

1. p.129, line 21 - insert "section" before "6(b)(1)(B)(i)" — **YES**

2. p. 130, line 16 - strike "section 4" and insert "sections 4, 5 or 6" - to conform with section 18(a)(1)(A) —**YES**

3. p. 130, line 21 - insert "section" before "6(b)(4)(D)" — **YES**

4. p. 157, line 19 - to section 6(b)(4)(A)(ii) should be replaced by a cross reference to section 6(b)(4)(C)(ii) — **YES**

5. p. 157, line 13 - to delete the words "and (ii)" since that appears to duplicate in part the corrected cross reference on page 157, line 19 — **YES**

6. p.173, strike lines 4-7 and replace with "(iii) in clause (ii), by striking "section 6 or 8" and all that follows through the end of the clause and inserting "section 6(a) or 8 or an order under section 5(f), the chemical substance or mixture to be subject to such rule or order presents or will present 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, under the conditions of use" — **YES**

7. p. 173, line 3 - strike "or (f)" — **YES**

8. A brief period of time between enactment and the effective date would be helpful in order for EPA to ensure that appropriate mechanisms are in place to implement our new responsibilities, particularly those contemplated in Sections 5 and 14. We suggest an effective date of the new law to be 30 days after enactment. — **CHANGE IS NOT TECHNICAL/CONFORMING but GROUP should DISCUSS**

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/27/2016 6:47:42 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: HEC TSCA TA Request on section 5 - followup

Jerry,
This TA responds to the request on the section 5 followup question.

How many are in the 90/180 day review window right now?

Response: There are approximately 150 PMNs under review between 0 and 90 days (this would include suspensions) and a handful between 90 and 180 days.

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, May 27, 2016 12:32 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC TSCA TA Request on section 5

Since you were so quick, how many are in the 90/180 day review window right now?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, May 27, 2016 11:59 AM
To: Couri, Jerry
Subject: HEC TSCA TA Request on section 5

Jerry,
This responds to the TA request on section 5 notifications.

1. **Currently, approximately how many PMNs and SNUNs are voluntarily suspended by the TSCA section 5(a)(1) notice submitter?**

Response: There are approximately 150 PMNs and SNUNs under voluntary suspensions.

2. **Approximately, what is the year of receipt of the oldest such notification?**

Response: The oldest PMN under voluntary suspension was received by EPA on 5/19/09. The oldest SNUN under voluntary suspension was received by EPA on 6/30/03.

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, May 27, 2016 10:14 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick TSCA question

Sven,

I know there was some concern by the Agency about getting an effective date included in the bill to give you guys some lead time on sections 5 and 14. To that end, I have 2 questions:

1. Currently, approximately how many PMNs and SNUNs are voluntarily suspended by the TSCA section 5(a)(1) notice submitter?
2. Approximately, what is the year of receipt of the oldest such notification?

Thanks in advance for your help in trying, on the Friday before the break to turn this one around for me.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)
<image001.png><image002.png><image003.png><image004.png><image005.png>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/22/2016 1:06:24 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Re: Section 21 - constitutional issues

Flag: Flag for follow up

Michal,
This TA responds to the request on section 21 constitutional issues.

If we were to grant a petition based on the standard that is easier to meet than the section 6 standard--i.e., the standard in section 21 as it currently stands--industry could potentially challenge the grant on the unconstitutional delegation ground. Industry could point out that the finding required for EPA to act under section 6(a) -- a determination of unreasonable risk following a risk evaluation -- has not been made, and argue that EPA is powerless to act under that provision. While we are not sure of the result, it seems to us that if the courts were to find the section 21 petition standard as written to be unconstitutional there are two possible outcomes--either they say the provision is a nullity because it is unconstitutional or say that it can only be applied to the extent it is constitutional, i.e., say that it remains in place, but that petitions can only be granted if EPA could undertake the rulemaking on its own in accordance with the section 6 standard.

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 22, 2016, at 5:55 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

There is not full agreement on including the conforming changes (item 12 on the list I sent you yesterday) in the Senate package of changes.

There has always been a debate about these provisions and whether the change in standard for a citizen suit is needed.

Separate and apart from that, you've raised some constitutional issues about these changes. Could you please, as soon as possible, send me more about why EPA thinks the provision could be at risk if these changes aren't made?

Thanks

M

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: 2/22/2016 9:50:36 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: TA request -section 6(e)

Great - thanks

On Feb 22, 2016, at 4:50 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Yes – thanks/

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
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 22, 2016 4:50 PM
To: Freedhoff, Michal (Markey)
Subject: Fwd: TA request -section 6(e)

Michal,
Did we address this on the call with Dimitri and other folks? Thanks,
Sven

From: <Kaiser.Sven-Erik@epa.gov>
Date: February 14, 2016 at 12:50:14 PM EST
To: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Subject: Re: TA request -section 6(e)

Michal,
Got it. Thanks,
Sven

On Feb 14, 2016, at 11:34 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

When the Senate 'fixed' unreasonable risk throughout TSCA, it did not address instances in section 6(e) on stated grounds that these regulations had been completed and that there had not been litigation surrounding them. I was ok with that at the time, but have since been made aware that EPA is considering changing its PCB regulations.

Does EPA have a concern that 'unreasonable risk' determinations in section 6(e) also need to be somehow addressed by removing costs?

Thanks
Michal

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: 7/19/2016 7:20:55 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Followup Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal,
I see both followup requests. I'll check with folks here and get back with a response. 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 3:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

And, actually, a second followup here – say the scenario I have below works. You have 1 chemical on the WP, and you create a category that ropes in an additional 12 non-WP chemicals that are structurally analogous. What happens to those 12 non-WP chemicals if they hitch a ride on one of the first 10 WP REs by way of preemption? are they exempt from pause? If not, since they are not high-prioritized, what are they preemption-wise?

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: Tuesday, July 19, 2016 2:49 PM
To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

As a follow-up question – what if there were some chemically analogous substances on the WP, but some chemically analogous substances that were NOT on the WP. Could the latter non-WP chemicals be evaluated/regulated as part of a first 10 WP group? ie do ALL the chemicals in the category need to be on the WP in order to be in the first 10 list?

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, July 19, 2016 12:17 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal,
This responds to the inquiry on using TSCA section 26 for the first 10 Workplan chemicals. You ask whether EPA believes it would be legally defensible to deem a category of chemically analogous Workplan chemicals to be a single chemical substance, for purposes of section 6(b)(2)(A) (EPA to commence risk evaluations for 10 chemical substances within 180 days of enactment). We believe this would be a legally defensible exercise of EPA's authority under 26(c).

EPA has broad discretion under section 26(c) to define chemical categories, including based on similar uses and similar chemical properties. With respect to such categories, section 26(c) establishes a general rule of construction that applies throughout the whole Act: "any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category." Thus, one of the 10 chemical substances referenced in 6(b)(2)(A) could be actually be a category that EPA established under 26(c).

The question you raise is not beyond debate, but we believe ours is the better reading of the statute. Congress knew about the existence of 26(c) at the time TSCA was amended to add 6(b)(2)(A), and yet did not limit 26(c) to prevent it from being applied to 6(b)(2)(A). We therefore believe that the stronger implication is that Congress did not intend to modify 26(c) so that it applies more narrowly in the context of 6(b)(2)(A). Furthermore, in terms of section 6 implementation, a category of chemically analogous Workplan chemicals would take the functional place of a single chemical substance – EPA could practicably issue a single risk evaluation for that category and address any unreasonable risk by a single rule.

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: 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: 8/11/2015 1:09:29 PM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]
Subject: Cong. Shimkus Inquiry on Nanoscale Materials

Dave,
Following up on your question, EPA proposed the nanoscale rule due to lack of information on how nanoscale chemical substances might act differently than their full scale counterparts. The data rule under TSCA 8(a) would provide EPA with any available information that could then be used to properly consider potential risks to human health and the environment under TSCA. The nano web page provides more information about the rule: http://epa.gov/oppt/nano/nano-fact-sheet.html. The rule was proposed in March 2015 and EPA conducted a public meeting on June 11 to allow public comments for the rule. The comment period ended on August 5 and EPA has begun to review the 66 public comments in the docket.

Also, in case it comes up, we think HR 2576 doesn't amend section 8 or TSCA's definition of a chemical substance, so likely wouldn't have a direct effect on the proposed nano rule.

Please let me know if any additional questions and if a briefing would be helpful. 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: Monday, August 10, 2015 11:08 AM
To: Snyder, Raquel; McCarthy, David
Subject: Cong. Shimkus Inquiry on Nanoscale Materials

Dave,
Thanks for the question about nanoscale materials reporting. I'm checking in with the program office and will provide an update shortly. 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: McCarthy, David
Sent: Monday, August 10, 2015 10:54 AM
To: levine.carolyn@epa.gov
Subject: FW: Nano chemicals

Carolyn, Got the following from Mr. Shimkus over the weekend. Can you provide an explanation of what it's about? My desk is 226-9606 if you'd like to call. Thanks. Dave

Nano chemicals?

EPA to Redo Nano Chemical Rule

By Pat Rizzuto | August 07, 2015 06:48PM ET

Collecting Information on Nanoscale Chemicals in Commerce

Key Development: EPA doesn't have legal authority to require manufacturers, processors of nanoengineered chemicals to report information agency sought to obtain under proposed data-collection rule, industry groups say.

Other Views: California's Public Health Department is among organizations saying EPA should broaden scope of rule to ensure people and environment are protected.

Aug. 7 (BNA) -- The Environmental Protection Agency does not have the legal authority to require chemical manufacturers and processors to report information the agency sought to obtain under a proposed data-collection rule for nanoscale chemicals, industry groups told the agency in comments on its proposed rule.

Sent from my iPhone

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/27/2016 4:45:49 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: HEC TSCA TA Request on section 5 - followup

Jerry – 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: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Friday, May 27, 2016 12:32 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC TSCA TA Request on section 5

Since you were so quick, how many are in the 90/180 day review window right now?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, May 27, 2016 11:59 AM
To: Couri, Jerry
Subject: HEC TSCA TA Request on section 5

Jerry,
This responds to the TA request on section 5 notifications.

1. **Currently, approximately how many PMNs and SNUNs are voluntarily suspended by the TSCA section 5(a)(1) notice submitter?**

Response: There are approximately 150 PMNs and SNUNs under voluntary suspensions.

2. **Approximately, what is the year of receipt of the oldest such notification?**

Response: The oldest PMN under voluntary suspension was received by EPA on 5/19/09. The oldest SNUN under voluntary suspension was received by EPA on 6/30/03.

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, May 27, 2016 10:14 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick TSCA question

Sven,

I know there was some concern by the Agency about getting an effective date included in the bill to give you guys some lead time on sections 5 and 14. To that end, I have 2 questions:

1. Currently, approximately how many PMNs and SNUNs are voluntarily suspended by the TSCA section 5(a)(1) notice submitter?
2. Approximately, what is the year of receipt of the oldest such notification?

Thanks in advance for your help in trying, on the Friday before the break to turn this one around for me.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)
<image001.png><image002.png><image003.png><image004.png><image005.png>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/21/2016 9:11:50 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; 'maryam.brown@mail.house.gov' [maryam.brown@mail.house.gov]; 'gary.andres@mail.house.gov' [gary.andres@mail.house.gov]; 'McCarthy, David' [David.McCarthy@mail.house.gov]; 'jeff.carroll@mail.house.gov' [jeff.carroll@mail.house.gov]; 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]; 'kenneth.degraff@mail.house.gov' [kenneth.degraff@mail.house.gov]; 'mary.frances.repko@mail.house.gov' [mary.frances.repko@mail.house.gov]; 'Jackson, Ryan (EPW)' [Ryan_Jackson@epw.senate.gov]; 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; 'bettina_poirier@epw.senate.gov' [bettina_poirier@epw.senate.gov]; Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Wallace, Andrew (Tom Udall) [Andrew_Wallace@tomudall.senate.gov]; 'alexander_mcdonough@reid.senate.gov' [alexander_mcdonough@reid.senate.gov]; 'neil_chatterjee@mcconnell.senate.gov' [neil_chatterjee@mcconnell.senate.gov]; 'gary.andres@mail.house.gov' [gary.andres@mail.house.gov]
Subject: EPA Technical and Conforming Comments on HLC 5-20
Attachments: EPA.TSCA TA.technical and conforming changes (HLC 5-20).docx

Attached please find EPA's technical and conforming comments on HLC 5-20. This is the sum of EPA's technical and conforming comments on the HLC 5-20 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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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.

EPA Technical and Conforming Comments on HLC 5-20

P129, line 21, insert "section" before "6(b)(1)(B)(i)"

P130, line 16, strike "section 4" and insert "sections 4, 5 or 6" - to conform with section 18(a)(1)(A)

P130, line 21, insert "section" before "6(b)(4)(D)"

P157, line 19

- EPA believes the cross reference on page 157, line 19 should be to section 6(b)(4)(C)(ii). The provision referenced doesn't exist, but making it (C)(ii) results in some redundancy with the preceding provision (see line 13) and we're not sure whether to suggest deleting that reference to (C)(ii) as well as fixing one in line 19. Here's language to do both:
- The cross reference on page 157, line 19 to section 6(b)(4)(A)(ii) should be replaced by a cross reference to section 6(b)(4)(C)(ii). In addition a conforming change should be made to page 157, line 13 to delete the words "and (ii)" since that appears to duplicate in part the corrected cross reference on page 157, line 19.

P173, strike lines 4-7 and replace with "(iii) in clause (ii), by striking "section 6 or 8" and all that follows through the end of the clause and inserting "section 6(a) or 8 or an order under section 5(f), the chemical substance or mixture to be subject to such rule or order presents or will present 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, under the conditions of use"

- This is a conforming change to ensure that citizens are not empowered under section 21 to force action by EPA under a standard that is lower than the standard that applies to the same action if initiated by EPA.

P173, line 3 - strike "or (f)"

- As provided in previous EPA TA, confusion will be created by the fact that section 5(f) orders are referenced in both clauses (i) and (ii) of section 21(b)(4)(B). Thus, the bill would provide that judicial action to force EPA to act under section 5(f) is governed by both the "may present" standard and the "presents or will present" standard. Section 5(f) should have only one standard for judicial action, and consistent with section 5, it should be in clause (ii), which operates on a "presents or will present" standard. This language creates a potential constitutional issue with respect to 5(f) that is analogous to the issue we have discussed with respect to section 6, by empowering a citizen to force action under a lower standard than EPA's standard for action. The fix would be to drop "or (f)" on p.173, line 3.

Effective Date

- A brief period of time between enactment and the effective date would be helpful in order for EPA to ensure that appropriate mechanisms are in place to implement our new

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responsibilities, particularly those contemplated in Sections 5 and 14. We suggest an effective date of the new law to be 30 days after enactment.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 8/6/2015 9:00:25 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: SEPW TSCA Reform TA on Nomenclature
Attachments: SEPW TSCA TA on Nomenclature.docx

Dimitri and Jonathan,
This follows up on your technical assistance request on nomenclature. The attached technical assistance addresses concerns about potentially open ended drafting of section 8(b)(3)(A)(iii). The suggested revisions deal with two concerns: (1) To clarify that there aren't other statutory mixtures other than the six that are expressly enumerated; and (2) to clarify that these statutory mixtures are defined in terms of the specific circumstances of manufacture. For example: it should be made clear that the manufacture of a chemical substance that can be found in glass isn't the manufacture of "glass, oxide, chemicals" unless the chemical substance was actually manufactured as part of the production of glass. Along with the text language and comments, the attachment includes a relevant excerpt from 1995 guidance on statutory mixtures.

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 questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

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Technical comments on current draft:

"(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.

Commented [A1]: As drafted, this could be misconstrued as much broader than the 1995 guidance. Here's why: It doesn't clearly reflect that whether or not a chemical fits within one of these 6 listings depends on the circumstances of manufacture.

For example, the Inventory listing in the guidance below reflects that about a third of the periodic table, in various combinations, could be covered under the single listing of "glass, oxide, chemicals," but only when such substances are manufactured in the course of manufacturing glass.

Drafters presumably do not intend to require EPA to treat a host of potential chemical substances as "glass, oxide, chemicals," when they are produced under other circumstances, not actually covered in the description of CAS No. 65997-18-4.

Potential resolution of technical comments:

"(iii) treat all ~~components of categories that are considered to be statutory mixtures under this Act~~ **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),** 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.

Commented [A2]: Unless the intent is to expand the concept of statutory mixtures beyond the scope of the 1995 guidance, this should be an exclusive list.

While the 1995 guidance contemplates a degree of flexibility within each of the 6 categorical listings, the guidance is also clear that it is referring to exactly 6 categorical listings.

Commented [A3]: This is clearer than "considered to be statutory mixtures." Each of the 6 listings below defines a single category of chemical substances, the members of which would be treated as a single chemical substance for purposes of the TSCA Inventory.

Commented [A4]: To make clear that membership in the category is not just about molecular identity, but also the circumstances of manufacture.

Consistent with § 8(b)(3)(A)(ii), Appendix A of the 1985 TSCA Inventory document is the reference source for looking up the pertinent descriptions of these category listings.

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Excerpt from March 29, 1995 Guidance Document:

Products Containing Two or More Substances: Formulated and Statutory Mixtures

B. Combinations that are considered to be statutory mixtures under TSCA

1. Certain alloys, inorganic glasses, ceramics, frits and cements, including Portland cement are considered to be statutory mixtures by the Agency.

Inorganic glasses, ceramics, frits and cements, including Portland cements, are considered to be statutory mixtures under TSCA. Manufacturers of these products are not required to report them. When the initial Inventory was being developed, both EPA and industry recognized that the individual substances comprising these mixtures are complex solids and would be very difficult to identify. Therefore, instead of requiring industry to identify and report every such substance for the Inventory, several special categories were created to include the various substances formed when cement, glass, frit or ceramic are produced. These categories were reported during the initial Inventory reporting period and are currently listed on the TSCA Inventory. Each category contains a definition that describes the various components of that category in terms of the elements and the various types of chemical substances that may be formed with these elements. These categories of substances are:

Cement, Portland, Chemicals	[65997-15-1*]
Cement, Alumina, Chemicals	[65997-16-2*]
Glass, Oxide, Chemicals	[65997-17-3*]
Frits, Chemicals	[65997-18-4*]
Steel Manufacture, Chemicals	[65997-19-5*]
Ceramic Materials and Wares, Chemicals	[66402-68-4*]

For example, a category such as Ceramic Material and Wares, Chemicals includes any combination of the elements listed in the Inventory definition, as oxides, borides, carbides, etc., in multiple oxidation states, or in more complex compounds. The listed elements included in the definition of each of these categories are not intended to be inclusive. EPA recognizes that the list of elements may need to be updated from time to time as the state of the technology changes.

Example 7. Glass, oxide, chemicals (CASRN 65997-17-3*)

The definition of this substance is as follows:

Synonym: Chemical substances manufactured in the production of inorganic glass

This category encompasses the various chemical substances manufactured in the production of inorganic glasses. For purposes of this category, "glass" is defined as an amorphous, inorganic, transparent, translucent or opaque material traditionally formed by

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fusion of sources of silica with a flux, such as an alkali-metal carbonate, boron oxide, etc. and a stabilizer, into a mass which is cooled to a rigid condition without crystallization in the case of transparent or liquid-phase separated glass or with controlled crystallization in the case of glass-ceramics. The category consists of the various chemical substances, other than by-products or impurities, which are formed during the production of various glasses and concurrently incorporated into a glass mixture. All glasses contain one or more of these substances, but few, if any, contain all of them. The elements listed below are principally present as components of oxide systems but some may also be present as halides or chalcogenides, in multiple oxidation states, or in more complex compounds. Trace amounts of other oxides or chemical compounds may be present. Oxides of the first seven elements listed* comprise more than 95 percent, by weight, of the glass produced.

Aluminum*	Lanthanum
Boron*	Lead
Calcium*	Lithium
Magnesium*	Manganese
Potassium*	Molybdenum
Silicon*	Neodymium
Sodium*	Nickel
Antimony	Niobium
Arsenic	Nitrogen
Barium	Phosphorus
Bismuth	Praseodymium
Cadmium	Rudibium
Carbon	Selenium
Cerium	Silver
Cesium	Strontium
Chromium	Sulfur
Cobalt	Tellurium
Copper	Tin
Germanium	Titanium
Gold	Tungsten
Holmium	Uranium
Iron	Vanadium
	Zinc

Definitions such as this may be subject to revision to reflect changes in the underlying technology.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/22/2016 9:44:36 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen Markey TSCA TA request on section 5

Thanks

On Feb 22, 2016, at 4:41 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

I'm drafting everything as a markup to existing tsca because it is difficult to mix and match House/Senate lexicons and constructs and even remotely hope to get it right if you don't understand what you're doing to the entire section. The Section 4 draft I sent you a couple weeks ago was Senate's markup of the House redlined amdt to TSCA 4 – I have word files that are redlines showing what the House did to each section and what the Senate did to each section. This text is the Senate's markup of a redlined TSCA 5 (as amended by 697), and is intended to be responsive to issues raised in House-Senate discussions. I am not sure when it will be transmitted to the House.

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
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 22, 2016 4:37 PM
To: Freedhoff, Michal (Markey)
Subject: Sen Markey TSCA TA request on section 5

Michal- can you tell me if this is going to the house or result of house-senate discussion? It looks like this is a mark up of current TSCA. Thanks,
Sven

On Feb 22, 2016, at 3:51 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

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
<5-02-22-16SENATEMF.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/13/2016 5:19:28 PM
To: jonathan_black@tomudall.senate.gov
Subject: Fwd: Urgent Sen. Udall TA request on New Chemicals
Attachments: May 13 TA on Section 5 v2.docx; ATT00001.htm

Jonathan - this is ok as sent (v2). Thanks,
Sven

Begin forwarded message:

From: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Date: May 13, 2016 at 1:12:04 PM EDT
To: "jonathan_black@tomudall.senate.gov" <jonathan_black@tomudall.senate.gov>
Subject: Urgent Sen. Udall TA request on New Chemicals

Jonathan,
The attached TA responds to the request on new chemicals.

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

You inquired whether there would be a path for manufacture of a new chemical substance to proceed, pending the development of information, under the following version of 5(e):

***

(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); or~~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, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use; 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 shall ~~may~~ issue an ~~proposed~~ order, to take effect on the expiration of the applicable review ~~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 to the extent necessary to protect against 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 by the Administrator under the conditions of use.

——(B~~B~~) An ~~proposed~~ order may not be issued under subparagraph (A)~~(ii)~~ respecting a chemical substance (i) later than 45 days before the expiration of the applicable review ~~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.

***

The answer is yes, there is such a path, but there is an important typographical change to be made, to clarify this path.

Manufacture can proceed under 5(a)(1)(B)(ii)(II) once the Administrator "takes the actions required in association" with the 5(a)(3)(B) determination. The actions required in association with the 5(a)(3)(B) determination are "the actions required under subsection (e)." Regardless of whether EPA makes the 5(a)(3)(B) determination based on 5(a)(3)(B)(i) or 5(a)(3)(B)(ii), the actions required of EPA under subsection (e) are to issue an order to prohibit or limit the chemical substance in question within the applicable review period.

The words "the Administrator shall issue an order," in 5(e)(1)(A), are intended to follow from either 5(e)(1)(A)(i) or 5(e)(1)(A)(ii). Yet the presence of the comma following the final "substance" in

5(e)(1)(A)(ii)(II) could create confusion, giving rise to an argument that "the Administrator shall issue an order" is only associated with 5(e)(1)(A)(ii). The fix is to replace the comma with a semicolon.

Once EPA issues the mandatory 5(e) order, the 5(a)(1)(B)(ii)(II) prohibition on manufacture is lifted. The 5(e) order may only contain such restrictions as EPA finds are necessary to protect against an unreasonable risk.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/27/2016 2:25:41 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: RE: HEC TSCA TA Request on section 5

Okay -will let folks know and see if we can get it today. 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, May 27, 2016 10:24 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC TSCA TA Request on section 5

Prefer today, but Tuesday's fine.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, May 27, 2016 10:19 AM
To: Couri, Jerry
Subject: HEC TSCA TA Request on section 5

Jerry – got it, checking. Urgency – next week okay? 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, May 27, 2016 10:14 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick TSCA question

Sven,

I know there was some concern by the Agency about getting an effective date included in the bill to give you guys some lead time on sections 5 and 14. To that end, I have 2 questions:

1. Currently, approximately how many PMNs and SNUNs are voluntarily suspended by the TSCA section 5(a)(1) notice submitter?
2. Approximately, what is the year of receipt of the oldest such notification?

Thanks in advance for your help in trying, on the Friday before the break to turn this one around for me.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/13/2016 5:12:04 PM
To: jonathan_black@tomudall.senate.gov
Subject: Urgent Sen. Udall TA request on New Chemicals
Attachments: May 13 TA on Section 5 v2.docx; ATT00001.htm

Jonathan,
The attached TA responds to the request on new chemicals.

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/18/2015 3:44:32 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Bill Text Request
Attachments: S.697 - Inhofe Substitute - (10-21-15).pdf

Jonathan,
I think I've got it - we're working from the Inhofe substitute – right? 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, December 18, 2015 10:37 AM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Bill Text Request

Jonathan,
Can you send me the version of the bill that passed. 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: 5/21/2016 7:17:55 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Jackson, Ryan (Inhofe) [Ryan_Jackson@inhofe.senate.gov]
Subject: Correction- Sen. Inhofe TSCA TA on 10 work plan chemicals

Dimitri,
We have one correction to the TA we just sent. If your intention is to limit the number of chemical substances EPA may identify to only 10, as well as to ensure that the exclusion from pause preemption applies to only 10 chemicals, then in addition to the changes we recommended to section (6)(b)(2)(A), section 18(b)(1) should be changed *by dropping entirely the phrase on p 129 lines 21-23:* "such chemical substance that has been identified under section 6(b)(2)(A) (except for the first 10 chemical substances so identified),".

We had suggested just dropping the word "first", but on reflection think the entire phrase should be dropped.

Please let me know if any questions. Thanks,

Sven

On May 21, 2016, at 2:56 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

Dimitri - apologies. We just spotted something in our TA. Will send something shortly. Thanks,
Sven

On May 21, 2016, at 2:26 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

Dimitri,
This TA responds to the request on the 10 workplan chemicals issue.

The nature of the changes depends on what you are trying to achieve.

If the intent is simply that only 10 identified work plan chemicals be exempted from pause preemption then no change to the 5/20 HLC draft is needed. Section 6(b)(2)(A) (page 40 line 24) currently provides that EPA shall conduct risk evaluations on "at least 10 chemical substances." Section 18(b)(1) (page 129 lines 22-23 of that draft) exempts the "first 10 chemical substances so identified" from the pause. The intersection of those two provisions is exactly 10 chemicals. EPA may identify more, but only 10 are exempt from the pause.

If, however, the intention is to limit the number of chemical substances EPA may identify to only 10, as well as to ensure that the exclusion from pause preemption applies to only 10 chemicals, then changes to both section (6)(b)(2)(A) and section 18(b)(1) are needed. The words "at least" should be stricken from line 24 of page 40 in section 6(b)(2)(A) and replaced by another word, such as "exactly" or "precisely". Alternatively, "at least" could be stricken and the phrase ", and no more than 10," could be added after the "10" that is currently there so it would read "conducted on 10, and no more than 10, chemical substances". If a change like that is made, then section 18(b)(1) should be changed as well since the reference to the "first 10" no longer makes sense, as EPA clearly is not authorized to identify any number other than 10. The simplest

change would be to strike the word "first" so section 18(b)(1) would exclude from pause preemption the "10 chemical substances so identified".

Please let me know if any additional questions. Thanks,

Sven

On May 21, 2016, at 1:09 PM, Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven,

We wanted to reach out directly on this since it is such an important part of the bipartisan/bicameral deal we reached this week. Our goal is to ensure that both sides get exactly what was negotiated and as you can imagine we all are concerned about unintended consequences.

What we would like is your thoughts on how best to ensure that the first ten, but only the first ten chemicals epa reviews are exempted from the work place.

I know some language has been floating around on changes in both section 6 and 18 - do you all believe in order to ensure that only ten chemicals are exempted from pause the change in 6 is necessary?

Any help or suggestions would be much appreciated.

Thanks

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/27/2016 2:18:46 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: HEC TSCA TA Request on section 5

Jerry – got it, checking. Urgency – next week okay? 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, May 27, 2016 10:14 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick TSCA question

Sven,

I know there was some concern by the Agency about getting an effective date included in the bill to give you guys some lead time on sections 5 and 14. To that end, I have 2 questions:

1. Currently, approximately how many PMNs and SNUNs are voluntarily suspended by the TSCA section 5(a)(1) notice submitter?
2. Approximately, what is the year of receipt of the oldest such notification?

Thanks in advance for your help in trying, on the Friday before the break to turn this one around for me.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/18/2016 6:22:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Inquiry on Preemption and Partial Risk Evaluations

Michal,
Thank you for the inquiry on preemption and partial risk evaluations. 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
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 18, 2016 2:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: partial RE question

Hi Sven

Section 18 describes the scope of preemption as follows:

> 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).
>
> 18(c)(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

Section 6(b)(4)(D) states

> (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, and, for each designation of a high-priority chemical substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

EPA's partial RE chemicals will result in 6(a) rules – but will never have been subjected to section 6(b)(4)(D), nor met its requirements when EPA was first initiating the partial-REs. Is there an argument (even a tenuous one) to be made that the partial RE chemicals would not be subjected to preemption because section 18 was clearly referring to chemicals that EPA studies in the FUTURE, not chemicals it has already studied but not yet regulated?

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: 5/21/2016 6:56:47 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Jackson, Ryan (Inhofe) [Ryan_Jackson@inhofe.senate.gov]
Subject: HOLD Re: Sen. Inhofe TSCA TA on 10 work plan chemicals

Dimitri - apologies. We just spotted something in our TA. Will send something shortly. Thanks,
Sven

On May 21, 2016, at 2:26 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

Dimitri,
This TA responds to the request on the 10 workplan chemicals issue.

The nature of the changes depends on what you are trying to achieve.

If the intent is simply that only 10 identified work plan chemicals be exempted from pause preemption then no change to the 5/20 HLC draft is needed. Section 6(b)(2)(A) (page 40 line 24) currently provides that EPA shall conduct risk evaluations on "at least 10 chemical substances." Section 18(b)(1) (page 129 lines 22-23 of that draft) exempts the "first 10 chemical substances so identified" from the pause. The intersection of those two provisions is exactly 10 chemicals. EPA may identify more, but only 10 are exempt from the pause.

If, however, the intention is to limit the number of chemical substances EPA may identify to only 10, as well as to ensure that the exclusion from pause preemption applies to only 10 chemicals, then changes to both section (6)(b)(2)(A) and section 18(b)(1) are needed. The words "at least" should be stricken from line 24 of page 40 in section 6(b)(2)(A) and replaced by another word, such as "exactly" or "precisely". Alternatively, "at least" could be stricken and the phrase ", and no more than 10," could be added after the "10" that is currently there so it would read "conducted on 10, and no more than 10, chemical substances". If a change like that is made, then section 18(b)(1) should be changed as well since the reference to the "first 10" no longer makes sense, as EPA clearly is not authorized to identify any number other than 10. The simplest change would be to strike the word "first" so section 18(b)(1) would exclude from pause preemption the "10 chemical substances so identified".

Please let me know if any additional questions. Thanks,

Sven

On May 21, 2016, at 1:09 PM, Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven,

We wanted to reach out directly on this since it is such an important part of the bipartisan/bicameral deal we reached this week. Our goal is to ensure that both sides get exactly what was negotiated and as you can imagine we all are concerned about unintended consequences.

What we would like is your thoughts on how best to ensure that the first ten, but only the first ten chemicals epa reviews are exempted from the work place.

I know some language has been floating around on changes in both section 6 and 18 - do you all believe in order to ensure that only ten chemicals are exempted from pause the change in 6 is necessary?

Any help or suggestions would be much appreciated.

Thanks

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/21/2016 6:31:29 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Jackson, Ryan (Inhofe) [Ryan_Jackson@inhofe.senate.gov]
Subject: Re: Sen. Inhofe TSCA TA on 10 work plan chemicals

Dimitri,
Glad to help - please let me know if any other questions. Thanks,
Sven

On May 21, 2016, at 2:30 PM, Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov> wrote:

Thanks Sven - appreciate the help on the weekend.

From: Kaiser, Sven-Erik
Sent: Saturday, May 21, 2016 2:26 PM
To: Karakitsos, Dimitri (EPW)
Cc: Jackson, Ryan (Inhofe)
Subject: Sen. Inhofe TSCA TA on 10 work plan chemicals

Dimitri,
This TA responds to the request on the 10 workplan chemicals issue.

The nature of the changes depends on what you are trying to achieve.

If the intent is simply that only 10 identified work plan chemicals be exempted from pause preemption then no change to the 5/20 HLC draft is needed. Section 6(b)(2)(A) (page 40 line 24) currently provides that EPA shall conduct risk evaluations on "at least 10 chemical substances." Section 18(b)(1) (page 129 lines 22-23 of that draft) exempts the "first 10 chemical substances so identified" from the pause. The intersection of those two provisions is exactly 10 chemicals. EPA may identify more, but only 10 are exempt from the pause.

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Please let me know if any additional questions. Thanks,

Sven

On May 21, 2016, at 1:09 PM, Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov> wrote:

Sven,

We wanted to reach out directly on this since it is such an important part of the bipartisan/bicameral deal we reached this week. Our goal is to ensure that both sides get exactly what was negotiated and as you can imagine we all are concerned about unintended consequences.

What we would like is your thoughts on how best to ensure that the first ten, but only the first ten chemicals epa reviews are exempted from the work place.

I know some language has been floating around on changes in both section 6 and 18 - do you all believe in order to ensure that only ten chemicals are exempted from pause the change in 6 is necessary?

Any help or suggestions would be much appreciated.

Thanks

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/19/2016 9:14:03 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on section 5 prioritization and restrictions
Attachments: Markey.TSCA TA.Section 5 - prioritization and restrictions.docx

Michal,
Attached is TA responding to your questions on section 5 of the Senate bill on: 1) prioritization, and 2) restrictions. We are working on the remaining section 5 question on scope of preemption. 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. 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 technical assistance is provided by EPA 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.

1. There is a provision in Senate Section 5 (below) that seems to say "EPA can use its prioritization and/or section 6 authority even after taking action under section 5". I don't see where this was ever really a question. Can you comment on whether this language solves a real problem or concern?

(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 (e); or

(2) new information regarding the chemical substance.

EPA Response: Without this provision, it is already clear that EPA can prioritize an existing chemical substance (previously reviewed under the new chemicals program) under § 4A where there is both new information and an NOC. Similarly, it is already reasonably clear that EPA should not be prioritizing a new chemical substance (previously reviewed under the new chemicals program) under § 4A where there is neither new information nor any NOC. Section 4A is generally directed at prioritizing existing chemical substances. § 4A(a)(1).

In the scenario where EPA receives an NOC for a chemical substance, but no other new information, this provision clarifies that EPA is allowed to prioritize the chemical substance under § 4A, even though EPA hasn't received any other new information that wasn't considered when EPA reviewed the chemical under the "likely to meet," standard. The introduction of this clarification into § 5(f) was probably unnecessary. The § 5(d) "likely to meet," standard is distinct from a prioritization for the full § 6 safety determination and there does not appear to be any obstacle built into § 4A that would otherwise preclude the prioritization of a substance that completed review under § 5(d).

However, in the scenario where EPA receives new information about a chemical after the new chemical review period has lapsed, but before EPA receives an NOC for the chemical, this provision seems to provide that EPA is allowed to prioritize the chemical substance under § 4A. This would not be clear without § 5(f), since § 4A(a)(1) generally refers to "existing" chemical substances and the chemical in question would be a new chemical, since there has been no NOC.

If the drafters ultimately decide to delete § 5(f), it will be important to clearly state the grounds for the deletion in the legislative history, to avoid unintentional signaling that Congress is repudiating a principle for which § 5(f) is merely superfluous. Specifically: the principle that EPA is allowed to prioritize a chemical substance under § 4A, previously reviewed under § 5(d), after the new chemical becomes an existing chemical (following the submission of an NOC)

This technical assistance is provided by EPA 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.

2. Senate section 5 lists the types of restrictions EPA can take in response to a determination that a new chemical needs to be restricted (below). In EPA's view, does it require such specificity in order to take any of these measures? I know the list is derived from the Section 6 analogue, but the basis for my question is that EPA has been imposing restrictions under Section 5 without this list for some time.

C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—
(i) subject to section 18(g), 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 minimum warnings and instructions to be prescribed by the Administrator;
(ii) a requirement that manufacturers or processors of the chemical substance—
(I) make and retain records of the processes used to manufacture or process 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 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;
(III) any method of disposal of the chemical substance; or
(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—
(I) in general; or
(II) for a particular use.

EPA Response: EPA does not require a statutory litany of inclusions, beyond the authority already conferred in §5(d)(4)(A) to "prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal" of a chemical substance, in order to implement § 5(d)(4). The inclusions at § 5(d)(4)(C) could actually be construed as a subset of the § 5(d)(4)(A) authority, and thus could actually be construed as *narrowing* EPA's authority through their presence.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/21/2016 4:01:56 PM
To: Michal_Freedhoff@markey.senate.gov; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]
Subject: Fwd: Technicals EPA Comments
Attachments: Senate Technicals (5.20) - EPA comments.docx; ATT00001.htm

Michal,
Please see EPA comments on your technicals doc. Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: May 20, 2016 at 10:18:20 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>, "Distefano, Nichole" <DiStefano.Nichole@epa.gov>
Subject: FW: Technicals.docx

Pls take a look and let me know if there are any issues.

Thx

m

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

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202-224-2742

Connect with Senator Markey

Technical Edits - Senate

1) Conform section 5(f) with modification that was made in section 5(e) by making the following changes
   - Before Page 30 line 22 – in the matter following section 5(f)(2)(C) of *current TSCA*, insert "and a person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, only in compliance with the final rule" after "and apply with respect to such rule"
   - Before Page 31 line 12 – at the end of section 5(f)(3)(A)(i) of *current TSCA*, insert ", and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, only in compliance with the order" after "finding was made under paragraph (1)".

Commented [A1]: This should logically be "proposed", since section 5(f) creates authority for EPA to issue an immediately effective proposed rule.

2) Conforming change to reflect that low-hazard substances are a subset of low-priority substances
   - Pg 38 Line 7, strike "except as provided in clause (iii)"

3) Conforming change to reflect intent of first 10 workplan chemical pause preemption exemption
   - On page 40, line 24, strike "at least"
   - On page 129, lines 21-23, strike ", such chemical substance that has been identified under section 6(b)(2)(A) (except for the first 10 chemical substances so identified),"

4) Conforming change with intent to ensure there is a way for manufacturers to request risk evaluations on PBTs. The date in base text would not allow for this because there would be no risk evaluation or fee rule in place at that time.
   - Pg 62, Line 1, strike "date of enactment of the Frank R Lautenberg Chemical Safety for the 21st Century Act" and insert "Administrator publishes a rule under section 6(b)(4)(B)".

5) Conform savings clause in Confidential Information to agreed-upon intent

- On page 107 line 4, insert a period after "information" and delete the rest of the paragraph. AND

- Make ONE of the following two sets of changes to restore the intent:
  a) page 109 line 3 delete "and"
  b) page 109 line 6 delete the period, and insert "; and (9) shall be subject to the condition that nothing in this Act that nothing in this Act prohibits the disclosure of any information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or state law.

  OR

  a) page 96 line 13 delete "or"
  b) page 96 line 22 delete the period, add "; or"

Commented [A2]: Note that there is a logic to the way the bill is written, without these edits. Section 14(a) protects information from disclosure only by the Administrator, so it should not prevent disclosure, at least by other parties, pursuant to subpoena or court order (or for any other reason). The placement of the provision to that effect in 14(d)(5) w respect to health professionals was presumably intended to provide that the *confidentiality agreement* (not section 14 generally) would not prevent disclosure.

Commented [A3]: This is probably the better approach if this change is to be made, because it is a global statement about the Act, rather than a statement about subsection (a). See comment on that below.

c) page 96 line 23 insert "(C) any information through discovery subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law."

Commented [A4]: This would provide that section 14(a) does not prohibit disclosure in this circumstance. As stated above, it would not anyway, but saying so explicitly might be taken to mean that 14(a) does not prohibit disclosure by the Administrator under these circumstances but might by other parties.

6) Technical clarification to ensure both subsections that apply to the information under the provision are named.

- Page 109 lines 11 and 12 – strike "described in subsection (a)" and replace with "subject to subsections (a) and (c)"

Commented [A5]: "Subject to" is potentially problematic. *All* information submitted to EPA is subject to these subsections. Do you mean "that meets the requirements of subsections (a) and (c)"?

7) Technical edit to clarify that non-confidential information about a chemical whose identity is non-public is made public and associated with the unique identifier for the chemical

- Page 122 line 4 – after "unique identifier" insert "and is made public"

8) Conforms to section 18(a) and 18(b)(1) insertions of "criminal penalty" that were requested by the House

- Page 130 line 12, after "statute enacted," insert "criminal penalty,"

9) Edit to conform text to section 18(a)(1)(A)

- Page 130 Line 16, should read "4, 5, or 6"

10) Technical correction for language on scope of preemption.

- On p. 130, strike lines 17 – 21, and insert "(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"
- On page 130 line 22, strike "(3)" and insert "(4)"

11) Conforming change to reflect that low-hazard is a subset of low-priority (which itself is judicially reviewable)

- Page 143 line 19, delete "or (iii)"

12) Conforming change to ensure that citizen suits are held to the same standard as actions taken by EPA (raises Constitutional issues if not done)

- Page 173 delete lines 4-7 and replace with "(iii) in clause (ii), by striking "section 6 or 8" and all that follows through the end of the clause and inserting "section 6(a) or 8 or an order under section 5(f), the chemical substance or mixture to be subject to such rule or order presents or will present 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, under the conditions of use"

Commented [A6]: We agree with this change. Note that, per our earlier TA, confusion will be created by the fact that section 5(f) order are also referenced on p 173 line 3, as subject to judicial action based on a finding of "may present". Section 5(f) should have only one standard for judicial action, and consistent with section 5, it should be in clause (ii), which operates on a "presents or will present" standard. This issue can be addressed by striking " or 5(f)" on p 173. Note the current language creates a potential constitutional issue with respect to 5(f) that is analogous to the issue we have discussed with respect to section 6, by empowering a citizen to force action under a lower standard than EPA's standard for action.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/19/2016 7:14:41 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Prioritizing TA requests

Michal – we're doing our TSCA TA planning for today and the weekend. On sect 5 we are working on:

- section 5 scope of preemption – 2/8@1:10pm
- section 5 restrictions - 2/9@9:42am
- section 5 prioritization – 2/9@10:02am

Please let me know as soon as possible if you expect any additional TA requests for the weekend so we can prioritize workload. Thanks,
Sven

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202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/19/2016 6:14:38 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - more on section 4, SEnate 4(a)

Michal,
This responds to your TSCA section 4(a) TA request.

1) Senate 4(a)(1)(D) "allows for testing at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority". Does EPA view "regulatory testing needs" as the agency/office needs to be considering regulation? Going back to the example of the WVA spill, when clearly EPA would not have been thinking about listing that chemical for regulation under SDWA, does EPA believe it still could have requested testing?

EPA Response: Senate 4(a)(1)(D) "allows for testing at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority." This doesn't mean that the requesting authority needs to have already initiated rulemaking proceedings before they can request a test. We think "regulatory testing needs," represent a broader concept than that. They would include any information about the chemical substance that would help the requesting authority to later exercise (or decide whether to exercise) its legal powers to manage risks relating to that chemical substance. Thus, in the case of a chemical spill, any EPA office thinking about using one of its non-TSCA legal authorities to address the spill, and needing more information for that purpose, could use section 4(a)(1)(D).

2) Has EPA ever required TSCA testing outside a regulatory need? For example, if EPA wanted to do some testing to assist researchers, public health officials or local communities or to inform product stewardship/decisions, I'm assuming it really couldn't do so under Senate section 4, and could only do so if it could meet the risk finding in House section 4 (or one of the other criteria in TSCA 4(a). Has it ever required testing that falls into these categories?

EPA Response: Again, EPA understands "regulatory testing needs," broadly. EPA has not used TSCA to require chemical testing that was unnecessary for any regulatory purpose. Risk-relevant chemical information sought by researchers, public health officials, local communities, and product stewardship authorities would very plausibly also be within the scope of the regulatory testing needs of a variety of authorities implementing non-TSCA Federal law. If there was indeed a request from such an authority, EPA could use its testing authority under Senate 4(a)(1)(D). EPA could also use its testing authority under Senate 4(a)(2) if it wanted to decide whether or not the chemical that was the subject of such outside interest was a high or low priority chemical substance under TSCA. Under the House bill, with respect to the chemical of outside interest, EPA would need to make a "may present" an unreasonable risk finding, a substantial exposure/release finding, or have met the standard for commencing a risk evaluation (also "may present" an unreasonable risk) in order to require testing.

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. Thanks,
Sven

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From: Freedhoff, Michal (Markey)
Sent: Tuesday, February 16, 2016 4:39 PM
To: Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)
Subject: TA request - more on section 4, SEnate 4(a)

Sven – some additional follow ups for you guys on section 4.

1) Senate 4(a)(1)(D) "allows for testing at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority". Does EPA view "regulatory testing needs" as the agency/office needs to be considering regulation? Going back to the example of the WVA spill, when clearly EPA would not have been thinking about listing that chemical for regulation under SDWA, does EPA believe it still could have requested testing?
2) Has EPA ever required TSCA testing outside a regulatory need? For example, if EPA wanted to do some testing to assist researchers, public health officials or local communities or to inform product stewardship/decisions, I'm assuming it really couldn't do so under Senate section 4, and could only do so if it could meet the risk finding in House section 4 (or one of the other criteria in TSCA 4(a). Has it ever required testing that falls into these categories?

Thanks
Michal

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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: 5/11/2016 2:23:55 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: HEC Min TSCA TA request on section 18 preemption (Senate 5-9)
Attachments: Boxer 18.pdf

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

Sven-Erik Kaiser

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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
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202-225-4407

[DISCUSSION DRAFT]

1 **SEC. ___. STATE-FEDERAL RELATIONSHIP.**

2 Section 18 of the Toxic Substances Control Act (15
3 U.S.C. 2617) is amended—

4 (1) by amending subsection (a) to read as fol-
5 lows:

6 "(a) IN GENERAL.—

7 "(1) ESTABLISHMENT OR ENFORCEMENT.—Ex-
8 cept as otherwise provided in subsections (c), (d),
9 (e), (f), and (g), and subject to paragraph (2), no
10 State or political subdivision of a State may estab-
11 lish or continue to enforce any of the following:

12 "(A) DEVELOPMENT OF INFORMATION.—A
13 statute or administrative action to require the
14 development of information about a chemical
15 substance or category of chemical substances
16 that is reasonably likely to produce the same in-
17 formation required under section 4, 5, or 6 in—

18 "(i) a rule promulgated by the Admin-
19 istrator;

20 "(ii) a consent agreement entered into
21 by the Administrator; or

"(iii) an order issued by the Administrator.

"(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) 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 re-

1 quired notification pursuant to a rule promul-
2 gated under section 5.
3 "(2) EFFECTIVE DATE OF PREEMPTION.—
4 Under this subsection, Federal preemption of stat-
5 utes and administrative actions applicable to specific
6 chemical substances shall not occur until the effec-
7 tive date of the applicable action described in para-
8 graph (1) taken by the Administrator.";
9 (2) by amending subsection (b) to read as fol-
10 lows:
11 "(b) NEW STATUTES, CRIMINAL PENALTIES, OR AD-
12 MINISTRATIVE ACTIONS CREATING PROHIBITIONS OR
13 OTHER RESTRICTIONS.—
14 "(1) IN GENERAL.—Except as provided in sub-
15 sections (c), (d), (e), (f), and (g), beginning on the
16 date on which the Administrator defines the scope of
17 a risk evaluation for a chemical substance under sec-
18 tion 6(b)(4)(D) and ending on the date on which the
19 deadline established pursuant to section 6(b)(4)(G)
20 for completion of the risk evaluation expires, or on
21 the date on which the Administrator publishes the
22 risk evaluation under section 6(b)(4)(C), whichever
23 is earlier, no State or political subdivision of a State
24 may establish a statute, criminal penalty, or admin-
25 istrative action prohibiting or otherwise restricting

1 the manufacture, processing, distribution in com-
2 merce, or use of such chemical substance that is a
3 high-priority substance designated under
4 6(b)(1)(B)(i), such chemical substance that has been
5 identified under section 6(b)(2)(A), or such chemical
6 substance that has been selected for risk evaluation
7 under section 6(b)(4)(E)(iii)(II).

8 "(2) EFFECT OF SUBSECTION.—

9 "(A) IN GENERAL.—This subsection does
10 not restrict the authority of a State or political
11 subdivision of a State to continue to enforce
12 any statute enacted, or administrative action
13 taken, prior to the date on which the Adminis-
14 trator defines and publishes the scope of a risk
15 evaluation under section 6(b)(4)(D).

16 "(B) LIMITATION.—Subparagraph (A)
17 does not allow a State or political subdivision of
18 a State to enforce any new prohibition or re-
19 striction under a statute or administrative ac-
20 tion described in that subparagraph, if the pro-
21 hibition or restriction is established after the
22 date described in that subparagraph."; and

23 (3) by adding at the end the following:

24 "(c) SCOPE OF PREEMPTION.—Federal preemption
25 under subsections (a) and (b) of statutes, criminal pen-

1 alties, and administrative actions applicable to specific
2 chemical substances shall apply only to—
3 "(1) with respect to subsection (a)(1)(A), the
4 chemical substances or category of chemical sub-
5 stances subject to a rule, order, or consent agree-
6 ment under section 4;
7 "(2) with respect to subsections (a)(1)(B) and
8 (b), the hazards, exposures, risks, and uses or condi-
9 tions of use of such chemical substances that are
10 identified by the Administrator as subject to review
11 in a risk evaluation and included in the scope of the
12 risk evaluation published by the Administrator for
13 the chemical substance under section 6(b)(4)(D), or
14 of any rule the Administrator promulgates pursuant
15 to section 6(c); or
16 "(3) with respect to subsection (a)(1)(C), the
17 uses of such chemical substances that the Adminis-
18 trator has specified as significant new uses and for
19 which the Administrator has required notification
20 pursuant to a rule promulgated under section 5.
21 "(d) EXCEPTIONS.—
22 "(1) NO PREEMPTION OF STATUTES AND AD-
23 MINISTRATIVE ACTIONS.—
24 "(A) IN GENERAL.—Nothing in this Act,
25 nor any amendment made by the Frank R.

1 Lautenberg Chemical Safety for the 21st Cen-
2 tury Act, nor any rule, standard of perform-
3 ance, risk evaluation, or scientific assessment
4 implemented pursuant to this Act, shall affect
5 the right of a State or a political subdivision of
6 a State to adopt or enforce any rule, standard
7 of performance, risk evaluation, scientific as-
8 sessment, or any other protection for public
9 health or the environment that—
10 "(i) is adopted or authorized under
11 the authority of any other Federal law or
12 adopted to satisfy or obtain authorization
13 or approval under any other Federal law;
14 "(ii) implements a reporting, moni-
15 toring, or other information obligation for
16 the chemical substance not otherwise re-
17 quired by the Administrator under this Act
18 or required under any other Federal law;
19 "(iii) is adopted pursuant to authority
20 under a law of the State or political sub-
21 division of the State related to water qual-
22 ity, air quality, or waste treatment or dis-
23 posal, except to the extent that the ac-
24 tion—

1 "(I) imposes a restriction on the
2 manufacture, processing, distribution
3 in commerce, or use of a chemical
4 substance; and
5 "(II)(aa) addresses the same haz-
6 ards and exposures, with respect to
7 the same conditions of use as are in-
8 cluded in the scope of the risk evalua-
9 tion published pursuant to section
10 6(b)(4)(D), but is inconsistent with
11 the action of the Administrator; or
12 "(bb) would cause a violation of
13 the applicable action by the Adminis-
14 trator under section 5 or 6; or
15 "(iv) subject to subparagraph (B), is
16 identical to a requirement prescribed by
17 the Administrator.
18 "(B) IDENTICAL REQUIREMENTS.—
19 "(i) IN GENERAL.—The penalties and
20 other sanctions applicable under a law of a
21 State or political subdivision of a State in
22 the event of noncompliance with the iden-
23 tical requirement shall be no more strin-
24 gent than the penalties and other sanctions

available to the Administrator under section 16 of this Act.

"(ii) PENALTIES.—In the case of an identical requirement—

"(I) a State or political subdivision of a State may not assess a penalty for a specific violation for which the Administrator has assessed an adequate penalty under section 16; and

"(II) if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.

"(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—

1 "(A) Nothing in this section shall be con-
2 strued as modifying the preemptive effect under
3 this section, as in effect on the day before the
4 effective date of the Frank R. Lautenberg
5 Chemical Safety for the 21st Century Act, of
6 any rule or order promulgated or issued under
7 this Act prior to that effective date.
8 "(B) With respect to a chemical substance
9 or mixture for which any rule or order was pro-
10 mulgated or issued under section 6 prior to the
11 effective date of the Frank R. Lautenberg
12 Chemical Safety for the 21st Century Act with
13 regards to manufacturing, processing, distribu-
14 tion in commerce, use, or disposal of a chemical
15 substance or mixture, this section (as in effect
16 on the day before the effective date of the
17 Frank R. Lautenberg Chemical Safety for the
18 21st Century Act) shall govern the preemptive
19 effect of any rule or order that is promulgated
20 or issued respecting such chemical substance or
21 mixture under section 6 of this Act after that
22 effective date, unless the latter rule or order is
23 with respect to a chemical substance or mixture
24 containing a chemical substance and follows a
25 designation of that chemical substance as a

1 high-priority substance under section
2 6(b)(1)(B)(i), the identification of that chemical
3 substance under section 6(b)(2)(A), or the se-
4 lection of that chemical substance for risk eval-
5 uation under section 6(b)(4)(E)(iii)(II).
6 "(e) PRESERVATION OF CERTAIN LAWS.—
7 "(1) IN GENERAL.—Nothing in this Act, sub-
8 ject to subsection (g) of this section, shall—
9 "(A) be construed to preempt or otherwise
10 affect the authority of a State or political sub-
11 division of a State to continue to enforce any
12 action taken or requirement imposed or require-
13 ment enacted relating to a specific chemical
14 substance before April 22, 2016, under the au-
15 thority of a law of the State or political subdivi-
16 sion of the State that prohibits or otherwise re-
17 stricts manufacturing, processing, distribution
18 in commerce, use, or disposal of a chemical sub-
19 stance; or
20 "(B) be construed to preempt or otherwise
21 affect any action taken pursuant to a State law
22 that was in effect on August 31, 2003.
23 "(2) EFFECT OF SUBSECTION.—This sub-
24 section does not affect, modify, or alter the relation-
25 ship between Federal law and laws of a State or po-

1 litical subdivision of a State pursuant to any other
2 Federal law.
3 "(f) WAIVERS.—
4 "(1) DISCRETIONARY EXEMPTIONS.—Upon ap-
5 plication of a State or political subdivision of a
6 State, the Administrator may, by rule, exempt from
7 subsection (a), under such conditions as may be pre-
8 scribed in the rule, a statute, criminal penalty, or
9 administrative action of that State or political sub-
10 division of the State that relates to the effects of, or
11 exposure to, a chemical substance under the condi-
12 tions of use if the Administrator determines that—
13 "(A) compelling conditions warrant grant-
14 ing the waiver to protect health or the environ-
15 ment;
16 "(B) compliance with the proposed require-
17 ment of the State or political subdivision of the
18 State would not unduly burden interstate com-
19 merce in the manufacture, processing, distribu-
20 tion in commerce, or use of a chemical sub-
21 stance;
22 "(C) compliance with the proposed require-
23 ment of the State or political subdivision of the
24 State would not cause a violation of any appli-
25 cable Federal law, rule, or order; and

1 "(D) in the judgment of the Adminis-
2 trator, the proposed requirement of the State or
3 political subdivision of the State is designed to
4 address a risk of a chemical substance, under
5 the conditions of use, that was identified—
6 "(i) consistent with the best available
7 science;
8 "(ii) using supporting studies con-
9 ducted in accordance with sound and ob-
10 jective scientific practices; and
11 "(iii) based on the weight of the sci-
12 entific evidence.
13 "(2) REQUIRED EXEMPTIONS.—Upon applica-
14 tion of a State or political subdivision of a State, the
15 Administrator shall exempt from subsection (b) a
16 statute, criminal penalty, or administrative action of
17 a State or political subdivision of a State that re-
18 lates to the effects of exposure to a chemical sub-
19 stance under the conditions of use if the Adminis-
20 trator determines that—
21 "(A)(i) compliance with the proposed re-
22 quirement of the State or political subdivision
23 of the State would not unduly burden interstate
24 commerce in the manufacture, processing, dis-

1 tribution in commerce, or use of a chemical
2 substance;
3 "(ii) compliance with the proposed require-
4 ment of the State or political subdivision of the
5 State would not cause a violation of any appli-
6 cable Federal law, rule, or order; and
7 "(iii) the State or political subdivision of
8 the State has a concern about the chemical sub-
9 stance or use of the chemical substance based
10 in peer-reviewed science; or
11 "(B) no later than 18 months after the
12 date on which the Administrator has initiated
13 the prioritization process for a chemical sub-
14 stance under section 6(b)(3)(A)(i), or the date
15 on which the Administrator publishes the scope
16 of the risk evaluation under section 6(b)(4)(D),
17 whichever is sooner, the State or political sub-
18 division of the State has enacted a statute, es-
19 tablished a criminal penalty, or proposed or fi-
20 nalized an administrative action intended to
21 prohibit or otherwise restrict the manufacture,
22 processing, distribution in commerce, or use of
23 the chemical substance.
24 "(3) DETERMINATION OF A WAIVER RE-
25 QUEST.—The duty of the Administrator to grant or

1 deny a waiver application shall be nondelegable and
2 shall be exercised—
3 "(A) not later than 180 days after the date
4 on which an application under paragraph (1) is
5 submitted; and
6 "(B) not later than 110 days after the
7 date on which an application under paragraph
8 (2) is submitted.
9 "(4) FAILURE TO MAKE A DETERMINATION.—
10 If the Administrator fails to make a determination
11 under paragraph (3)(B) during the 110-day period
12 beginning on the date on which an application under
13 paragraph (2) is submitted, the statute, criminal
14 penalty, or administrative action of the State or po-
15 litical subdivision of the State that was the subject
16 of the application shall not be considered to be an
17 existing statute, criminal penalty, or administrative
18 action for purposes of subsection (b) by reason of
19 the failure of the Administrator to make a deter-
20 mination.
21 "(5) NOTICE AND COMMENT.—Except in the
22 case of an application approved under paragraph
23 (9), the application of a State or political subdivision
24 of a State under this subsection shall be subject to
25 public notice and comment.

1 "(6) FINAL AGENCY ACTION.—The decision of
2 the Administrator on the application of a State or
3 political subdivision of a State shall be—
4 "(A) considered to be a final agency ac-
5 tion; and
6 "(B) subject to judicial review.
7 "(7) DURATION OF WAIVERS.—A waiver grant-
8 ed under paragraph (2) or approved under para-
9 graph (9) shall remain in effect until such time as
10 the Administrator publishes the risk evaluation
11 under section 6(b).
12 "(8) JUDICIAL REVIEW OF WAIVERS.—Not later
13 than 60 days after the date on which the Adminis-
14 trator makes a determination on an application of a
15 State or political subdivision of a State under para-
16 graph (1) or (2), any person may file a petition for
17 judicial review in the United States Court of Appeals
18 for the District of Columbia Circuit, which shall
19 have exclusive jurisdiction over the determination.
20 "(9) APPROVAL.—
21 "(A) AUTOMATIC APPROVAL.—If the Ad-
22 ministrator fails to meet the deadline estab-
23 lished under paragraph (3)(B), the application
24 of a State or political subdivision of a State
25 under paragraph (2) shall be automatically ap-

1 proved, effective on the date that is 10 days
2 after the deadline.
3 "(B) REQUIREMENTS.—Notwithstanding
4 paragraph (6), approval of a waiver application
5 under subparagraph (A) for failure to meet the
6 deadline under paragraph (3)(B) shall not be
7 considered final agency action or be subject to
8 judicial review or public notice and comment.
9 "(g) SAVINGS.—
10 "(1) NO PREEMPTION OF COMMON LAW OR
11 STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF
12 OR CRIMINAL CONDUCT.—
13 "(A) IN GENERAL.—Nothing in this Act,
14 nor any amendment made by the Frank R.
15 Lautenberg Chemical Safety for the 21st Cen-
16 tury Act, nor any standard, rule, requirement,
17 standard of performance, risk evaluation, or sci-
18 entific assessment implemented pursuant to this
19 Act, shall be construed to preempt, displace, or
20 supplant any State or Federal common law
21 rights or any State or Federal statute creating
22 a remedy for civil relief, including those for civil
23 damage, or a penalty for a criminal conduct.
24 "(B) CLARIFICATION OF NO PREEMP-
25 TION.—Notwithstanding any other provision of

1 this Act, nothing in this Act, nor any amend-
2 ments made by the Frank R. Lautenberg
3 Chemical Safety for the 21st Century Act, shall
4 preempt or preclude any cause of action for
5 personal injury, wrongful death, property dam-
6 age, or other injury based on negligence, strict
7 liability, products liability, failure to warn, or
8 any other legal theory of liability under any
9 State law, maritime law, or Federal common
10 law or statutory theory.
11 "(2) NO EFFECT ON PRIVATE REMEDIES.—
12 "(A) IN GENERAL.—Nothing in this Act,
13 nor any amendments made by the Frank R.
14 Lautenberg Chemical Safety for the 21st Cen-
15 tury Act, nor any rules, regulations, require-
16 ments, risk evaluations, scientific assessments,
17 or orders issued pursuant to this Act shall be
18 interpreted as, in either the plaintiff's or de-
19 fendant's favor, dispositive in any civil action.
20 "(B) AUTHORITY OF COURTS.—This Act
21 does not affect the authority of any court to
22 make a determination in an adjudicatory pro-
23 ceeding under applicable State or Federal law
24 with respect to the admission into evidence or
25 any other use of this Act or rules, regulations,

1 requirements, standards of performance, risk
2 evaluations, scientific assessments, or orders
3 issued pursuant to this Act.".

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<section id="HAE19ACC9A3A144989F67D713392B8F75"><enum>__.</enum><header>State-Federal relationship</header><text display-inline="no-display-inline">Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amendedâ€"</text>
<paragraph id="H4F8D9144398C452F89BC2A3EE54142F3"><enum>(1)</enum><text>by amending subsection (a) to read as follows:</text>
<quoted-block display-inline="no-display-inline" id="H093A8892A67A411B9991508417139551" style="OLC">
<subsection id="HF155D411C5C54DB3B03237EF4355D48B"><enum>(a)</enum><header>In general</header>
<paragraph id="H91EB328EA9FE4D239138C6A8039AEB38"><enum>(1)</enum><header>Establishment or enforcement</header><text display-inline="yes-display-inline">Except as otherwise

provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:</text>
<subparagraph id="HD992AED6EB254F1C8C00FE7731975A65"><enum>(A)</enum><header>Development of information</header><text display-inline="yes-display-inline">A statute or administrative action to require the development of information about a chemical substance or category of chemical substances that is reasonably likely to produce the same information required under section 4, 5, or 6 inâ€"</text>
<clause id="H7C36857CE65F4AACAD159EA719E254D2"><enum>(i)</enum><text>a rule promulgated by the Administrator;</text> </clause>
<clause id="HC2375EDCB99A464E9CE9451735FEFF5A"><enum>(ii)</enum><text>a consent agreement entered into by the Administrator; or</text> </clause>
<clause id="H23A97DC78D1C40B6ADAC149C9CCF3493"><enum>(iii)</enum><text>an order issued by the Administrator.</text> </clause></subparagraph>
<subparagraph id="HCE79C3A98F954EC1B4A1110932B7C969"><enum>(B)</enum><header>Chemical substances found not to present an unreasonable risk or restricted</header><text display-inline="yes-display-inline">A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substanceâ€"</text>
<clause id="H7D04526B9687467FA55D1673FCFE2E47"><enum>(i)</enum><text display-inline="yes-display-inline">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</text> </clause>
<clause id="H7866F1BEE9D1434A9BA825EFFADD9C46"><enum>(ii)</enum><text display-inline="yes-display-inline">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).</text> </clause></subparagraph>
<subparagraph id="H00C32D459B1545ADA92FF5BDE7247959"><enum>(C)</enum><header>Significant new use</header><text>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.</text> </subparagraph></paragraph>
<paragraph id="HFB03EEC59FF64FC397782E4378CCA5A3"><enum>(2)</enum><header>Effective date of preemption</header><text display-inline="yes-display-inline">Under this subsection, Federal preemption of statutes and administrative actions applicable to specific chemical substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.</text>
</paragraph></subsection> <after-quoted-block>;</after-quoted-block></quoted-block></paragraph>
<paragraph id="H3C392DA943584739A571900842C0C447"><enum>(2)</enum><text>by amending subsection (b) to read as follows:</text>
<quoted-block style="OLC" id="HD977ED6AC1204821BFD6A8556ED8CD75" display-inline="no-display-inline">
<subsection id="H364A8EAD5FE74F9FA4E04FB132BAB443" commented="no"><enum>(b)</enum><header>New statutes, criminal penalties, or

administrative actions creating prohibitions or other restrictions</header>
<paragraph id="HF314E6ECBD0B45F39580E0D1E6E47255"><enum>(1)</enum><header>In general</header><text>Except as provided in subsections (c), (d), (e), (f), and (g), beginning on the date on which the Administrator defines the scope of a risk evaluation for a chemical substance under section 6(b)(4)(D) and ending on the date on which the deadline established pursuant to section 6(b)(4)(G) for completion of the risk evaluation expires, or on the date on which the Administrator publishes the risk evaluation under section 6(b)(4)(C), whichever is earlier, no State or political subdivision of a State may establish a statute, criminal penalty, or administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce, or use of such chemical substance that is a high-priority substance designated under 6(b)(1)(B)(i), such chemical substance that has been identified under section 6(b)(2)(A), or such chemical substance that has been selected for risk evaluation under section 6(b)(4)(E)(iii)(II).</text></paragraph>
<paragraph id="HAEE78CE80802477DB2FE94D664EED581"><enum>(2)</enum><header>Effect of subsection</header>
<subparagraph id="H792C0A6A2FFA464495FBE5E4A6C0A813"><enum>(A)</enum><header>In general</header><text display-inline="yes-display-inline">This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any statute enacted, or administrative action taken, prior to the date on which the Administrator defines and publishes the scope of a risk evaluation under section 6(b)(4)(D).</text></subparagraph>
<subparagraph id="H36DB6EDF90834E919A1D23AC1EA49DFA"><enum>(B)</enum><header>Limitation</header><text display-inline="yes-display-inline">Subparagraph (A) does not allow a State or political subdivision of a State to enforce any new prohibition or restriction under a statute or administrative action described in that subparagraph, if the prohibition or restriction is established after the date described in that subparagraph.</text>
</subparagraph></paragraph></subsection><after-quoted-block>; and</after-quoted-block></quoted-block></paragraph>
<paragraph id="HCF9548B947F5445E98BE9EDA3D94074B"><enum>(3)</enum><text>by adding at the end the following:</text>
<quoted-block style="OLC" id="HDF226A4A79CB4A568E3E448A09F7FE36" display-inline="no-display-inline">
<subsection id="H43A841DD26E04F24BD374FFB4E30DA13"><enum>(c)</enum><header>Scope of preemption</header><text display-inline="yes-display-inline">Federal preemption under subsections (a) and (b) of statutes, criminal penalties, and administrative actions applicable to specific chemical substances shall apply only toâ€"</text>
<paragraph id="H67D49713D932451B8F9DAC14054BEBD2"><enum>(1)</enum><text display-inline="yes-display-inline">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;</text> </paragraph>
<paragraph id="H90457C27ECAE4300A1A598BA512CB669"><enum>(2)</enum><text display-inline="yes-display-inline">with respect to subsections (a)(1)(B) and (b), the hazards, exposures, risks, and uses or conditions of use of such chemical 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); or</text> </paragraph>
<paragraph id="H7051AE1745524E3A95FB32A9EE5B736B"><enum>(3)</enum><text display-inline="yes-display-inline">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.</text> </paragraph></subsection>
<subsection id="H3F6C16F41661424A838D9B2406D8E647"><enum>(d)</enum><header>Exceptions</header>
<paragraph id="H1782D6187E2B4295861317C760313A54"><enum>(1)</enum><header>No preemption of statutes and administrative actions</header>
<subparagraph id="H4143FD0C7907488CA77ED26B83A2D64F"><enum>(A)</enum><header>In general</header><text display-inline="yes-display-inline">Nothing in this Act, nor any amendment made by the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>, nor any rule, standard of performance, risk evaluation, 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 rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment thatâ€"</text>
<clause id="H6F685586C3954B7C9E4C4C9497E23039"><enum>(i)</enum><text>is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;</text> </clause>
<clause id="H7FDC26FC606645A3B881AB2AB6FF1E18"><enum>(ii)</enum><text>implements a reporting, monitoring, or other information obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law;</text> </clause>
<clause id="H8458470B05E54D81B461DA04EFE71903"><enum>(iii)</enum><text>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, except to the extent that the actionâ€"</text>
<subclause id="H21FCE66D787A4219B271458DDABAEB67"><enum>(I)</enum><text>imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and</text> </subclause>
<subclause id="H1C3C63F0278E440B8362FECAFD72A57A"><enum>(II)</enum>
<item commented="no" display-inline="yes-display-inline" id="HF009D686CBEF405DB6D33FBFC95DE74F"><enum>(aa)</enum><text display-inline="yes-display-inline">addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the risk evaluation published pursuant to section 6(b)(4)(D), but is inconsistent with the action of the Administrator; or</text> </item>
<item id="H928234C0BD5A447BB181E98C09D3B43E" indent="up1"><enum>(bb)</enum><text>would cause a violation of the applicable action by the Administrator under section 5 or 6; or</text> </item></subclause></clause>
<clause id="H2600B696B88F4A79BD62A93CB4B45576"><enum>(iv)</enum><text>subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.</text> </clause></subparagraph>
<subparagraph id="HABF5D58B9EF04F7E944DDE9A2549C577"><enum>(B)</enum><header>Identical requirements</header>
<clause id="HC51237055B5C4283A02474DD642DC3E2"><enum>(i)</enum><header>In

general</header><text>The penalties and other sanctions applicable under a law of a State or political subdivision of a State in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.</text> </clause>
<clause id="HDEF32626852E4021BB9989F9FFC5AFFC"><enum>(ii)</enum><header>Penalties</header><text>In the case of an identical requirementâ€"</text>
<subclause id="H82B7BAFCDD1D4F2982EBD47BDDBAFAE6"><enum>(I)</enum><text>a State or political subdivision of a State may not assess a penalty for a specific violation for which the Administrator has assessed an adequate penalty under section 16; and</text>
</subclause>
<subclause id="HD5BD9AE604B04465B2D6F063EB799708"><enum>(II)</enum><text>if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.</text>
</subclause></clause></subparagraph></paragraph>
<paragraph id="H445D1324C24D4FE0AF117CA8563D35D3"><enum>(2)</enum><header>Applicability to certain rules or orders</header>
<subparagraph id="H376D703DEF3A4ED2922AE2C2EC01D4F0"><enum>(A)</enum><text>Nothing in this section shall be construed as modifying the preemptive effect under this section, as in effect on the day before the effective date of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>, of any rule or order promulgated or issued under this Act prior to that effective date.</text>
</subparagraph>
<subparagraph id="HFF11FE1FEE904CE1A1228FB2FD979447"><enum>(B)</enum><text display-inline="yes-display-inline">With respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title> with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, this section (as in effect on the day before the effective date of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>) 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 that effective date, unless the latter 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 6(b)(1)(B)(i), the identification of that chemical substance under section 6(b)(2)(A), or the selection of that chemical substance for risk evaluation under section 6(b)(4)(E)(iii)(II).</text> </subparagraph></paragraph></subsection>
<subsection id="HA3A885AA477F4AD59E04CB5F6734F3AF"><enum>(e)</enum><header>Preservation of certain laws</header>
<paragraph id="H6B30F48A3F8C4FAF95BD1B4FC2BE1A13"><enum>(1)</enum><header>In general</header><text>Nothing in this Act, subject to subsection (g) of this section, shallâ€"</text>
<subparagraph id="H0C7BE620623B451298F152B5EF2FAE56"><enum>(A)</enum><text display-inline="yes-display-inline">be construed to preempt or otherwise affect the authority

of a State or political subdivision of a State to continue to enforce any action taken or requirement imposed or requirement enacted relating to a specific chemical substance before April 22, 2016, under the authority of a law of the State or political subdivision of the State that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or</text> </subparagraph>
<subparagraph id="HEBF80C613D954EE8B1EA4A6A06590CB5"><enum>(B)</enum><text>be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.</text> </subparagraph></paragraph>
<paragraph id="H5B1B19162DB5494DB4663D992AFA5307"><enum>(2)</enum><header>Effect of subsection</header><text>This subsection does not affect, modify, or alter the relationship between Federal law and laws of a State or political subdivision of a State pursuant to any other Federal law.</text></paragraph></subsection>
<subsection id="HC37C84004D424E20B6C64459BC5440EB"><enum>(f)</enum><header>Waivers</header>
<paragraph id="H3A1A3DF480744E1EA4E634EA4151F0FD"><enum>(1)</enum><header>Discretionary exemptions</header><text display-inline="yes-display-inline">Upon application of a State or political subdivision of a State, the Administrator may, by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute, criminal penalty, or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines thatâ€"</text>
<subparagraph id="H031823748BE646F7B2F139B5C44116D0"><enum>(A)</enum><text>compelling conditions warrant granting the waiver to protect health or the environment;</text></subparagraph>
<subparagraph id="H95206158FDC14348B18B5D547DCD89A2"><enum>(B)</enum><text>compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;</text></subparagraph>
<subparagraph id="HE8C6EF5AC632444DA09F065BEE7B4EA4"><enum>(C)</enum><text>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</text></subparagraph>
<subparagraph id="HAE40AF3C63BE45889E4215AC789A4C07"><enum>(D)</enum><text>in the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is designed to address a risk of a chemical substance, under the conditions of use, that was identifiedâ€"</text>
<clause id="H83CDD516E66A4A39924E2A87D1BC4030"><enum>(i)</enum><text>consistent with the best available science;</text></clause>
<clause id="HA11E39A50B1A45EC81B4CD52AA1D9EA4"><enum>(ii)</enum><text>using supporting studies conducted in accordance with sound and objective scientific practices; and</text></clause>
<clause id="H71F3AC4DBECD4EB39113012B46A944B3"><enum>(iii)</enum><text>based on the weight of the scientific evidence.</text></clause></subparagraph></paragraph>
<paragraph id="H1ED9599391BA40019D846D2655D665CC"><enum>(2)</enum><header>Required exemptions</header><text display-inline="yes-display-inline">Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute, criminal penalty, 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 conditions of use if the Administrator determines thatâ€"</text>
<subparagraph id="HE8CAEC2468A4450F87E1536BF310B2AF"><enum>(A)</enum>
<clause id="H322C629B49654BB8A60FEE502648915A" display-inline="yes-display-inline"><enum>(i)</enum><text>compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;</text></clause>
<clause id="H5B679C602648445AAF3599D37DA27FB7" indent="up1"><enum>(ii)</enum><text>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</text></clause>
<clause id="H121941E1959A4F9C9A4A34748E23C477" indent="up1"><enum>(iii)</enum><text>the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or</text></clause></subparagraph>
<subparagraph id="HA5802CFADB314FFD8154332ED59D2A7D"><enum>(B)</enum><text display-inline="yes-display-inline">no later than 18 months after the date on which the Administrator has initiated the prioritization process for a chemical substance under section 6(b)(3)(A)(i), or the date on which the Administrator publishes the scope of the risk evaluation under section 6(b)(4)(D), whichever is sooner, the State or political subdivision of the State has enacted a statute, established a criminal penalty, or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance.</text></subparagraph> </paragraph>
<paragraph id="HBC2B58E1975242079E8F5238602265EF"><enum>(3)</enum><header>Determination of a waiver request</header><text display-inline="yes-display-inline">The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercisedâ€"</text>
<subparagraph id="H6BC8793D6BD34EE482A4D0872A3EA682"><enum>(A)</enum><text>not later than 180 days after the date on which an application under paragraph (1) is submitted; and</text></subparagraph>
<subparagraph id="H36313B623FC44489ABB63149AF7BA0B7"><enum>(B)</enum><text>not later than 110 days after the date on which an application under paragraph (2) is submitted.</text></subparagraph></paragraph>
<paragraph id="H740A6685F1394476B81D0A3FD248A1C2"><enum>(4)</enum><header>Failure to make a determination</header><text display-inline="yes-display-inline">If the Administrator fails to make a determination under paragraph (3)(B) during the 110-day period beginning on the date on which an application under paragraph (2) is submitted, the statute, criminal penalty, or administrative action of the State or political subdivision of the State that was the subject of the application shall not be considered to be an existing statute, criminal penalty, or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.</text></paragraph>
<paragraph id="H23385BD407284278A2617C8E79A47C95"><enum>(5)</enum><header>Notice and comment</header><text display-inline="yes-display-inline">Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of a State under this subsection shall be subject to public notice and

comment.</text></paragraph>
<paragraph id="HA671C4B694DA40A09E2C3E9D12C7AFFA"><enum>(6)</enum><header>Final agency action</header><text>The decision of the Administrator on the application of a State or political subdivision of a State shall beâ€"</text>
<subparagraph id="H5CC7D9F364F644BC912B42EA24FDAC74"><enum>(A)</enum><text>considered to be a final agency action; and</text></subparagraph>
<subparagraph id="HABC11374BCF244F290FAE6978D570B5E"><enum>(B)</enum><text>subject to judicial review. </text></subparagraph></paragraph>
<paragraph id="H7208ED08C36A45A79EDC81D08B5B5763"><enum>(7)</enum><header>Duration of waivers</header><text display-inline="yes-display-inline">A waiver granted under paragraph (2) or approved under paragraph (9) shall remain in effect until such time as the Administrator publishes the risk evaluation under section 6(b).</text></paragraph>
<paragraph id="H50FC199CCEA74D69B1B2D2DEEF2ADF3C"><enum>(8)</enum><header>Judicial review of waivers</header><text>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 a State under paragraph (1) or (2), 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.</text></paragraph>
<paragraph
id="H82D38CFAD4C3474790F232F4C5D5C40F"><enum>(9)</enum><header>Approval</header>
<subparagraph id="H8AC58E1FCB2C415BBB6F30C73B92E132"><enum>(A)</enum><header>Automatic approval</header><text>If the Administrator fails to meet the deadline established under paragraph (3)(B), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved, effective on the date that is 10 days after the deadline.</text></subparagraph>
<subparagraph
id="HC407A15647204D2881BC34AD77A7FD57"><enum>(B)</enum><header>Requirements</header><text>Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadline under paragraph (3)(B) shall not be considered final agency action or be subject to judicial review or public notice and comment.</text> </subparagraph></paragraph></subsection>
<subsection
id="H23082B4ACEB34481AAA6B426F6D74DEF"><enum>(g)</enum><header>Savings</header>
<paragraph id="HBEC81FFBC8DD412EA273C510B0120328"><enum>(1)</enum><header>No preemption of common law or statutory causes of action for civil relief or criminal conduct</header>
<subparagraph id="H290869BE7F824AE8BB05F009E23F14D0"><enum>(A)</enum><header>In general</header><text>Nothing in this Act, nor any amendment made by the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>, nor any standard, rule, requirement, standard of performance, risk evaluation, 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.</text> </subparagraph>
<subparagraph commented="no"
id="HA6CA4BCA9BB949F3B39827F2A0490152"><enum>(B)</enum><header>Clarification of no preemption</header><text>Notwithstanding any other provision of this Act, nothing in

this Act, nor any amendments made by the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>, 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 law, maritime law, or Federal common law or statutory theory.</text> </subparagraph></paragraph>
<paragraph id="H0F0C6475D8204CA98A50B01941620270"><enum>(2)</enum><header>No effect on private remedies</header>
<subparagraph id="H7960BD73D400464BB177AD62FE5E8FD4"><enum>(A)</enum><header>In general</header><text display-inline="yes-display-inline">Nothing in this Act, nor any amendments made by the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>, nor any rules, regulations, requirements, risk evaluations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiffâ€™s or defendantâ€™s favor, dispositive in any civil action.</text> </subparagraph>
<subparagraph id="H5D4D839014D6454282B5D59E2AB3E9CA"><enum>(B)</enum><header>Authority of courts</header><text display-inline="yes-display-inline">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, risk evaluations, scientific assessments, or orders issued pursuant to this Act.</text></subparagraph></paragraph></subsection><after-quoted-block>.</after-quoted-block></quoted-block> </paragraph></section>
</legis-body>
</bill>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/10/2016 12:04:28 AM
To: McCarthy, David [David.McCarthy@mail.house.gov]
Subject: HEC TSCA TA Request on section 5 injunction process

Dave,
This TA responds to the request on the section 5 injunction process.

The Senate 5.9 command is to strike the House 5.6 command to strike the injunction process...which would effectively keep the injunction process.

Seems like an error, given the Senate's explanatory comment – "Deleting current law injunction process because it is not necessary."

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 9, 2016, at 6:41 PM, McCarthy, David <David.McCarthy@mail.house.gov> wrote:

Sven – Doesn't our current draft delete the section 5 injunction process? We have a confusing suggestion from the senate on section 5. They want to strike page 29 line 18 through page 30 line 8 "to delete current law injunction process because it is not necessary." But we think our bill does eliminate the current law injunction process. Thanks for your help. D

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, May 05, 2016 5:43 PM
To: McCarthy, David; Cohen, Jacqueline
Subject: HEC TSCA TA Request on narrative questions on implementation (HLC 5-4)

Dave and Jackie,
This TA responds to the questions about the implementation of HLC (5-4).

Just want to confirm with you that, as you see it whole, you think it's language that you can implement.

Response: EPA confirms that it has not identified any major technical issues in the language that would prevent implementation. The EPA TA provided on the HLC (5-4) version flags a number of issues where clarifying edits could be made to ease implementation.

In particular, will you know how to administer Section 5 as drafted?

Response: Yes, EPA will know how to administer Section 5.

Does it clearly provide that an affirmative action by EPA is needed before a manufacturer may begin manufacturing?

Response: EPA understands the draft to require that, prior to commencement of manufacturing, EPA must (1) review PMN notices, (2) make one of four determinations, and (3) take additional actions associated with those determinations, all within the applicable review period. Inaction by EPA (including a failure to make a determination or take any of the associated actions within the applicable review period) would NOT authorize manufacturing to begin.

Is that decision risk-based?

Response: The affirmative determination required under Section 5(a) before a manufacturer may begin manufacturing would be risk-based.

In Section 6 will EPA be able to implement the prioritization provision?

Response: Yes, with the important changes made to the "low priority" category in Section 6(b)(1)(B), EPA now believes it will be able to implement the prioritization provisions.

Are EPA's choices clear at the end of the prioritization phase?

Response: The decisions to be made during and at the end of the prioritization process are clear to EPA: the Agency shall designate a chemical as high-priority, low-priority or low hazard. For chemicals designated as high-priority, EPA must initiate a risk evaluation. Upon completion, EPA must designate at least one additional high priority substance. Designations of low-priority or low-hazard can be revised based on new information.

In Section 26, do you understand what your discretion and limitations are in setting, collecting, and using user fees?

Response: Yes, EPA understands the discretion and limitations related to setting, collecting and using fees pursuant to the authorities in Section 26.

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

From: McCarthy, David [mailto:David.McCarthy@mail.house.gov]
Sent: Wednesday, May 04, 2016 11:58 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: confidential please

Dear Sven

Thanks for chatting just now. Later today, we expect to receive a new draft that incorporates changes to the April 22 draft we've discussed over the last couple days. When we send it to you, we think we will be asking questions such as the following: Just want to confirm with you that, as you see it whole, you think it's language that you can implement. In particular, will you know how to administer Section 5 as drafted? Does it clearly provide that an affirmative action by EPA is needed before a manufacturer may begin manufacturing? Is that decision risk-based? ? In Section 6 will EPA be able to implement the prioritization provision? Are EPA's choices clear at the end of the prioritization phase? In Section 26, do you understand what your discretion and limitations are in setting, collecting, and using user fees? As you guys know pretty much what to expect based on your extraordinary help yesterday, just wanted to give you a head-start thinking through these questions. Thanks to you, we are confident that there are no implementation stumbling blocks in the bill. I don't recall significant changes from April 22 to the sections we did not work on yesterday.
Thanks ever so much. Dave

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/20/2016 9:30:42 PM
To: dimitri_karakitsos@epw.senate.gov
Subject: Fwd: Revised Language

Dimitri,
This responds to your questions. Please let me know if any followup. Thanks,
Sven

Q: What "action" is taken in 6(i)(1)? It is not a regulation like 6(a) so I am not sure it is an action.

The "action" in 6(i)(1) is an order determining that a chemical substance does not present an unreasonable risk of injury to health or the environment. The bill explicitly identifies this order as a "final agency action" in 6(i)(1).

Q: In (3) don't we need to restore the "consistent with the scope of the risk evaluation" – the question is if EPA looks at 10 conditions of use, and regulates 5, what happens to the other 5? I think if we take this formulation we need to make sure that everything in the scope gets a determination one way or the other.

We don't think that there is need to restore the "consistent with the scope of the risk evaluation" language. EPA's rule under 6(a) must be "so that the chemical substance or mixture no longer presents such [unreasonable] risk." If EPA's final rule regulates just 5 of 10 uses contained in the scope of the risk evaluation, and doesn't include a determination regarding the remaining 5 uses, EPA would be left with a legally insufficient rule under 6(a). In order to meet its statutory requirements, EPA must make a determination respecting all of the conditions use identified in the scope of the risk evaluation.

From: "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov>
Date: May 20, 2016 at 4:58:03 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: Revised Language

Do these questions make sense to your folks? This is based on the Boxer language request. Need quick turn around please. Thank you and the team Sven

So another question – what "action" is taken in 6(i)(1)? It is not a regulation like 6(a) so I am not sure it is an action.

In (3) don't we need to restore the "consistent with the scope of the risk evaluation" – the question is if EPA looks at 10 conditions of use, and regulates 5, what happens to the other 5? I think if we take this formulation we need to make sure that everything in the scope gets a determination one way or the other.

From: Albritton, Jason (EPW)
Sent: Friday, May 20, 2016 4:34 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW)
Cc: Poirier, Bettina (EPW)
Subject: RE: Revised Language

Yes. That makes sense. Revised version below.

1 "(2) with respect to subsection (b)

2 the hazards, exposures, risks, and uses or condi-

3 tions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D); and

4 "(3) with respect to subsection (a)(1)(B) the hazards, exposures, risks, and uses or conditions of use of such substances included in any final action the Administrator takes pursuant to section 6(a) or 6(i)(1).

From: Jackson, Ryan (Inhofe)
Sent: Friday, May 20, 2016 4:27 PM
To: Albritton, Jason (EPW); Karakitsos, Dimitri (EPW)
Cc: Poirier, Bettina (EPW)
Subject: RE: Revised Language

Do we need the cross reference to the scoping paragraph? I think that should be added in (2) and then we should be good.

From: Albritton, Jason (EPW)
Sent: Friday, May 20, 2016 4:18 PM
To: Karakitsos, Dimitri (EPW)
Cc: Jackson, Ryan (Inhofe); Poirier, Bettina (EPW)
Subject: FW: Revised Language

This is what we came up with after talking to EPA. They have this language and are ok with it. We will call to explain.

1 "(2) with respect to subsection (b)

2 the hazards, exposures, risks, and uses or condi-

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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: 5/9/2016 10:50:20 PM
To: McCarthy, David [David.McCarthy@mail.house.gov]
Subject: Re: HEC TSCA TA Request on narrative questions on implementation (HLC 5-4)

Dave - got it checking. Thanks,
Sven

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Sven – Doesn't our current draft delete the section 5 injunction process? We have a confusing suggestion from the senate on section 5. They want to strike page 29 line 18 through page 30 line 8 "to delete current law injunction process because it is not necessary." But we think our bill does eliminate the current law injunction process. Thanks for your help. D

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To: McCarthy, David; Cohen, Jacqueline
Subject: HEC TSCA TA Request on narrative questions on implementation (HLC 5-4)

Dave and Jackie,
This TA responds to the questions about the implementation of HLC (5-4).

Just want to confirm with you that, as you see it whole, you think it's language that you can implement.

Response: EPA confirms that it has not identified any major technical issues in the language that would prevent implementation. The EPA TA provided on the HLC (5-4) version flags a number of issues where clarifying edits could be made to ease implementation.

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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

From: McCarthy, David [mailto:David.McCarthy@mail.house.gov]
Sent: Wednesday, May 04, 2016 11:58 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: confidential please

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Thanks ever so much. Dave

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/19/2016 1:27:44 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: TA request - more on section 4, SEnate 4(a)

Got it- will speed it up

On Feb 19, 2016, at 5:27 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Hi Sven - could you please accelerate this one? Thanks!

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

From: Freedhoff, Michal (Markey)
Sent: Tuesday, February 16, 2016 4:39 PM
To: Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)
Subject: TA request - more on section 4, SEnate 4(a)

Sven – some additional follow ups for you guys on section 4.

1) Senate 4(a)(1)(D) "allows for testing at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority". Does EPA view "regulatory testing needs" as the agency/office needs to be considering regulation? Going back to the example of the WVA spill, when clearly EPA would not have been thinking about listing that chemical for regulation under SDWA, does EPA believe it still could have requested testing?
2) Has EPA ever required TSCA testing outside a regulatory need? For example, if EPA wanted to do some testing to assist researchers, public health officials or local communities or to inform product stewardship/decisions, I'm assuming it really couldn't do so under Senate section 4, and could only do so if it could meet the risk finding in House section 4 (or one of the other criteria in TSCA 4(a). Has it ever required testing that falls into these categories?

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
<image001.png><image002.png><image003.png><image004.jpg>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/20/2016 8:59:44 PM
To: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: Revised Language

Got it - checking

On May 20, 2016, at 4:58 PM, Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov> wrote:

Do these questions make sense to your folks? This is based on the Boxer language request. Need quick turn around please. Thank you and the team Sven

So another question – what "action" is taken in 6(i)(1)? It is not a regulation like 6(a) so I am not sure it is an action.

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From: Albritton, Jason (EPW)
Sent: Friday, May 20, 2016 4:34 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW)
Cc: Poirier, Bettina (EPW)
Subject: RE: Revised Language

Yes. That makes sense. Revised version below.

1 "(2) with respect to subsection (b)

2 the hazards, exposures, risks, and uses or condi-

3 tions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D); and

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Sent: Friday, May 20, 2016 4:27 PM
To: Albritton, Jason (EPW); Karakitsos, Dimitri (EPW)
Cc: Poirier, Bettina (EPW)
Subject: RE: Revised Language

Do we need the cross reference to the scoping paragraph? I think that should be added in (2) and then we should be good.

From: Albritton, Jason (EPW)
Sent: Friday, May 20, 2016 4:18 PM
To: Karakitsos, Dimitri (EPW)
Cc: Jackson, Ryan (Inhofe); Poirier, Bettina (EPW)
Subject: FW: Revised Language

This is what we came up with after talking to EPA. They have this language and are ok with it. We will call to explain.

1 "(2) with respect to subsection (b)

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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: 5/9/2016 8:49:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on section 5(f)(2)

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: Monday, May 09, 2016 4:46 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick q

Someone just said epa was ok w getting rid of 5(f)(2). True? Or is it that the list of restrictions under 6 that are available to epa that you were ok w striking?

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: 5/9/2016 3:07:14 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: HEC TSCA TA request on section 18 preemption

Jacqueline,
Got it - checking. Timing? 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: 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: 2/18/2016 4:54:01 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on section 4f

Got it - we're discussing now

On Feb 18, 2016, at 11:48 AM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks

I am sure this will come up on the call later, but flag for you now the question -- if you currently consider costs in 4(f) unreasonable risk findings, why would you also be arguing for their exclusion? Is it because they have to be considered as a result of Corrosion Proof Fittings? Did you consider costs when you did the 1984 formaldehyde exemptions?

michal

Does EPA believe that it could decide not to regulate the super dangerous thing because it would be too expensive to do so, or does it believe that "unreasonable risk" is solely risk-based?

> **EPA Response: We believes that an unreasonable risk determination in section 4(f) of current TSCA would factor in costs as well as benefits. Such a determination would not be solely risk-based.**

Do you believe that the exclusion of costs in 4(f) that I sent you in the file yesterday in this section is needed to maintain consistency with the rest of the bill?

> **EPA Response: We believe the exclusion-of-costs language would be important to ensure consistency with the rest of the bill.**

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
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, February 18, 2016 10:16 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 4f

Michal,
Responding to your request, TA on section 4(f) attached. Please let me know if any additional questions.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/20/2016 8:00:20 PM
To: jason_albritton@epw.senate.gov; Bettina_Poirier@epw.senate.gov
Subject: Fwd:
Attachments: section 18 fix.docx; ATT00001.htm

Resend

Begin forwarded message:

From: "Schmit, Ryan" <schmit.ryan@epa.gov>
Date: May 20, 2016 at 3:57:28 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>

Ryan N. Schmit
Special Assistant to Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention (OCSPP)
Telephone: 202-564-0610
Email: schmit.ryan@epa.gov

"(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;

"(2) with respect to subsection (b) the hazards, exposures, risks, and uses or conditions of use of such chemical substances consistent with the scope of the risk evaluation; and

"(3) with respect to subsection (a)(1)(B) the hazards, exposures, risks, and uses or conditions of use of such substances consistent with the scope of any rule the Administrator promulgates pursuant to section 6(a)

"(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.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/18/2016 4:23:00 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request - House section 6(b)

Michal – apologies for the misunderstanding. We'll relook at the question. 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, February 18, 2016 11:21 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request - House section 6(b)

This isn't exactly what I was asking I don't think, and I'm sorry for not providing more context.

House 6(b) allows EPA to initiate a risk evaluation only if it first makes an unreasonable risk finding. But it does not require such a finding to be made for workplan chemicals, which presumably is to enable EPA to move more quickly to start risk evaluations on workplan chemicals, and also recognizes that by their inclusion on the workplan in the first place, there probably is some concern about the chemical already.

My question is if one retained a House 6(b) requirement that EPA make an unreasonable risk finding in order to initiate a risk evaluation on a substance while also deleting the automatic authority for EPA to initiate risk evaluations on workplan chemicals, does there exist a substance currently on the workplan on which EPA believes such a finding could **not** be made absent additional testing?

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

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, February 18, 2016 10:39 AM

To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request - House section 6(b)

Michal,
This responds to your TA request on House section 6(b). We issued a data needs assessment for the brominated phthalates flame retardant cluster fo this reason. We expect there will be other examples going forward.

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)" <Michal_Freedhoff@markey.senate.gov>

Date: February 13, 2016 at 9:50:09 AM EST
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - House section 6(b)

Sven

Are there any workplan chemicals that could not meet the 6(b) risk finding without additional testing/information? I know House 6 does not require it to be made for workplan chemicals - I'm just asking because alternative formulations that do require it to be made are being discussed.

Thanks

Michal

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: 5/9/2016 1:43:01 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Booker TSCA TA Request on voluntary testing

Adam,
This TA responds to the request on voluntary testing.

The language you suggested below looks fine to EPA.

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

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Sunday, May 08, 2016 8:01 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: TSCA TA on Senate edits to HLC 5.6

Hello Sven!

For the Page 18, Line 6 EPA suggestion of adding back language related to the Voluntary Testing provision, would the following language achieve what EPA is hoping to achieve:

"This paragraph shall authorize, but does not require, the Administrator to review the basis upon which a person conducted testing described in subparagraph (A)." ?

I would suggest this language be added at the end of (3)(B) so the entire section would then read as below:

"(3) Voluntary testing.—
"(A) In general.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing.

"(B) Effect of paragraph.—Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator. In addition, this paragraph shall authorize, but does not require, the Administrator to review the basis upon which a person conducted testing described in subparagraph (A).
"(C) Relationship to other law.—A violation of this paragraph shall not be a prohibited act under section 15."

From: Black, Jonathan (Tom Udall)
Sent: Sunday, May 8, 2016 2:00 PM
To: Zipkin, Adam (Booker)
Subject: Fw: TSCA TA on Senate edits to HLC 5.6

Epa has another suggestion.

Buzz me when available on cell.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Sent: Sunday, May 8, 2016 11:10 AM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall)
Subject: TSCA TA on Senate edits to HLC 5.6

Michal and Jonathan,
The attached TA responds to the request on the senate edits to HLC 5-6. Section 5 coming separately.

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/20/2016 7:57:55 PM
To: jason_albritton@epw.senate.gov; Bettina_Poirier@epw.senate.gov
Subject: Fwd:
Attachments: section 18 fix.docx; ATT00001.htm

Begin forwarded message:

From: "Schmit, Ryan" <schmit.ryan@epa.gov>
Date: May 20, 2016 at 3:57:28 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>

Ryan N. Schmit
Special Assistant to Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention (OCSPP)
Telephone: 202-564-0610
Email: schmit.ryan@epa.gov

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/9/2016 1:37:31 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 5(e) "unreasonable risk"

Michal,
This responds to the TA request on 5(e).

We believe it is important to have a standard in (e). Although "such risk" doesn't work, "ensure no unreasonable risk" (or some formulation along those lines) does work.

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: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, May 08, 2016 11:47 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: One thing for quick turn around

The question we were talking about on section 5 that Jim said he'd like more time to think about -

Replacing "such risk" in e with "an unreasonable risk" as qualified by our usual string (no costs, etc).

You mentioned a potential concern that "an unreasonable risk" could be hard to quantify when the order was being issues esp for insufficient information or a wide exposure/unknown hazard situation.

Can we get your quick take on this? Is there harm in including language like this?

Thx
M

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: 5/9/2016 12:12:29 AM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: TSCA TA on Senate edits to HLC 5.6

Adam- got it - checking. Thanks,
Sven

On May 8, 2016, at 8:01 PM, Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov> wrote:

Hello Sven!

For the Page 18, Line 6 EPA suggestion of adding back language related to the Voluntary Testing provision, would the following language achieve what EPA is hoping to achieve:

"This paragraph shall authorize, but does not require, the Administrator to review the basis upon which a person conducted testing described in subparagraph (A)." ?

I would suggest this language be added at the end of (3)(B) so the entire section would then read as below:

"(3) Voluntary testing.—
"(A) In general.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing.
"(B) Effect of paragraph.—Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator. In addition, this paragraph shall authorize, but does not require, the Administrator to review the basis upon which a person conducted testing described in subparagraph (A).
"(C) Relationship to other law.—A violation of this paragraph shall not be a prohibited act under section 15."

From: Black, Jonathan (Tom Udall)
Sent: Sunday, May 8, 2016 2:00 PM
To: Zipkin, Adam (Booker)
Subject: Fw: TSCA TA on Senate edits to HLC 5.6

Epa has another suggestion.

Buzz me when available on cell.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Sent: Sunday, May 8, 2016 11:10 AM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall)

Subject: TSCA TA on Senate edits to HLC 5.6

Michal and Jonathan,
The attached TA responds to the request on the senate edits to HLC 5-6. Section 5 coming separately.

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/18/2016 3:15:52 PM
To: Michal Freedhoff [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on section 4f
Attachments: Section 4(f) TA Feb 18, final.docx; ATT00001.htm

Michal,
Responding to your request, TA on section 4(f) attached. Please let me know if any additional questions.

Section 4(f) says "if EPA thinks something is super dangerous, regulate it quickly or tell everyone why there is no unreasonable risk".

Does EPA believe that it could decide not to regulate the super dangerous thing because it would be too expensive to do so, or does it believe that "unreasonable risk" is solely risk-based?

> **EPA Response: We believes that an unreasonable risk determination in section 4(f) of current TSCA would factor in costs as well as benefits. Such a determination would not be solely risk-based.**

Do you believe that the exclusion of costs in 4(f) that I sent you in the file yesterday in this section is needed to maintain consistency with the rest of the bill?

> **EPA Response: We believe the exclusion-of-costs language would be important to ensure consistency with the rest of the bill.**

Do you believe that, if we exclude costs as drafted in the document sent yesterday, that EPA would still be required to consider costs when developing regulatory action? If not ,how would EPA draft 4)f(that1 (does not remove the words "unreasonable risk" and substitute another standard and 2) ensures that costs are considered as appropriate when regulating, but not when deciding WHETHER to regulate.

> **EPA Response: We believe that EPA would be required to consider costs when developing regulatory action to the extent cost consideration is required by section 5, 6 or 7 as modified by the Senate bill, even if cost is eliminated as a consideration under section 4(f). In fact, we believe the elimination of cost considerations from the unreasonable risk judgment in section 4(f) would be consistent with the usage of "unreasonable risk" in sections 5, 6 and 7. As we interpret those sections, and the definition of the safety standard in section 3, cost is not a factor in judgments about whether a risk is unreasonable. EPA must nonetheless consider cost in its risk management decisions. For example, under section 6, EPA would to consider cost and other factors in determining the most appropriate restrictions to eliminate any unreasonable risk, but the determination of whether any remaining risk is unreasonable would be made without regard to cost. In addition, under section 6, EPA could consider cost in deciding whether to issue exemptions under section 6(d)(5).**

We note that sections 5 and 6 in S bill now require an affirmative finding on the part of EPA. Would one solution be to end the sentence in4)f)(2 (after "5,6 or 7" and then go to "For good cause"?

> **EPA Response: Per the answer to the question above, we do not see a problem with the drafting that needs to be solved. And we believe implementation issues could be created by dropping the text you suggest from section 4(f). Without that text, EPA would be required to take action under section 5, 6 or 7 for every chemical for which information "*indicates* to the Administrator that there *may be a reasonable***

***basis* to conclude that [the] chemical substance or mixture presents or will present a *significant* risk of serious or widespread harm to human beings" (emphasis added). This finding is a tentative one, and the standard – significant risk – is different from "unreasonable risk". Thus, it is not clear that every chemical for which this tentative finding was made would be determined to warrant action under section 5, 6 or 7 upon more comprehensive review.**

More generally, has this provision ever been used and when?

EPA Response: EPA used this provision in 1984 for formaldehyde.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/27/2016 1:46:26 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on section 6 - PCBs

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: Friday, May 27, 2016 9:39 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: quick (I hope) PCB question

Are EPA's PCB disposal regulations under 6(e) or 6(a)(6)? If the former, was there any reference to (a)(6) in the (e) regulations?

Ty – would also be interested in any edits to the table of enviro votes you might have time to provide now that we have a bit more time (unfortunately).

m

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: 5/8/2016 7:44:11 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Revised TSCA TA on section 21 (SEPW edits to HLC 5-6)
Attachments: SEPW.TSCA TA.section 21 (SEPW edits to HLC 5-6).docx

Michal,
Revised TA attached on section 21. The TA includes suggested specific language to address section 4, 5(e) and 6(a) issues. The attachment is just pp.123-126 (the page numbers might not be completely consistent with the original document) from the SEPW edits to HLC 5-6 with TA in comment bubbles.

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

19 SEC. 16. CITIZENS' PETITIONS.

20 Section 21(b)(4) of the Toxic Substances Control Act
21 (15 U.S.C. 2620(b)(4)) is amended by striking subpara-
22 graph (B) and inserting the following:

23 "(B) DE NOVO PROCEEDING.—

24 "(i) IN GENERAL.—In an action under
25 subparagraph (A) respecting a petition to ini-

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.

1 tiate a proceeding to issue a rule under section
2 4, 5, 6, or 8 or issue an order under section 4
3 or 5(e) or (f), the petitioner shall be provided
4 an opportunity to have the petition considered
5 by the court in a de novo proceeding.
6 "(ii) DEMONSTRATION.—
7 "(I) IN GENERAL.—The court in a de
8 novo proceeding under this subparagraph
9 shall order the Administrator to initiate
10 the action requested by the petitioner if
11 the petitioner demonstrates to the satisfac-
12 tion of the court by a preponderance of the
13 evidence that—
14 "(aa) in the case of a petition to
15 initiate a proceeding for the issuance
16 of a rule or order under section 4, the
17 information is needed for a purpose
18 identified in section 4(a);
19 "(bb) in the case of a petition to
20 issue an order under section 5(f), the
21 chemical substance may present an
22 unreasonable risk in accordance with
23 section 5(a)(3)(A) ø*clause (i) covers*
24 *rules under section 5 and orders under*
25 *section 5(e) and (f), but this only*

Commented [A1]: Section 21(a) does not currently provide for petitions for section 5 rules, and there is no judicial review standard below for section 5 rules. We are not sure what you intend to subject to petitions, since you have stricken the House conforming changes to sec 21(a) and not substituted anything, but we will assume you did not mean to strike HEC changes to 21(a), which would mean that petitionable actions include rules under 4, 6, and 8, and orders under 4 and 5e and f.

Commented [A2]: Now that the "old" section 4(a) basis for testing has been restored, this new text, which aligns with the "new" basis, does not provide a very good basis for judicial review of denial of a petition based on the old basis. We also note that the bill does not address judicial review of section 5(e) order petitiondenials. Under TSCA, those are handled in the same provision as section 4 rules, since both are premised on inadequate information. A solution to both issues would be to divide judicial action on test petitions here into two subclauses – (aa) and (bb) – and add 5(e), as follows (with cc and dd redesignated accordingly):

1 "(aa) in the case of a petition to
2 initiate a proceeding for the issuance
3 of a rule under section 4(a)(1) or an
order under section 5(e), information
available to the Administrator is
insufficient to permit a reasoned
evaluation of the health and
environmental effects of the chemical
substance to be subject to such rule or
order; and, in the absence of such
information, the substance may
present an unreasonable risk to health
or the environment, or the substance is
or will be produced in substantial
quantities and it enters or may
reasonably be anticipated to enter the
environment in substantial quantities
or there is or may be significant or
substantial human exposure;
4 "(bb) in the case of a petition to
5 initiate a proceeding for the issuance
6 of a rule or order under section
4(a)(2), the
7 information is needed for a purpose
8 identified in such section;

Commented [A3]: The finding under 5(a)(3)(A) is presents, not may present, and section 5(f) requires (f) orders based on a presents finding, so the formulation here is incorrect.

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.

1 *speaks of orders under 5(e). Is that in-*
2 *tentional?¿*;
3 "(cc) in the case of a petition to
4 initiate a proceeding for the issuance
5 of a rule under section 6(a), the
6 chemical substance presents an unrea-
7 sonable risk in accordance with sec-
8 tion 6(b)(4)(A); or
9 "(dd) in the case of a petition to
10 initiate a proceeding for the issuance
11 of a rule under section 8, there is a
12 reasonable basis to conclude that the
13 rule is necessary to protect health or
14 the environment or ensure that the
15 chemical substance does not present
16 an unreasonable risk of injury to
17 health or the environment, as deter-
18 mined without consideration of costs
19 or other nonrisk factors, under the
20 conditions of use, including an unrea-
21 sonable risk to a potentially exposed
22 or susceptible subpopulation identified
23 by the Administrator.
24 "(II) DEFERMENT.—The court in a
25 de novo proceeding under this subpara-

Commented [A4]: Consistent with comments on sections 5 and 9, this does not conform with the section 6(a) standard.

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.

1 graph may permit the Administrator to
2 defer initiating the action requested by the
3 petitioner until such time as the court pre-
4 scribes, if the court finds that—
5 "(aa) the extent of the risk to
6 health or the environment alleged by
7 the petitioner is less than the extent
8 of risks to health or the environment
9 with respect to which the Adminis-
10 trator is taking action under this Act;
11 and
12 "(bb) there are insufficient re-
13 sources available to the Administrator
14 to take the action requested by the
15 petitioner.".

Commented [A5]: Consistent with the revisions to section 6 – in particular, the addition of the prioritization scheme and the mandatory risk evaluation and management provisions – we suggest adding a version of this language into (cc) above (section 6(a) rules). This would address the fact that, unlike current TSCA, section 6 now has mandatory throughput provisions, and section 6 rule petitions under section 21 have the potential to create obligations on EPA that compete with the priorities established through the prioritization process. Ie, if a citizen is able to show, under cc, that a chemical substance presents unreasonable risk, a court would be directed to order EPA to initiate rulemaking on that substance, even if it is a lower priority than other substances. A court could permit EPA to defer action on such a rulemaking under the highlighted provision here ((II)(aa)), but neither a court nor EPA would be able to deny a petition on that basis. This could be addressed by inserting the following at the end of (cc): "and the extent of the risk is greater than the risk presented by other chemical substances that at that time are subject to risk evaluation under section 6(b) or rulemaking under section 6(a)". This provision in (cc) would not be duplicative of (II)(aa), because (II)(aa) would apply to petitions for actions other than 6(a) rules.

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.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/19/2016 4:22:17 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: FYI

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: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, May 19, 2016 12:08 PM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>; Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Harding, Stephenne S. EOP/CEQ <Stephenne_S_Harding@ceq.eop.gov>; Billingsley, Tara <Tara_L_Billingsley@who.eop.gov>
Cc: Wallace, Andrew (Tom Udall) <Andrew_Wallace@tomudall.senate.gov>
Subject: FYI

This is what has gone back to House:

1. Preemption -- Remove first ten chemicals of the TSCA Work Plan Chemicals from Priority Pause.

The current draft specifies that Work Plan chemicals identified in 6(b)(2)(A) are subject to the priority pause in section 18(b). We could provide that the first ten work plan chemicals would not be subject to 18(b) pause.

2. Testing – Order authority. Add language back to the section authorizing testing by order of chemicals that may present an unreasonable risk.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/17/2016 6:53:57 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Scheduling

Ok – will pass along to the crew

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 17, 2016 1:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Scheduling

Thx. Def prioritize the section 4s, followed by 5 and then 6. Hoping we are close to getting you a new version of 4 to look at.

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

From: Kaiser, Sven-Erik
Sent: Wednesday, February 17, 2016 1:52 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Scheduling

Ok – still on for Thurs at 4:30pm. Will push on 4(f). Please let me know if anything comes up. Best, Sven

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 17, 2016 1:50 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Unreasonable risk q

Ok sorry. 4:30 again works. But the 4(f) TA would still be good.

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

From: Kaiser, Sven-Erik
Sent: Wednesday, February 17, 2016 1:49 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Unreasonable risk q

checking

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, February 17, 2016 1:49 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Unreasonable risk q

We continue to have scheduling questions about tomorrow. Do you have Friday timeslots? And could you get the 4(f) unreasonable risk TA previously requested back soon, esp if we aren't going to be able to schedule the call for tomorrow?
Thanks

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: 5/8/2016 3:50:52 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: TSCA TA on Senate edits to HLC 5.6

Got it - checking- nice day for a game (hope you can enjoy it).

On May 8, 2016, at 11:46 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

I have one question on the PBT language change - apologies if I am reading your comments wrong but I'm at a kid's soccer game and don't have all my materials with me, and I won't get home until after you guys all go offline. We made that edit because there would be no manufacturer-requested RES 90 days after enactment because there would be no RE rule, no fee rule, etc. If I'm remembering that edit correctly, we thought it basically precluded the avenue from being used at all.

All clarifications welcome
M

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

From: Kaiser, Sven-Erik
Sent: Sunday, May 8, 2016 11:11 AM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall)
Subject: TSCA TA on Senate edits to HLC 5.6

Michal and Jonathan,
The attached TA responds to the request on the senate edits to HLC 5-6. Section 5 coming separately.

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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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 3:41:17 PM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov
Subject: TSCA TA on senate edits on section 5 of HLC 5-6
Attachments: EPA TA on 5.7 Senate Edits to Section 5.doc; ATT00001.htm

Michal and Jonathan,
The attached TA responds to the request on the senate edits to HLC 5-6. This is just section 5.

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

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202-566-2753

TSCA 5 - HLC 5-6 with Senate proposed additions

TSCA as amended by ~~BARRY 2.0~~HLC 5-6-16

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

(a) IN GENERAL.—(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may—

(i~~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

(ii~~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.~~,~~

(B) A person may take the actions described in subparagraph (A) if—

(i) ~~unless~~ such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b), (e) or (f), and

(ii) the Administrator—

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), (C), or (D) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(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) REVIEW AND DETERMINATION.—Within the applicable review period under paragraph (1), subject to section 18, the Administrator shall review such notice and determine—

(A) that the relevant chemical substance or significant new use presents ~~or will present~~ 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 by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; ~~and~~or

Commented [A1]: (D) has been stricken.

Commented [A2]: This is a change from HLC that was not highlighted. This addition creates an issue, because the applicable review period is not exclusively under (1); it is defined more broadly in (i). We have not independently compared this document to the HEC document to catch un-highlighted changes.

Commented [A3]: EPA notes that this change would result in section 5 no longer conforming with the standard in 6(a). .

Commented [A4]: As we interpret it, this change would require a 5(e) order based on insufficient info alone.

(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, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; 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,

in which case the Administrator shall take the actions required under subsection (e); ~~or~~

(C) that a determination under subsection (a)(3)(A) or (a)(3)(B) is not warranted, in which case subsection (g) shall apply~~that the relevant chemical substance or significant new use is likely not to present 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 by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use; or~~

~~(D) that the relevant chemical substance is a low-hazard~~ substance, in which case the submitter of the notice may ~~commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use.~~

(4) FAILURE TO RENDER DETERMINATION.—

(A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1), and the Administrator shall not be relieved of any requirement to make such determination.

(B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review.

(ii) A failure of the Administrator to render a decision shall not be considered a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) ARTICLE CONSIDERATION.—The Administrator may require 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)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure

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to the chemical substance through the article or category of articles subject to the rule justifies notification.

(5) ARTICLE CONSIDERATION.—In promulgating a rule under paragraph (2), the Administrator may consider whether there is likely potential for exposure to a chemical substance through an article or category of articles, and if the Administrator finds such a likely potential, the Administrator shall require notification under this section for the import or processing of a chemical substance as part of an article or category of articles.

(b) SUBMISSION OF INFORMATION~~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 information ~~test data~~ for such substance pursuant to a rule, order or consent agreement ~~promulgated~~ under section 4 before the submission of such notice, such person shall submit to the Administrator such information ~~data~~ in accordance with such rule, order or consent agreement 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 ~~or order 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 required date of ~~the~~ submission ~~in accordance with such rule~~ of the information ~~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)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(A~~B~~)(ii).

(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, order or consent agreement ~~promulgated~~ under section 4 before the submission of such notice to submit information ~~test data~~ for such substance,

such person may ~~shall~~ submit to the Administrator information ~~data~~ prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information ~~Data~~ submitted pursuant to subparagraph (A) shall be information ~~data~~ which the person submitting the information ~~data~~ believes shows that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A)(i), 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)(A~~B~~)(ii), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

Commented [A5]: This is another change from HLC that was not highlighted. This creates an issue. The purpose of section 5(b)(1)(B) of TSCA, as we understand it, is to ensure that the review period does not begin to run until information required by section 4 has been submitted. As amended, the review period would begin to run on the date the information is required under section 4, even if the submission requirement has not been complied with and the information has not been submitted.

(3) Information ~~Data~~ submitted under paragraph (1) or (2) of this subsection or under subsection (e) 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 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, without consideration of costs or other nonrisk factors.

(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 AND REVIEW ~~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.

Commented [A6]: Why is this added back in? The period is otherwise consistently referred to in the section as the review period, not the notice and review period.

(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 information ~~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 information ~~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 information ~~data~~ under subsection (b), the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or information ~~data~~ has been received;

(B) lists the uses ~~or intended uses~~ of such substance identified in the notice ~~and any additional uses of the substance that are reasonably foreseeable by the~~ Administrator; and

(C) in the case of the receipt of information ~~data~~ under subsection (b), describes the nature of the tests performed on such substance and any information ~~data~~ which was developed pursuant to subsection (b) or a rule, order, or consent agreement 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 applicable review ~~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 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 by the Administrator under the conditions of use; 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 shall ~~may~~ issue an ~~proposed~~ order, to take effect on the expiration of the applicable review ~~notification~~ period ~~applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c)~~, to prohibit or limit the manufacture, processing,

Commented [A7]: Upon further review, we believe it would be difficult for EPA to identify reasonably foreseeable uses within 5 days of submission of a section 5 notice, as this provision would require.

Commented [A8]: S version lists options for getting information

Commented [A9R8]: Senate comment, not EPA.

distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against such risk.

(B) If the Administrator issues an order under paragraph (1)(A), the submitter of the notice under subsection (a) may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection only in compliance with the restrictions specified in the order.

(~~C~~B) An ~~proposed~~ order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the applicable review ~~notification~~ period ~~applicable to the manufacture or processing of such substance under subsection (a), (b), or (e)~~, 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—~~

~~(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~~

Commented [A10]: This standard will not work as drafted, since an (e) order under this section as amended no longer requires a risk finding.

Commented [A11]: We believe this is unnecessary since (a) is clear that manufacture/processing cannot commence until EPA takes necessary action, and an (e) order is binding by its own terms. But we do not have concerns with including it if it is conformed with comparable provision in f.

~~(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 determines that a chemical substance or significant new use ~~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,~~ may present or presents ~~or will present~~ an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, ~~before a rule promulgated under section 6 can protect against such risk,~~ the Administrator shall ~~before the expiration of the applicable review notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance,~~ issue an order, to take effect on or before the expiration of the applicable review period to prohibit or limit the manufacturing, processing, distribution in commerce, use, or disposal of such substance, or of such chemical substance for a significant new use, or to prohibit or limit any combination of such activities, ~~take the action authorized by paragraph (2) or (3)~~ to the extent necessary to protect against such risk.

(2) No person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a

Commented [A12]: The addition of "may" does not conform to (a), which routes a chemical to (f) only upon a "presents" finding. Also, the bill now, read literally, would require EPA to issue both an e order and an f order if EPA makes a may present finding based on insufficient information. The intention may be that EPA issues an e order if it makes the finding based on insufficient information, and an f order if it makes the finding based on sufficient information, but the text does not say that.

Commented [A13]: EPA notes that this change would result in section 5 no longer conforming with the standard in 6(a). .

significant new use, pursuant to this subsection except in compliance with the restrictions specified in the order.

(32) 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

(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)(32)(B) shall apply with respect to such rule.

(4) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance that is subject to the requirements of this subsection and that 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 scoring system), the Administrator shall, in selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), reduce the potential for exposure to the substance, to the extent practicable.

~~(3)(A) The Administrator may—~~

~~(i) issue an proposed order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period, 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.~~

(BC) The provisions of subparagraph~~s~~ (CB) ~~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~~

Commented [A14]: We think it could be stricken, but only if the comparable provision in (e) is stricken. If retained, it should be conformed with (e). That begins with: "If the Administrator issues an order under paragraph (1)(A),". We suggest either consistently referencing the order (as per e), or the findings (as suggested in your comment option 2 below). The latter seems preferable, since it makes the requirement seem less conditional upon issuance of the order.

Commented [A15]: For EPA, please comment: Two options:

1) Strike this paragraph.
OR
2) Insert at the beginning: "If the Administrator makes the determination under subsection (a)(3)(A),"

Commented [A16]: We note that these PBT provisions do not apply to e orders.

~~(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.~~

(4) Not later than 90 days after ~~taking an action under paragraph (2) or (3) or~~ issuing an order under ~~this subsection or~~ subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(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 action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) 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 relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

(g) STATEMENT OF ~~ADMINISTRATOR FINDING~~~~REASONS FOR NOT TAKING~~ ACTION.—If the Administrator finds ~~in accordance with subsection (a)(3)(C)~~ that a determination under subsection (a)(3)(A) or (a)(3)(B) is ~~not warranted~~~~chemical substance or significant new use is likely not to present an unreasonable risk of injury to health or the environment, or in accordance with subsection (a)(3)(D) that the chemical substance is a low-hazard substance~~, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, ~~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,~~ and the Administrator shall make public ~~publish~~ a statement of the Administrator's finding~~reasons for not initiating such action~~. Such a statement shall be submitted for publication ~~published~~ in the Federal Register as soon as practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application;, 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 information ~~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 information ~~data~~ has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information ~~data~~ by the applicant on such substance would be duplicative of information ~~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 information ~~data~~ on such substance. No exemption which is granted under this subparagraph with respect to the submission of information ~~data~~ for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information~~data~~.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information ~~data~~ required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information ~~data~~ and if such exemption is granted during the reimbursement period for such information~~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 information ~~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 information~~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 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 information ~~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 information ~~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 information~~data~~,

whichever is later.

(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.

(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 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 subpopulation identified by the Administrator for the specific conditions of use. ~~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)~~.

(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.

(6) Immediately upon receipt of an application under paragraph (1) or (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 Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) DEFINITION.—(1) For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

(2) For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.

(3) For purposes of this section, the term 'applicable review period' means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided in subsection (b)(1) or (c).
[15 U.S.C. 2604]

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/8/2016 3:08:43 PM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov
Subject: TSCA TA on Senate edits to HLC 5.6
Attachments: EPA TA on Senate Edits for HLC (5-7), v3.docx; ATT00001.htm; 21 - Markey.TSCA TA.21-WEI16217.docx; ATT00002.htm

Michal and Jonathan,
The attached TA responds to the request on the senate edits to HLC 5-6. Section 5 coming separately.

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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EPA TA on Senate Line Edits to 5/6/16 1:01 PM draft
Sections refer to sections of TSCA

Section 4

- Page 5, Lines3-7 – delete and revert to current law "rule"

*No objection, but as a conforming edit, the opening words of the new subsection (b)(3)(C) will need to be revised as follows: "(C) A rule or order under paragraph (2) of subsection (a). . . ."

- Page 7, line 22: Strike "shall consider employing" and insert "shall employ"

- Page 8, line 5: Strike "considering"

- Page 8, line 7: Insert in the header to subsection (b), "order or consent agreement".
  - This change conforms the header to what the paragraph does (and it was conformed in the House bill as passed)

- Page 13, line 19 – after "reduce" insert "and replace"

- Page13,line 23 – strike "when" and replace with "prior to"

- Page 14, line 13 – after "reduce" insert "or replace"

- Page 17, line 5 – strike "for specific health and environmental health points"

- Page17, lines 10-11 – after "scientific" insert "reliability and" and strike "and value for risk assessment purposes"

- Page 18, after line 6 – insert (this has EPA TA that is responsive to House concerns)

"(3) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing.

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator.

"(C) RELATIONSHIP TO OTHER LAW.—A violation of this paragraph shall not be a prohibited act under section 15."

* Per earlier TA, this formulation does not include language that had been in previous versions clarifying that EPA was not responsible for policing the requirements of (A). We think this would be helpful to avoid questions as to whether EPA can review test information submitted that may not have

conformed with (A). You could add back language that was in S 697, slightly modified to fit new context:

"Nothing in this paragraph requires the Administrator to review the basis on which a person conducted testing described in subparagraph (A)"

Section 5

*See separate document with Senate changes and EPA TA, expected shortly.

Section 6

- Page 35, Line 12-13 – Delete "which shall not take longer than one year".
- Page 36, Lines 1-8 – Delete to conform with changes on page 38
- Page 36, line 25 to Page 37 line 9 – Conform to the previous House offer language from(4-22) with some edits "The Administrator shall designate as a low-priority substance a chemical substance that the Administrator concludes, based on sufficient information, without consideration of costs or other non-risk factors, that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

*EPA previously flagged a significant issue with the "likely not to present" language here. The issue was addressed in the 5/6 House draft, but your current suggested drafting revives the same issue. The "not likely to present an unreasonable risk of injury" language could be read to mean that any chemical with less than a 50% chance of presenting an unreasonable risk would be a "low priority substance." Note that in the HLC 4.22, the standard was "likely not to present" as opposed your current drafting of "not likely to present." On 4.27, EPA provided TA that would help more clearly define the relationship between high priority and low priority substances.

1. Insert the word "highly" or the word "very" in front of "likely" in section 6(b)(1)(B)(ii) (page 34, line 1, of 4/22 draft)—so that it would read the "chemical substance is highly [very] likely not to present an unreasonable risk of injury."

2. Strike the words "is likely not to present" and replace with "has a low likelihood of presenting" so that it would read the "chemical substance has a low likelihood of presenting an unreasonable risk of injury."

- Page 37, line 10 – after "a" strike "chemical" and replace with "low-priority"
- Page 37, line 16 – delete "or exposure"
- Page 37, lines 17 and 18 – delete "(I)" and add at that subclause to the end of line 17 and after "environment" on 19 add "under the conditions of use"

- Page 37, line 22 – strike "; and" and insert "." And delete all of subclause (II) from lines 23 to page 38 line 2.

- Page 38, line 3 to line 16 – Strike and insert new "C" below.

(C) Information Request and Review and Proposed and Final Prioritization Designation.. (i) The rulemaking required in subsection (b)(1)(A) shall ensure that the time required to make a priority designation of a chemical substance be no shorter than nine months and no longer than 1 year, and that the process for such designations includes:

(I) A requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided;

(II) A requirement that the Administrator publish each proposed designation of a chemical substance as a high or low priority substance, along with an identification of the information, analysis and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation; and

(III) A process by which the Administrator may extend the deadline in clause (i) for up to three months in order to receive or evaluate information required to be submitted in accordance with section 4(a)(2)(B), subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

- Page 39, line 2 (was Page 34, line 18) – after "Assessments" insert "and that the Administrator publish the list of such chemical substances during the 180 day period"

- Page 39, Line 17-21 (was Page 35 line 8) – make subparagraph read "The Administrator shall continue to designate priority substances, subject to the limitation described in subparagraph (B) until all substances drawn from the 2014 update of the TSCA Work plan for Chemical Assessments have undergone risk evaluations, until the priority of all active chemical substances has been designated, at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

- Page 40, lines 11-20 – Replace Metals language with – ""The Administrator shall prioritize and assess metals and metal compounds in accordance with the U.S. Environmental Protection Agency's Framework for Metals Assessment (EPA 120/R-07/001) (March 2007), or a successor document developed in consultation with expert scientists in metals risk assessment, based on the process used in the development of the 2007 framework."

- Page 42 line 22 (was Page 38 line 13) – replace (D) with "(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, and, for each designation of a high-priority chemical substance, ensure not less than twelve months

between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance.

- Page 43, line 23 (was Page 39, line 15) – add a new "(iii) Preference.—In deciding whether to grant requests under subparagraph (B)(ii), the Administrator shall give preference to requests for risk evaluations on chemical 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.

- Page 45, line 20 (Was Page 41 line 23) – after "more than" add "6 months." and delete the rest of the clause.

- Page 48 lines 13 and 17 (Was Page 44 at the end of lines 15 and 19) – "as identified by the Administrator in the risk evaluation"

- Page 48, line 21 (Was Page 44 line 23) – after "consequences" should read "of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator, including consideration of"

*We suggest the following to clarify EPA's obligations with respect to economic analysis of alternatives is not broader than in (II) and (III)

"after "consequences" should read "of the proposed and final regulatory action(,) and of the 1 or more primary alternative regulatory actions considered by the Administrator as described in (II) and (III), including consideration of"

- Page 51 line 24 – after "or mixture" insert "in the article or category of articles"

*Consistent with S697 language as passed, this should be "<u>from</u> the article or category of articles."

- Page 54, line 7 – in subparagraph (A)(i)(I), as so redesignated insert "without consideration of costs or other non-risk factors" after "such effective date"

*EPA was unable to find where this change should be applied.

- Page 54, line 22 – before "and either" insert ",in accordance with paragraph 3 of subsection (c)(3),"

- Page 59, line 3 – strike "of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act" and insert "on which the Administrator proposes a rule under paragraph (1) with respect to a chemical substance."

*This could have the effect of requiring EPA to go through the process of developing a proposal under 6(h) for a PBT chemical, only to have the chemical rerouted through the ordinary risk evaluation and management under 6(a) and 6(c), thereby adding significant time and burdening EPA with additional unnecessary work. It would also frequently result in extending the time required to implement risk reduction for PBTs beyond that allowed for non-PBT priorities.

Section 7

- Page 148, line 3 – in 7(a)(2) strike the reference to 6(d)(2)(A)(i) and replace with 6(d)(3)(A)(i)

Section 8

- Existing TSCA 8(a)(1) – for HLC, make sure this is not redoing the entire inventory it is just an update to the inventory – need to maintain reference in current law to the original TSCA date of enactment.

- Page 64 line 16 to page 65 line 10 – Strike – per EPA TA this is unnecessary and it is strongly opposed by industry and Senate republicans.

*EPA TA on previous versions of these savings clauses suggested that they were not "necessary" to address any technical implementation issues. The previous versions also seemed to be ineffective. However, as revised in HLC 5.6, the savings clauses do accomplish certain policy objectives.

- Page 67 line 13, 25 – strike "against" and insert "from" to conform to Section 14

- Page 75, line 6 (was Page 72 line 6) – insert at the end: "along with the Administrator's designation of the chemical substance as an active or inactive substance"

Section 9

- Page 79, line 6 – insert "by striking 'or will present' after 'presents'"

*EPA notes that this change would result in Section 9 no longer conforming with the standard in section 6(a).

- Page 80, line 19 – edit (A) to read "initiate or complete appropriate action under section 6"

*This change is incorrect. It appears to require another agency to act under section 6.

- Page 80, line 22 – after "section 7" insert "as applicable"

- Page 81 line 15: Insert "to the extent practicable" before "based on"

Section 12

Page 82 line 6 – Per deletion of the safety standard we need this conforming change to unreasonable risk

- 12(a)(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator determines, without consideration of costs or other non-risk factors, that* the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States, under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator. The Administrator may require, under section 4, the development of new information for any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining, without consideration of costs or other non-risk factors, whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

*For parallelism, we think the second sentence should include the language with respect to conditions of use and subpopulations that appears in the first sentence.

- Page 85 line 13 through page 91 line 13 – These are not amendments to TSCA so they should not be in Section 8.

Section 14

- Page 97 lines 9-11 – Strike and insert "section (g)(1)(A), the Administrator shall, as practicable, promptly make the information public."

- Page 99, line 23 – delete "subject to subsection (f)" – this unnecessary and opens the door for forcing substantiation of this information. Subsection (f) already provides for what is needed without this.

- Page 101 lines 1 and 2 – strike "Except as provided in paragraph (2)"

*This is OK, although it provided useful (though not essential) clarification that substantiation is not needed for CBI claims for presumptively protected information.

- Page 107 lines 1 and 2 – Move "Subject to paragraph (2), subsection (f)(3), and section 8(b)," to (B) on line 18

*The relocation of this text, so that it does not apply to the "presumptively protected" (c)(2) information, creates issues, because (f)(3) (the period of protection following EPA approval after a request for re-substantiation) and 8(b) (the requirements for re-asserting existing chem id claims) apply to that type of information. While paragraph (2) does not apply to (c)(2) information, we don't think the placement of this text in the House discussion draft indicates that it does. The simplest solution is probably not to relocate the text. Alternatively, you could relocate the text per your edit, but also insert "Subject to subsection (f)(3) and section 8(b)" at the beginning of (A).

- Page 107 lines 3 and 4 – Strike "described in subsection (a)" and replace with "that meets the requirements of subsection (a) and the applicable requirements of subsection (c)" There are requirements in (a) that need to be followed (those of FOIA)

- Page 105 lines 2-3 – Strike "information shall not be protected from disclosure under this section; or" and insert "Administrator shall, as practicable, promptly make the information available to the public; or" – this should not be passive, it needs to be active disclosure

- Page 108 lines 7-9 – Strike "in which case the information shall not be protected from disclosure under this section; or" and insert "in which case the Administrator shall, as practicable promptly make the information available to the public; or" – this also should be active not passive disclosure.

- Page 118 line 4 – delete "Subject to subsection (d)," – you can challenge disclosure under (d) why would we want it to be released during those appeals.

*Subject to subsection (d)" was added in response to EPA TA pointing out that, without some revision, this non-disclosure provision would bar the release by EPA of information subject to appeal even on grounds unrelated to the appeal. For example, it would bar EPA release to contractors of information during the pendency of an appeal of an EPA notice of intent to release it more broadly. Here is an alternative revision to this provision to address this issue:

1 The intended disclosure of the information ~~Administrator shall~~
2 ~~not disclose information~~ that is the
3 subject of an appeal under this para-
4 graph shall be stayed until ~~before~~ the date on which the
5 applicable court rules on an action
6 under clause (i).

- Page 118 line 11 – strike "Subclause (I)" and replace with "Clause (i)" and redesignate (II) as (iii)

*EPA does not object to this change, but we note that the effect is to make an EPA decision to release information to Congress or a state un-appealable, rather than to simply provide that an appeal does not automatically stay the release.

- Page 119 line 23 – after "unique identifier" insert "and is made public"

Section 18
Drafted to the 4/18 3:23 pm draft

Page 1 line 8 – change "this section" to "subsections (c), (d), (e), (f) and (g),"

Page 1 line 15 – "chemical substances"

Page 1 line 12 change header to "DEVELOPMENT OF INFORMATION"

Page 1 line 14 – change "on" to "about", and add the word "chemical" after "category of"

Page 1 line 20 – we are no longer referring to "testing" – delete word

Page 2 line 3 – header should read CHEMICAL SUBSTANCES FOUND NOT TO PRESENT AN UNREASONABLE RISK OR RESTRICTED

Page 2 line 5 – after "statute" add ", criminal penalty,"

Page 2 lines 9-13 replace with "(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"

Page 2 lines 14-20 – replace with "(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)."

Page 3 line 6, add "chemical" before "substances"

Page 3 line 13 – make all of 18(b)(1) read as follows: "New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions. Except as provided in subsections (c), (d), (e), (f), and (g), beginning on the date on which the Administrator defines the scope of a risk evaluation for a chemical substance under section 6(b)(4)(D) and ending on the date on which the deadline established pursuant to section 6(b)(4)(G) for completion of the risk evaluation expires, or on the date on which the Administrator publishes the risk evaluation under section 6(b)(4)(C), whichever is earlier, no State or political subdivision of a State may establish a statute, criminal penalty, or administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce or use of such chemical substance that is a high-priority substance designated under 6(b)(1)(B)(i), such chemical substance that has been identified under section 6(b)(2)(A), or such chemical substance that has been selected for risk evaluation under section 6(b)(4)(E)(iv)(II)."

Page 4 line 22 – should be "subsections (a) and (b)"

Page 5 line 1, before "the" add "with respect to subsection (a)(1)(A),"

Page 5 line 4:, before "the" add "with respect to subsections (a)(1)(B) and (b),"

Page 5 line 8 –"change "safety determination made" to "risk evaluation published"

Page 5 line 9: before substance add "chemical", and after substance add "under section 6(b)(4)(D),"

Page 5 line 10 – should be 6(c)

Page 5 line 11: before "the" add "with respect to subsection (a)(1)(C)," and before "substances" add "chemical"

Page 5 line 18-20 – first answer is "Act", second, please use short title of bill.

Page 5 line 22 – risk evaluation

Page 6 line 1-2: delete "safety determination" and insert "risk evaluation, delete the "or" before "scientific"

Page 6 line 10- delete "disclosure"

Page 7 line 4-5 – delete bracketed text, replace with "risk evaluation published pursuant to section 6(b)(4)(D),"

Page 8 line 20 – delete "notwithstanding subsection (e)"

Page 8 line 22 – make read "modifying the **preemptive** effect"

Page 8 line 23 and page 9 line 2 and page 9 line 7 and page 9 line 12 and page 9 line 18– yes, effective date

Page 9 line 11 – yes to q

Page 9 line 23 after "under" til end of that subparagraph should read: section 6(b)(1)(B)(i), the identification of that chemical substance under section 6(b)(2)(A), or the selection of that chemical substance for risk evaluation under section 6(b)(4)(E)(iv)(II).

Page 10 line 5 – subsection (g) not (f)

Page 10 line 9 – after "taken" insert "or requirement imposed or requirement enacted relating to a specific chemical substance" and replace "August 1, 2015" with "April 22, 2016"

Page 11 line 15 and page 12 line 19– not disposal

Page 12 line 8 – page 13 line 4 – replace with

(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall 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 conditions of use if the Administrator determines that—

(A)

(i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(ii) 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

(iii) the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science;

or

(B) no later than 18 months after the date on which the Administrator has initiated the prioritization process for a chemical substance under section 6(b)(3)(A)(i), or the date on which the Administrator publishes the scope of the risk evaluation under section 6(b)(4)(D), whichever is sooner, the state or political subdivision of the state has enacted a statute or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce or use of the chemical substance.

Page 14 line 4 – ok to italicized text

Page 14 line 15-16 – "risk evaluation under section 6(b)"

Page 15 line 19 and page 16 line 9 and page 16 line 19- FRL Act

Page 15 line 20 – delete "safety"

Page 15 line 21 – "risk evaluation"

Pls don't worry about the inconsistencies

Page 16 line 20 – delete "safety assessments, safety determinations" and replace with "risk evaluations,"

Page 17 line 7 – delete "safety assessments" and replace with "risk evaluations"

Section 19

- Page 125 line 1 – strike "or (iii)"

Section 20

- Page 125 lines 8-22 – Remove brackets – these are conforming changes that tie into preemption waivers that are very important to timely review of pause waivers when deadlines are missed.

Section 21

- Page 125 line 23 – Restore Section 21 amendments from 4-22 draft. If these changes are not made a court could order EPA to restrict a chemical on a lesser basis that EPA has to meet.

*EPA has provided TA on this version of Section 21, and will forward in a separate document.

- Page 153 line 17 through 154 line 14: Strike because of restoration on 125.

*Only p 154 lines 3-14 should be stricken, because only that is replaced by restoration on 125.

Section 26

- Page 127, lines 18 through Page 128 line 2 – add at the beginning insert "Subject to the conditions of subparagraph (C) and strike line 20 through Page 128 line 2. This is a CBO scoring issue (redesignate D and E appropriately), contact Jon Sperl-J'Nell Blanco-Suchy

- Page 130 line 12 – insert "annual" after "to"

*This should be "annually" not "annual."

- Page 135 line 22 – strike "as a high-substance, low-priority substance, or low-hazard substance" and insert "under section (6)(b),"

- Page 140, line 9 (was Page 140 line 13), after "be" add "initiated and"

Section 27

- Sustainable chemistry under discussion and compromise language is available the Senate would like to see included.

Section 31- probably ok (appears outside TSCA)

- Because we have taken out some rulemakings EPA suggests making the effective date 30 days after enactment.

Section 19 Conforming Amendments

- Changes not necessary because of restoration in Section 19

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/6/2016 4:25:47 PM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]; Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: HEC TSCA TA on section 19 (HLC 5-4)
Attachments: HEC.TSCA TA.section 19 (HLC 5-4).docx

HEC TSCA Team,
This TA responds to the request on HLC (5-4). Please see RLSO comments on section 19 on pp. 149-151 of the attached otherwise clean version of HLC (5-4). We are looking at any remaining sections. Although we do not expect many, if any, comments, I'll let you know what we find and when review of this draft is complete.

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

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.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings, policy, and intent.
Sec. 3. Definitions.

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 described in
5 subparagraph (A)(i), by rule, order, or
6 consent agreement," after "rule";
7 (II) by striking "data" each place
8 it appears and inserting "informa-
9 tion"; and
10 (III) by striking "and which are
11 relevant" and inserting "and which is
12 relevant"; and
13 (C) by adding at the end the following:
14 "(2) ADDITIONAL TESTING AUTHORITY.—In
15 addition to the authority provided under paragraph
16 (1), the Administrator may, by rule, order, or con-
17 sent agreement—
18 "(A) require the development of new infor-
19 mation relating to a chemical substance or mix-
20 ture if the Administrator determines that the
21 information is necessary—
22 "(i) to review a notice under section 5
23 or to perform a risk evaluation under sec-
24 tion 6(b);

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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 under a rule promulgated under sec-
5 tion 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 subsection (a)(2) may re-
22 quire the development of information by any person who
23 manufactures or processes, or intends to manufacture or
24 process, a chemical substance or mixture subject to the
25 rule or order.";

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

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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 data from such
5 testing available to the Administrator.
6 "(2) IMPLEMENTATION OF ALTERNATIVE TEST-
7 ING METHODS.—To promote the development and
8 timely incorporation of new scientifically valid test
9 methods and strategies that are not based on
10 vertebrate animals, the Administrator shall—
11 "(A) not later than 2 years after the date
12 of enactment of the Frank R. Lautenberg
13 Chemical Safety for the 21st Century Act, de-
14 velop a strategic plan to promote the develop-
15 ment and implementation of alternative test
16 methods and strategies to reduce, refine, or re-
17 place vertebrate animal testing and provide in-
18 formation of equivalent or better scientific qual-
19 ity and relevance for assessing risks of injury to
20 health or the environment of chemical sub-
21 stances or mixtures through, for example—
22 "(i) computational toxicology and
23 bioinformatics;
24 "(ii) high-throughput screening meth-
25 ods;

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1 "(iii) testing of categories of chemical
2 substances;
3 "(iv) tiered testing methods;
4 "(v) in vitro studies;
5 "(vi) systems biology;
6 "(vii) new or revised methods identi-
7 fied by validation bodies such as the Inter-
8 agency Coordinating Committee on the
9 Validation of Alternative Methods or the
10 Organization for Economic Co-operation
11 and Development; or
12 "(viii) industry consortia that develop
13 information submitted under this title;
14 "(B) as practicable, ensure that the stra-
15 tegic plan developed under subparagraph (A) is
16 reflected in the development of requirements for
17 testing under this section;
18 "(C) include in the strategic plan devel-
19 oped under subparagraph (A) a list, which the
20 Administrator shall update on a regular basis,
21 of particular alternative test methods or strate-
22 gies the Administrator has identified that do
23 not require new vertebrate animal testing and
24 are scientifically reliable, relevant, and capable
25 of providing information of equivalent or better

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1 scientific reliability and quality to that which
2 would be obtained from vertebrate animal test-
3 ing for specific health and environmental
4 endpoints;
5 "(D) provide an opportunity for public no-
6 tice and comment on the contents of the plan
7 developed under subparagraph (A), including
8 the criteria for considering scientific relevance
9 and value for risk assessment purposes of the
10 test methods and strategies that may be identi-
11 fied pursuant to subparagraph (C);
12 "(E) beginning on the date that is 5 years
13 after the date of enactment of the Frank R.
14 Lautenberg Chemical Safety for the 21st Cen-
15 tury Act, and every 5 years thereafter, submit
16 to Congress a report that describes the progress
17 made in implementing the plan developed under
18 subparagraph (A) and goals for future alter-
19 native test methods and strategies implementa-
20 tion; and
21 "(F) prioritize and, to the extent con-
22 sistent with available resources and the Admin-
23 istrator's other responsibilities under this title,
24 carry out performance assessment, validation,
25 and translational studies to accelerate the devel-

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1 opment of scientifically valid test methods and
2 strategies that reduce, refine, or replace the use
3 of vertebrate animals, including minimizing du-
4 plication, in any testing under this title.".

5 **SEC. 5. MANUFACTURING AND PROCESSING NOTICES.**

6 Section 5 of the Toxic Substances Control Act (15
7 U.S.C. 2604) is amended—
8 (1) in subsection (a)—
9 (A) in paragraph (1)—
10 (i) by striking "Except as provided
11 in" and inserting "(A) Except as provided
12 in subparagraph (B) of this paragraph
13 and";
14 (ii) by redesignating subparagraphs
15 (A) and (B) as clauses (i) and (ii), respec-
16 tively;
17 (iii) by striking all that follows "sig-
18 nificant new use" and inserting a period;
19 and
20 (iv) by adding at the end the fol-
21 lowing:
22 "(B) A person may take the actions described
23 in subparagraph (A) if—
24 "(i) such person submits to the Adminis-
25 trator, at least 90 days before such manufac-

1 ture or processing, a notice, in accordance with
2 subsection (d), of such person's intention to
3 manufacture or process such substance and
4 such person complies with any applicable re-
5 quirement imposed under subsection (b); and
6 "(ii) the Administrator—
7 "(I) conducts a review of the notice;
8 and
9 "(II) makes a determination under
10 subparagraph (A), (B), (C), or (D) of
11 paragraph (3) and takes the actions re-
12 quired in association with that determina-
13 tion under such subparagraph within the
14 applicable review period."; and
15 (B) by adding at the end the following new
16 paragraphs:
17 "(3) REVIEW AND DETERMINATION.—Within
18 the applicable review period, subject to section 18,
19 the Administrator shall review such notice and de-
20 termine—
21 "(A) that the relevant chemical substance
22 or significant new use presents or will present
23 an unreasonable risk of injury to health or the
24 environment, without consideration of costs or
25 other nonrisk factors, including an unreason-

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1 able risk to a potentially exposed or susceptible
2 subpopulation identified as relevant by the Ad-
3 ministrator under the conditions of use, in
4 which case the Administrator shall take the ac-
5 tions required under subsection (f);
6 "(B) that—
7 "(i) the information available to the
8 Administrator is insufficient to permit a
9 reasoned evaluation of the health and envi-
10 ronmental effects of the relevant chemical
11 substance or significant new use; and
12 "(ii)(I) in the absence of sufficient in-
13 formation to permit the Administrator to
14 make such an evaluation, the manufacture,
15 processing, distribution in commerce, use,
16 or disposal of such substance, or any com-
17 bination of such activities, may present an
18 unreasonable risk of injury to health or the
19 environment, without consideration of costs
20 or other nonrisk factors, including an un-
21 reasonable risk to a potentially exposed or
22 susceptible subpopulation identified as rel-
23 evant by the Administrator; or
24 "(II) such substance is or will be pro-
25 duced in substantial quantities, and such

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1 substance either enters or may reasonably
2 be anticipated to enter the environment in
3 substantial quantities or there is or may be
4 significant or substantial human exposure
5 to the substance,
6 in which case the Administrator shall take the actions re-
7 quired under subsection (e);
8 "(C) that the relevant chemical substance
9 or significant new use is likely not to present an
10 unreasonable risk of injury to health or the en-
11 vironment, without consideration of costs or
12 other nonrisk factors, including an unreason-
13 able risk to a potentially exposed or susceptible
14 subpopulation identified as relevant by the Ad-
15 ministrator under the conditions of use, in
16 which case the Administrator shall publish such
17 determination and the submitter of the notice
18 may commence manufacture of the chemical
19 substance or manufacture or processing for a
20 significant new use; or
21 "(D) that the relevant chemical substance
22 is a low-hazard substance, in which case the
23 Administrator shall publish such determination
24 and the submitter of the notice may commence
25 manufacture of the chemical substance or man-

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1 ufacture or processing of the chemical sub-
2 stance for 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 period of review.
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.

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";

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 by the Administrator"; 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"; and
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";
21 (C) by striking paragraph (1)(C); and
22 (D) by striking paragraph (2);
23 (6) in subsection (f)—
24 (A) in paragraph (1)—

1 (i) by striking "finds that there is a
2 reasonable basis to conclude that the man-
3 ufacture, processing, distribution in com-
4 merce, use, or disposal of a chemical sub-
5 stance with" and inserting "determines
6 that a chemical substance or significant
7 new use with";
8 (ii) by striking ", or that any com-
9 bination of such activities,";
10 (iii) by inserting ", without consider-
11 ation of costs or other nonrisk factors, in-
12 cluding an unreasonable risk to a poten-
13 tially exposed subpopulation identified as
14 relevant by the Administrator under the
15 conditions of use," after "health or envi-
16 ronment"; and
17 (iv) by striking "notification period
18 applicable under subsection (a), (b), or (c)
19 to the manufacturing or processing of such
20 substance" and inserting "applicable re-
21 view period";
22 (B) in paragraph (3)—
23 (i) in subparagraph (A)—
24 (I) by striking "Administrator
25 may" and all that follows through

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1 "issue a proposed order to prohibit
2 the" and inserting "Administrator
3 may issue an order to prohibit or limit
4 the"; and
5 (II) by striking "under para-
6 graph (1)" and all that follows
7 through "processing of such sub-
8 stance." and inserting "under para-
9 graph (1). Such order shall take effect
10 on the expiration of the applicable re-
11 view period.";
12 (ii) by striking subparagraph (B) and
13 redesignating subparagraph (C) as sub-
14 paragraph (B);
15 (iii) in subparagraph (B), as so redes-
16 ignated—
17 (I) by striking "subparagraphs
18 (B) and (C)" and inserting "subpara-
19 graph (B)";
20 (II) by striking "clause (i) of";
21 and
22 (III) by striking "; and the provi-
23 sions of subparagraph (C) of sub-
24 section (e)(2) shall apply with respect

1 to an injunction issued under sub-
2 paragraph (B)"; and
3 (iv) by striking subparagraph (D);
4 and

5 (C) by adding at the end the following:
6 "(4) TREATMENT OF NONCONFORMING USES.—
7 Not later than 90 days after taking an action under
8 paragraph (2) or (3) or issuing an order under sub-
9 section (e) relating to a chemical substance with re-
10 spect to which the Administrator has made a deter-
11 mination under subsection (a)(3)(A) or (B), the Ad-
12 ministrator shall consider whether to promulgate a
13 rule pursuant to subsection (a)(2) that identifies as
14 a significant new use any manufacturing, processing,
15 use, distribution in commerce, or disposal of the
16 chemical substance that does not conform to the re-
17 strictions imposed by the action or order, and, as ap-
18 plicable, initiate such a rulemaking or publish a
19 statement describing the reasons of the Adminis-
20 trator for not initiating such a rulemaking.
21 "(5) WORKPLACE EXPOSURES.—To the extent
22 practicable, the Administrator shall consult with the
23 Assistant Secretary of Labor for Occupational Safe-
24 ty and Health prior to adopting any prohibition or
25 other restriction relating to a chemical substance

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1 with respect to which the Administrator has made a
2 determination under subsection (a)(3)(A) to address
3 workplace exposures.";
4 (7) by amending subsection (g) to read as fol-
5 lows:
6 "(g) STATEMENT ON ADMINISTRATOR FINDING.—If
7 the Administrator finds in accordance with subsection
8 (a)(3)(C) that a chemical substance or significant new use
9 is likely not to present an unreasonable risk of injury to
10 health or the environment, or in accordance with sub-
11 section (a)(3)(D) that the chemical substance is a low-haz-
12 ard substance, then notwithstanding any remaining por-
13 tion of the applicable review period, the submitter of the
14 notice may commence manufacture of the chemical sub-
15 stance or manufacture or processing for a significant new
16 use, and the Administrator shall make public a statement
17 of the Administrator's finding. Such a statement shall be
18 submitted for publication in the Federal Register as soon
19 as is practicable before the expiration of such period. Pub-
20 lication of such statement in accordance with the pre-
21 ceding sentence is not a prerequisite to the manufacturing
22 or processing of the substance with respect to which the
23 statement is to be published.";
24 (8) in subsection (h)—

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1 (A) in paragraph (1)(A), by inserting ",
2 including an unreasonable risk to a potentially
3 exposed or susceptible subpopulation identified
4 by the Administrator for the specific uses iden-
5 tified in the application" after "health or the
6 environment";
7 (B) in paragraph (2), by striking "data"
8 each place it appears and inserting "informa-
9 tion"; and
10 (C) in paragraph (4), by striking ". A rule
11 promulgated" and all that follows through "sec-
12 tion 6(c)" and inserting ", including an unrea-
13 sonable risk to a potentially exposed or suscep-
14 tible subpopulation identified by the Adminis-
15 trator under the conditions of use"; and
16 (9) by amending subsection (i) to read as fol-
17 lows:
18 "(i) DEFINITIONS.—(1) For purposes of this section,
19 the terms 'manufacture' and 'process' mean manufac-
20 turing or processing for commercial purposes.
21 "(2) For purposes of this Act, the term 'requirement'
22 as used in this section shall not displace any statutory or
23 common law.
24 "(3) For purposes of this section, the term 'applicable
25 review period' means the period starting on the date the

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1 Administrator receives a notice under subsection (a)(1)
2 and ending 90 days after that date, or on such date as
3 is provided for in subsection (b)(1) or (c).".

4 **SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULA-**
5 **TION OF CHEMICAL SUBSTANCES AND MIX-**
6 **TURES.**

7 Section 6 of the Toxic Substances Control Act (15
8 U.S.C. 2605) is amended—
9 (1) by striking the section heading and insert-
10 ing "**PRIORITIZATION, RISK EVALUATION, AND**
11 **REGULATION OF CHEMICAL SUBSTANCES AND**
12 **MIXTURES**";
13 (2) in subsection (a)—
14 (A) by striking "finds that there is a rea-
15 sonable basis to conclude that" and inserting
16 "determines in accordance with subsection
17 (b)(4)(A)";
18 (B) by inserting "and subject to section
19 18, and in accordance with subsection (c)(2),"
20 after "shall by rule";
21 (C) by striking "to protect adequately
22 against such risk using the least burdensome
23 requirements" and inserting "so that the chem-
24 ical substance or mixture no longer presents
25 such risk";

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1 (D) by inserting "or otherwise restricting"
2 after "prohibiting" in paragraph (2)(A);
3 (E) by inserting "minimum" before "warn-
4 ings" both places it appears in paragraph (3);
5 (F) by striking "and monitor or conduct
6 tests" and inserting "or monitor or conduct
7 tests" in paragraph (4); and
8 (G) in paragraph (7)—
9 (i) by striking "such unreasonable
10 risk of injury" and inserting "such deter-
11 mination"; and
12 (ii) by striking "such risk of injury"
13 and inserting "such determination";
14 (3) by amending subsection (b) to read as fol-
15 lows:
16 "(b) RISK EVALUATIONS.—
17 "(1) PRIORITIZATION FOR RISK EVALUA-
18 TIONS.—
19 "(A) ESTABLISHMENT OF PROCESS.—
20 "(i) IN GENERAL.—Not later than 1
21 year after the date of enactment of the
22 Frank R. Lautenberg Chemical Safety for
23 the 21st Century Act, the Administrator
24 shall establish, by rule, a risk-based
25 screening process, including criteria for

1 designating chemical substances as high-
2 priority substances for risk evaluations or
3 low-priority substances for which risk eval-
4 uations are not warranted at the time. The
5 process to designate the priority of chem-
6 ical substances, which shall not take longer
7 than one year, shall include a consideration
8 of the hazard and exposure potential of a
9 chemical substance or a category of chem-
10 ical substances (including consideration of
11 persistence and bioaccumulation, poten-
12 tially exposed or susceptible subpopulations
13 and storage near significant sources of
14 drinking water), the conditions of use or
15 significant changes in the conditions of use
16 of the chemical substance, and the volume
17 or significant changes in the volume of the
18 chemical substance manufactured or proc-
19 essed.
20 "(ii) PUBLIC NOTICE AND COM-
21 MENT.—The process established under
22 clause (i) shall require the Administrator
23 to notify the public when prioritization be-
24 gins and allow for notice and comment
25 which shall be completed along with the

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1 rest of the process within the one year
2 deadline.
3 "(B) IDENTIFICATION OF PRIORITIES FOR
4 RISK EVALUATION.—
5 "(i) HIGH-PRIORITY SUBSTANCES.—
6 The Administrator shall designate as a
7 high-priority substance a chemical sub-
8 stance that the Administrator concludes,
9 without consideration of costs or other
10 nonrisk factors, may present an unreason-
11 able risk of injury to health or the environ-
12 ment because of potential hazard and a po-
13 tential route of exposure under the condi-
14 tions of use, including an unreasonable
15 risk to a potentially exposed or susceptible
16 subpopulation identified as relevant by the
17 Administrator.
18 "(ii) LOW-PRIORITY SUBSTANCES.—
19 Except as provided in clause (iii), the Ad-
20 ministrator shall designate a chemical sub-
21 stance as a low-priority substance if the
22 Administrator concludes, based on infor-
23 mation sufficient to establish, without con-
24 sideration of costs or other nonrisk factors,
25 that such substance does not meet the

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1 standard identified in clause (i) for desig-
2 nating a chemical substance a high-priority
3 substance.
4 "(iii) LOW-HAZARD SUBSTANCES.—
5 The Administrator may designate a chem-
6 ical substance as a low-hazard substance if
7 the Administrator concludes, based on in-
8 formation sufficient to establish, without
9 consideration of costs or other nonrisk fac-
10 tors or exposure, that the chemical sub-
11 stance—
12 "(I) poses no or low hazard to
13 human health or the environment, in-
14 cluding any hazard to a potentially ex-
15 posed or susceptible subpopulation
16 identified as relevant by the Adminis-
17 trator; and
18 "(II) does not meet the standard
19 identified in clause (i) for designating
20 a chemical substance a high-priority
21 substance.
22 "(C) EXTENSION OF DEADLINE.—The Ad-
23 ministrator shall, in the rulemaking required
24 under subparagraph (A), provide for a process
25 to extend the one year deadline under subpara-

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1 graph (A) for up to six months in order to re-
2 ceive or evaluate information required to be
3 submitted in accordance with section
4 4(a)(2)(B), subject to the limitation that if the
5 information available to the Administrator at
6 the end of such an extension remains insuffi-
7 cient to enable the designation of the chemical
8 substance as a low-priority substance, the Ad-
9 ministrator shall designate the substance as
10 high-priority substance.
11 "(2) INITIAL RISK EVALUATIONS AND SUBSE-
12 QUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY
13 SUBSTANCES.—
14 "(A) INITIAL RISK EVALUATIONS.—Not
15 later than 180 days after the date of enactment
16 of the Frank R. Lautenberg Chemical Safety
17 for the 21st Century Act, the Administrator
18 shall ensure that risk evaluations are being con-
19 ducted on at least 10 chemical substances
20 drawn from the 2014 update of the TSCA
21 Work Plan for Chemical Assessments.
22 "(B) ADDITIONAL RISK EVALUATIONS.—
23 Not later than three and one half years after
24 the date of enactment of the Frank R. Lauten-
25 berg Chemical Safety for the 21st Century Act,

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1 the Administrator shall ensure that risk evalua-
2 tions are being conducted on at least 20 high-
3 priority substances and that at least 20 chem-
4 ical substances have been designated as low-pri-
5 ority or low-hazard substances, subject to the
6 limitation that at least 50 percent of all chem-
7 ical substances on which risk evaluations are
8 being conducted by the Administrator are
9 drawn from the 2014 update of the TSCA
10 Work Plan for Chemical Assessments.
11 "(C) CONTINUING DESIGNATIONS AND
12 RISK EVALUATIONS.—The Administrator shall
13 continue to designate priority substances and
14 conduct risk evaluations in accordance with this
15 subsection.
16 "(D) PREFERENCE.—In designating high-
17 priority substances, the Administrator shall give
18 preference to—
19 "(i) chemical substances that are list-
20 ed in the 2014 update of the TSCA Work
21 Plan for Chemical Assessments as having a
22 Persistence and Bioaccumulation Score of
23 3; and
24 "(ii) chemical substances that are list-
25 ed in the 2014 update of the TSCA Work

1 Plan for Chemical Assessments that are
2 known human carcinogens and have high
3 acute and chronic toxicity.
4 "(E) METALS AND METAL COMPOUNDS.—
5 In identifying priorities for risk evaluation and
6 conducting risk evaluations of metals and metal
7 compounds, the Administrator shall use the
8 Framework for Metals Risk Assessment of the
9 Office of the Science Advisor, Risk Assessment
10 Forum, and dated March 2007, or a successor
11 document that addresses metals risk assessment
12 and is peer reviewed by the Science Advisory
13 Board.
14 "(3) INITIATION OF RISK EVALUATIONS; DES-
15 IGNATIONS.—
16 "(A) RISK EVALUATION INITIATION.—
17 Upon designating a chemical substance as a
18 high-priority substance, the Administrator shall
19 initiate a risk evaluation on the substance.
20 "(B) REVISION.—The Administrator may
21 revise the designation of a low-priority sub-
22 stance or a low-hazard substance based on in-
23 formation made available to the Administrator.
24 "(C) ONGOING DESIGNATIONS.—The Ad-
25 ministrator shall designate at least one high-

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1 priority substance upon the completion of each
2 risk evaluation (other than risk evaluations for
3 chemical substances designated under para-
4 graph (4)(C)(ii)).
5 "(4) RISK EVALUATION PROCESS AND DEAD-
6 LINES.—
7 "(A) IN GENERAL.—The Administrator
8 shall conduct risk evaluations pursuant to this
9 paragraph to determine whether a chemical
10 substance presents an unreasonable risk of in-
11 jury to health or the environment, without con-
12 sideration of costs or other nonrisk factors, in-
13 cluding an unreasonable risk to a potentially ex-
14 posed or susceptible subpopulation identified as
15 relevant to the risk evaluation by the Admini-
16 trator, under the conditions of use.
17 "(B) ESTABLISHMENT OF PROCESS.—Not
18 later than 1 year after the date of enactment of
19 the Frank R. Lautenberg Chemical Safety for
20 the 21st Century Act, the Administrator shall
21 establish, by rule, a process to conduct risk
22 evaluations in accordance with subparagraph
23 (A).
24 "(C) REQUIREMENT.—The Administrator
25 shall conduct and publish risk evaluations, in

1 accordance with the rule promulgated under
2 subparagraph (B), for a chemical substance—
3 "(i) that has been identified under
4 paragraph (2)(A) or designated under
5 paragraph (1)(B)(i); and
6 "(ii) subject to subparagraph (E),
7 that a manufacturer of the chemical sub-
8 stance has requested, in a form and man-
9 ner and using the criteria prescribed by
10 the Administrator in the rule promulgated
11 under subparagraph (B), be subjected to a
12 risk evaluation.
13 "(D) SCOPE.—The Administrator shall, as
14 soon as practicable and not later than 6 months
15 after each designation of a high-priority sub-
16 stance, publish the scope of the risk evaluation
17 to be conducted, including the hazards, expo-
18 sures, conditions of use, and the potentially ex-
19 posed or susceptible subpopulations the Admin-
20 istrator expects to consider.
21 "(E) LIMITATION AND CRITERIA.—
22 "(i) PERCENTAGE REQUIREMENTS.—
23 The Administrator shall ensure that, of the
24 number of chemical substances that under-
25 go a risk evaluation under clause (i) of

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1 subparagraph (C), the number of chemical
2 substances undergoing a risk evaluation
3 under clause (ii) of subparagraph (C) is—
4 "(I) not less than 25 percent, if
5 sufficient requests are made under
6 clause (ii) of subparagraph (C); and
7 "(II) not more than 50 percent.
8 "(ii) REQUESTED RISK EVALUA-
9 TIONS.—Requests for risk evaluations
10 under subparagraph (C)(ii) shall be subject
11 to the payment of fees pursuant to section
12 26(b)(3), and the Administrator shall not
13 expedite or otherwise provide special treat-
14 ment to such risk evaluations.
15 "(iii) EXCEPTIONS.—(I) Chemical
16 substances for which requests have been
17 granted under subparagraph (C)(ii) and
18 that are not drawn from the 2014 update
19 of the TSCA Work Plan for Chemical As-
20 sessments shall not be subject to section
21 18(b).
22 "(II) Requests for risk evaluations on
23 chemical substances which are made under
24 subparagraph (C)(ii) and that are drawn
25 from the 2014 update of the TSCA Work

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1 Plan for Chemical Assessments shall be
2 granted at the discretion of the Adminis-
3 trator and not be subject to clause (i)(II).
4 "(F) REQUIREMENTS.—In conducting a
5 risk evaluation under this subsection, the Ad-
6 ministrator shall—
7 "(i) integrate and assess available in-
8 formation on hazards and exposures for
9 the conditions of use of the chemical sub-
10 stance, including information that is rel-
11 evant to specific risks of injury to health or
12 the environment and information on poten-
13 tially exposed or susceptible subpopulations
14 identified as relevant by the Administrator;
15 "(ii) describe whether aggregate or
16 sentinel exposures to a chemical substance
17 under the conditions of use were consid-
18 ered, and the basis for that consideration;
19 "(iii) not consider costs or other
20 nonrisk factors;
21 "(iv) take into account, where rel-
22 evant, the likely duration, intensity, fre-
23 quency, and number of exposures under
24 the conditions of use of the chemical sub-
25 stance; and

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1 "(v) describe the weight of the sci-
2 entific evidence for the identified hazard
3 and exposure.
4 "(G) DEADLINES.—The Administrator—
5 "(i) shall complete a risk evaluation
6 for a chemical substance as soon as prac-
7 ticable, but not later than 3 years after the
8 date on which the Administrator initiates
9 the risk evaluation under subparagraph
10 (C); and
11 "(ii) may extend the deadline for a
12 risk evaluation for not more than 1 year,
13 if information relating to the chemical sub-
14 stance is required to be developed in a
15 rule, order, or consent agreement under
16 section 4 and has not yet been submitted
17 to the Administrator, or if such informa-
18 tion has been submitted to the Adminis-
19 trator within the time specified in the rule,
20 order, or consent agreement and on or
21 after the date that is 120 days before the
22 expiration of the deadline described in
23 clause (i).
24 "(H) NOTICE AND COMMENT.—The Ad-
25 ministrator shall provide no less than 30 days

1 public notice and an opportunity for comment
2 on a draft risk evaluation prior to publishing a
3 final risk evaluation.";
4 (4) by amending subsection (c) to read as fol-
5 lows:
6 "(c) PROMULGATION OF SUBSECTION (a) RULES.—
7 "(1) DEADLINES.—If the Administrator deter-
8 mines that a chemical substance presents an unrea-
9 sonable risk of injury to health or the environment
10 in accordance with subsection (b)(4)(A), the Admin-
11 istrator—
12 "(A) shall propose in the Federal Register
13 a rule under subsection (a) for the chemical
14 substance not later than 1 year after the date
15 on which the final risk evaluation regarding the
16 chemical substance is published;
17 "(B) shall publish in the Federal Register
18 a final rule not later than 2 years after the date
19 on which the final risk evaluation regarding the
20 chemical substance is published; and
21 "(C) may extend the deadlines under this
22 paragraph for not more than two years, subject
23 to the condition that the aggregate length of ex-
24 tensions under this subparagraph and sub-
25 section (b)(4)(G)(ii) does not exceed two years,

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1 and subject to the limitation that the Adminis-
2 trator may not extend a deadline for the publi-
3 cation of a proposed or final rule regarding a
4 chemical substance drawn from the 2014 up-
5 date of the TSCA Work Plan for Chemical As-
6 sessments or a chemical substance that, with
7 respect to persistence and bioaccumulation,
8 scores high for 1 and either high or moderate
9 for the other, pursuant to the TSCA Work Plan
10 Chemicals Methods Document published by the
11 Administrator in February 2012 (or a successor
12 scoring system), without adequate public jus-
13 tification that demonstrates, following a review
14 of the information reasonably available to the
15 Administrator, that the Administrator cannot
16 complete the proposed or final rule without ad-
17 ditional information regarding the chemical
18 substance.
19 "(2) REQUIREMENTS FOR RULE.—
20 "(A) STATEMENT OF EFFECTS.—In pro-
21 posing and promulgating a rule under sub-
22 section (a) with respect to a chemical substance
23 or mixture, the Administrator shall consider
24 and publish a statement based on reasonably
25 available information with respect to—

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1 "(i) the effects of the chemical sub-
2 stance or mixture on health and the mag-
3 nitude of the exposure of human beings to
4 the chemical substance or mixture;
5 "(ii) the effects of the chemical sub-
6 stance or mixture on the environment and
7 the magnitude of the exposure of the envi-
8 ronment to such substance or mixture;
9 "(iii) the benefits of the chemical sub-
10 stance or mixture for various uses; and
11 "(iv) the reasonably ascertainable eco-
12 nomic consequences of the rule, including
13 consideration of—
14 "(I) the likely effect of the rule
15 on the national economy, small busi-
16 ness, technological innovation, the en-
17 vironment, and public health;
18 "(II) the costs and benefits of
19 the proposed and final regulatory ac-
20 tion and of the 1 or more primary al-
21 ternative regulatory actions considered
22 by the Administrator; and
23 "(III) the cost effectiveness of
24 the proposed regulatory action and of
25 the 1 or more primary alternative reg-

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1 ulatory actions considered by the Ad-
2 ministrator.
3 "(B) SELECTING REQUIREMENTS.—In se-
4 lecting among prohibitions and other restric-
5 tions, the Administrator shall factor in, to the
6 extent practicable, the considerations under
7 subparagraph (A) in accordance with subsection
8 (a).
9 "(C) CONSIDERATION OF ALTER-
10 NATIVES.—Based on the information published
11 under subparagraph (A), in deciding whether to
12 prohibit or restrict in a manner that substan-
13 tially prevents a specific use of a chemical sub-
14 stance or mixture, and in setting an appropriate
15 transition period for such action, the Adminis-
16 trator shall consider, to the extent practicable,
17 whether technically and economically feasible al-
18 ternatives that benefit health or the environ-
19 ment, compared to the use so proposed to be
20 prohibited or restricted, will be reasonably
21 available as a substitute when the proposed pro-
22 hibition or other restriction takes effect.
23 "(D) REPLACEMENT PARTS.—
24 "(i) IN GENERAL.—For complex dura-
25 ble goods and complex consumer goods, the

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1 Administrator shall exempt replacement
2 parts that are designed prior to the date of
3 publication in the Federal Register of the
4 rule under subsection (a), unless the Ad-
5 ministrator finds that such replacement
6 parts contribute significantly to the risk,
7 identified in a risk evaluation conducted
8 under subsection (b)(4)(A), to the general
9 population or to an identified potentially
10 exposed or susceptible subpopulation.
11 "(ii) DEFINITIONS.—In this subpara-
12 graph—
13 "(I) the term 'complex consumer
14 goods' means electronic or mechanical
15 devices composed of multiple manu-
16 factured components, with an in-
17 tended useful life of 3 or more years,
18 where the product is typically not con-
19 sumed, destroyed, or discarded after a
20 single use, and the components of
21 which would be impracticable to rede-
22 sign or replace; and
23 "(II) the term 'complex durable
24 goods' means manufactured goods
25 composed of 100 or more manufac-

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1 tured components, with an intended
2 useful life of 5 or more years, where
3 the product is typically not consumed,
4 destroyed, or discarded after a single
5 use.
6 "(E) ARTICLES.—In selecting among pro-
7 hibitions and other restrictions, the Admini-
8 trator shall apply such prohibitions or other re-
9 strictions to an article or category of articles
10 containing the chemical substance or mixture
11 only to the extent necessary to address the
12 identified risks from exposure to the chemical
13 substance or mixture, so that the substance or
14 mixture does not present an unreasonable risk
15 of injury to health or the environment identified
16 in the risk evaluation conducted in accordance
17 with subsection (b)(4)(A).
18 "(3) PROCEDURES.—When prescribing a rule
19 under subsection (a) the Administrator shall proceed
20 in accordance with section 553 of title 5, United
21 States Code (without regard to any reference in such
22 section to sections 556 and 557 of such title), and
23 shall also—

1 "(A) publish a notice of proposed rule-
2 making stating with particularity the reason for
3 the proposed rule;
4 "(B) allow interested persons to submit
5 written data, views, and arguments, and make
6 all such submissions publicly available;
7 "(C) promulgate a final rule based on the
8 matter in the rulemaking record; and
9 "(D) make and publish with the rule the
10 determination described in subsection (a).";
11 (5) in subsection (d)—
12 (A) by redesignating paragraph (2) as
13 paragraph (3);
14 (B) by striking paragraph (1) and insert-
15 ing the following:
16 "(1) IN GENERAL.—In any rule under sub-
17 section (a), the Administrator shall—
18 "(A) specify the date on which it shall take
19 effect, which date shall be as soon as prac-
20 ticable;
21 "(B) except as provided in subparagraph
22 (D), specify mandatory compliance dates for all
23 of the requirements under a rule under sub-
24 section (a), which shall be as soon as prac-
25 ticable, but not later than 5 years after the date

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1 of promulgation of the rule, except in a case of
2 a use exempted under subsection (g);
3 "(C) specify mandatory compliance dates
4 for the start of ban or phase-out requirements
5 under a rule under subsection (a), which shall
6 be as soon as practicable, but not later than 5
7 years after the date of promulgation of the rule,
8 except in the case of the use exempted under
9 subsection (g);
10 "(D) specify mandatory compliance dates
11 for full implementation of ban or phase-out re-
12 quirements under a rule under subsection (a),
13 which shall be as soon as practicable; and
14 "(E) provide for a reasonable transition
15 period.
16 "(2) VARIABILITY.—As determined by the Ad-
17 ministrator, the compliance dates established under
18 paragraph (1) may vary for different affected per-
19 sons."; and
20 (C) in paragraph (3), as so redesignated
21 by subparagraph (A) of this paragraph, by
22 striking "upon its publication" and all that fol-
23 lows through "respecting such rule if" and in-
24 serting ", and compliance with the proposed re-
25 quirements to be mandatory, upon publication

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1 in the Federal Register of the proposed rule
2 and until the compliance dates applicable to
3 such requirements in a final rule promulgated
4 under section 6(a) or until the Administrator
5 revokes such proposed rule, in accordance with
6 subparagraph (B), if";
7 (6) in subsection (e)(4), by striking "para-
8 graphs (2), (3), and (4)" and inserting "paragraph
9 (3)"; and
10 (7) by adding at the end the following new sub-
11 sections:
12 "(g) EXEMPTIONS.—
13 "(1) CRITERIA FOR EXEMPTION.—The Admin-
14 istrator may, as part of a rule promulgated under
15 subsection (a), or in a separate rule, grant an ex-
16 emption from a requirement of a subsection (a) rule
17 for a specific condition of use of a chemical sub-
18 stance or mixture, if the Administrator finds that—
19 "(A) the specific use is a critical or essen-
20 tial use for which no technically and economi-
21 cally feasible safer alternative is available, tak-
22 ing into consideration hazard and exposure;
23 "(B) compliance with the requirement, as
24 applied with respect to the specific use, would

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1 significantly disrupt the national economy, na-
2 tional security, or critical infrastructure; or
3 "(C) the use of the chemical substance or
4 mixture, as compared to reasonably available al-
5 ternatives, provides a substantial benefit to
6 health, the environment, or public safety.
7 "(2) EXEMPTION ANALYSIS AND STATEMENT.—
8 In proposing an exemption under this subsection,
9 the Administrator shall analyze the need for the ex-
10 emption, and shall make public the analysis and a
11 statement describing how the analysis was taken
12 into account.
13 "(3) PERIOD OF EXEMPTION.—The Admini-
14 trator shall establish, as part of a rule under this
15 subsection, a time limit on any exemption for a time
16 to be determined by the Administrator as reasonable
17 on a case-by-case basis, and, by rule, may extend,
18 modify, or eliminate an exemption if the Admini-
19 trator determines, on the basis of reasonably avail-
20 able information and after adequate public justifica-
21 tion, the exemption warrants extension or modifica-
22 tion or is no longer necessary.
23 "(4) CONDITIONS.—As part of a rule promul-
24 gated under this subsection, the Administrator shall
25 include conditions, including reasonable record-

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1 keeping, monitoring, and reporting requirements, to
2 the extent that the Administrator determines the
3 conditions are necessary to protect health and the
4 environment while achieving the purposes of the ex-
5 emption.
6 "(h) CHEMICALS THAT ARE PERSISTENT, BIO-
7 ACCUMULATIVE, AND TOXIC.—
8 "(1) EXPEDITED ACTION.—Not later than 3
9 years after the date of enactment of the Frank R.
10 Lautenberg Chemical Safety for the 21st Century
11 Act, the Administrator shall propose rules under
12 subsection (a) with respect to chemical substances
13 identified in the 2014 update of the TSCA Work
14 Plan for Chemical Assessments—
15 "(A) that the Administrator has a reason-
16 able basis to conclude are toxic and that with
17 respect to persistence and bioaccumulation
18 score high for one and either high or moderate
19 for the other, pursuant to the TSCA Work Plan
20 Chemicals Methods Document published by the
21 Administrator in February 2012 (or a successor
22 scoring system), and are not a metal or a metal
23 compound, and for which the Administrator has
24 not completed a Work Plan Problem Formula-
25 tion, initiated a review under section 5, or en-

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1 tered into a consent agreement under section 4,
2 prior to the date of enactment of the Frank R.
3 Lautenberg Chemical Safety for the 21st Cen-
4 tury Act; and
5 "(B) exposure to which under the condi-
6 tions of use is likely to the general population
7 or to a potentially exposed or susceptible sub-
8 population identified by the Administrator, or
9 the environment, on the basis of an exposure
10 and use assessment conducted by the Admini-
11 trator.
12 "(2) NO RISK EVALUATION REQUIRED.—The
13 Administrator shall not be required to conduct risk
14 evaluations on chemical substances that are subject
15 to paragraph (1).
16 "(3) FINAL RULE.—Not later than 18 months
17 after proposing a rule pursuant to paragraph (1),
18 the Administrator shall promulgate a final rule
19 under subsection (a).
20 "(4) SELECTING RESTRICTIONS.—In selecting
21 among prohibitions and other restrictions promul-
22 gated in a rule under subsection (a) pursuant to
23 paragraph (1), the Administrator shall address the
24 risks of injury to health or the environment that the
25 Administrator determines are presented by the

1 chemical substance and shall reduce exposure to the
2 substance to the extent practicable.
3 "(5) RELATIONSHIP TO SUBSECTION (b).—If,
4 at any time prior to the date that is 90 days after
5 the date of enactment of the Frank R. Lautenberg
6 Chemical Safety for the 21st Century Act, the Ad-
7 ministrator makes a designation under subsection
8 (b)(1)(B)(i), or receives a request under subsection
9 (b)(4)(C)(ii) that meets the criteria prescribed by
10 the Administrator in the rule promulgated under
11 subsection (b)(4)(B), such chemical substance shall
12 not be subject to this subsection, except that in se-
13 lecting among prohibitions and other restrictions
14 promulgated in a rule pursuant to subsection (a),
15 the Administrator shall both ensure that the chem-
16 ical substance meets the rulemaking standard under
17 subsection (a) and reduce exposure to the substance
18 to the extent practicable.
19 "(i) FINAL AGENCY ACTION.—Under this section
20 and subject to section 18—
21 "(1) a determination by the Administrator
22 under subsection (b)(4)(A) that a chemical sub-
23 stance does not present an unreasonable risk of in-
24 jury to health or the environment shall be issued by
25 order and considered to be a final agency action, ef-

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1 fective beginning on the date of issuance of the
2 order; and
3 "(2) a final rule promulgated under subsection
4 (a), including the associated determination by the
5 Administrator under subsection (b)(4)(A) that a
6 chemical substance presents an unreasonable risk of
7 injury to health or the environment, shall be consid-
8 ered to be a final agency action, effective beginning
9 on the date of promulgation of the final rule.
10 "(j) DEFINITION.—For the purposes of this Act, the
11 term 'requirement' as used in this section shall not dis-
12 place statutory or common law.".
13 **SEC. 7. IMMINENT HAZARDS.**
14 Section 7 of the Toxic Substances Control Act (15
15 U.S.C. 2606) is amended—
16 (1) in subsection (b)(1), by inserting "(as iden-
17 tified by the Administrator without consideration of
18 costs or other nonrisk factors)" after "from the un-
19 reasonable risk"; and
20 (2) in subsection (f), by inserting ", without
21 consideration of costs or other nonrisk factors" after
22 "widespread injury to health or the environment".
23 **SEC. 8. REPORTING AND RETENTION OF INFORMATION.**
24 (a) IN GENERAL.—Section 8 of the Toxic Substances
25 Control Act (15 U.S.C. 2607) is amended—

1 (1) in subsection (a)—
2 (A) in paragraph (2), by striking the mat-
3 ter that follows subparagraph (G);
4 (B) in paragraph (3), by adding at the end
5 the following:
6 "(C) Not later than 180 days after the date of enact-
7 ment of the Frank R. Lautenberg Chemical Safety for the
8 21st Century Act, and not less frequently than once every
9 10 years thereafter, the Administrator, after consultation
10 with the Administrator of the Small Business Administra-
11 tion, shall—
12 "(i) review the adequacy of the standards pre-
13 scribed under subparagraph (B); and
14 "(ii) after providing public notice and an oppor-
15 tunity for comment, make a determination as to
16 whether revision of the standards is warranted.";
17 and
18 (C) by adding at the end the following:
19 "(4) CONTENTS.—The rules promulgated pur-
20 suant to paragraph (1)—
21 "(A) may impose differing reporting and
22 recordkeeping requirements on manufacturers
23 and processors; and
24 "(B) shall include the level of detail nec-
25 essary to be reported, including the manner by

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1 which use and exposure information may be re-
2 ported.
3 "(5) ADMINISTRATION.—In carrying out this
4 section, the Administrator shall, to the extent fea-
5 sible—
6 "(A) not require reporting which is unnec-
7 essary or duplicative;
8 "(B) minimize the cost of compliance with
9 this section and the rules issued thereunder on
10 small manufacturers and processors; and
11 "(C) apply any reporting obligations to
12 those persons likely to have information rel-
13 evant to the effective implementation of this
14 title.
15 "(6) NEGOTIATED RULEMAKING.—(A) The Ad-
16 ministrator shall enter into a negotiated rulemaking
17 pursuant to subchapter III of chapter 5 of title 5,
18 United States Code, to develop and publish, not
19 later than 3 years after the date of enactment of the
20 Frank R. Lautenberg Chemical Safety for the 21st
21 Century Act, a proposed rule providing for limiting
22 the reporting requirements, under this subsection,
23 for manufacturers of any inorganic byproducts,
24 when such byproducts, whether by the byproduct

1 manufacturer or by any other person, are subse-
2 quently recycled, reused, or reprocessed.
3 "(B) Not later than 3 and one-half years after
4 such date of enactment, the Administrator shall pub-
5 lish a final rule resulting from such negotiated rule-
6 making."; and
7 (2) in subsection (b), by adding at the end the
8 following:
9 "(3) NOMENCLATURE.—
10 "(A) IN GENERAL.—In carrying out para-
11 graph (1), the Administrator shall—
12 "(i) maintain the use of Class 2 no-
13 menclature in use on the date of enact-
14 ment of the Frank R. Lautenberg Chem-
15 ical Safety for the 21st Century Act;
16 "(ii) maintain the use of the Soap and
17 Detergent Association Nomenclature Sys-
18 tem, published in March 1978 by the Ad-
19 ministrator in section 1 of addendum III
20 of the document entitled 'Candidate List of
21 Chemical Substances', and further de-
22 scribed in the appendix A of volume I of
23 the 1985 edition of the Toxic Substances
24 Control Act Substances Inventory (EPA
25 Document No. EPA–560/7–85–002a); and

1 "(iii) treat the individual members of
2 the categories of chemical substances iden-
3 tified by the Administrator as statutory
4 mixtures, as defined in Inventory descrip-
5 tions established by the Administrator, as
6 being included on the list established under
7 paragraph (1).
8 "(B) MULTIPLE NOMENCLATURE LIST-
9 INGS.—If a manufacturer or processor dem-
10 onstrates to the Administrator that a chemical
11 substance appears multiple times on the list
12 published under paragraph (1) under different
13 CAS numbers, the Administrator may recognize
14 the multiple listings as a single chemical sub-
15 stance.
16 "(C) RELATIONSHIP TO SECTION 5.—
17 "(i) CHEMICAL SUBSTANCES DE-
18 SCRIBED BY CATEGORIES.—Notwith-
19 standing subparagraph (A), a chemical
20 substance that is described in subpara-
21 graph (A)(iii) is a new chemical substance
22 if the chemical substance is manufactured
23 for the first time after the date of enact-
24 ment of the Frank R. Lautenberg Chem-
25 ical Safety for the 21st Century Act and

1 has not after that date been listed individ-
2 ually on the list published under paragraph
3 (1), following review pursuant to section 5.
4 "(ii) CHEMICAL SUBSTANCES
5 GROUPED BY CAS NUMBER.—Nothing in
6 subparagraph (B), nor any action of the
7 Administrator pursuant to subparagraph
8 (B), shall be construed as a basis to con-
9 clude that any chemical substance is not a
10 new chemical substance.
11 "(4) CHEMICAL SUBSTANCES IN COMMERCE.—
12 "(A) RULES.—
13 "(i) IN GENERAL.—Not later than 1
14 year after the date of enactment of the
15 Frank R. Lautenberg Chemical Safety for
16 the 21st Century Act, the Administrator,
17 by rule, shall require manufacturers, and
18 may require processors, subject to the limi-
19 tations under subsection (a)(5)(A), to no-
20 tify the Administrator, by not later than
21 180 days after the date on which the final
22 rule is published in the Federal Register,
23 of each chemical substance on the list pub-
24 lished under paragraph (1) that the manu-
25 facturer or processor, as applicable, has

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1 manufactured or processed for a non-
2 exempt commercial purpose during the 10-
3 year period ending on the day before the
4 date of enactment of the Frank R. Lauten-
5 berg Chemical Safety for the 21st Century
6 Act.
7 "(ii) ACTIVE SUBSTANCES.—The Ad-
8 ministrator shall designate chemical sub-
9 stances for which notices are received
10 under clause (i) to be active substances on
11 the list published under paragraph (1).
12 "(iii) INACTIVE SUBSTANCES.—The
13 Administrator shall designate chemical
14 substances for which no notices are re-
15 ceived under clause (i) to be inactive sub-
16 stances on the list published under para-
17 graph (1).
18 "(iv) LIMITATION.—No chemical sub-
19 stance on the list published under para-
20 graph (1) shall be removed from such list
21 by reason of the implementation of this
22 subparagraph, or be subject to section
23 5ø(a)(1)(A)(i)¿ by reason of a change to
24 active status under paragraph (5)(B).

1 "(B) CONFIDENTIAL CHEMICAL SUB-
2 STANCES.—In promulgating a rule under sub-
3 paragraph (A), the Administrator shall—
4 "(i) maintain the list under paragraph
5 (1), which shall include a confidential por-
6 tion and a nonconfidential portion con-
7 sistent with this section and section 14;
8 "(ii) require any manufacturer or
9 processor of a chemical substance on the
10 confidential portion of the list published
11 under paragraph (1) that seeks to main-
12 tain an existing claim for protection
13 against disclosure of the specific chemical
14 identity of the chemical substance as con-
15 fidential pursuant to section 14 to submit
16 a notice under subparagraph (A) that in-
17 cludes such request;
18 "(iii) require the substantiation of
19 those claims pursuant to section 14 and in
20 accordance with the review plan described
21 in subparagraph (C); and
22 "(iv) move any active chemical sub-
23 stance for which no request was received to
24 maintain an existing claim for protection
25 against disclosure of the specific chemical

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1 identity of the chemical substance as con-
2 fidential from the confidential portion of
3 the list published under paragraph (1) to
4 the nonconfidential portion of that list.
5 "(C) REVIEW PLAN.—Not later than 1
6 year after the date on which the Administrator
7 compiles the initial list of active substances pur-
8 suant to subparagraph (A), the Administrator
9 shall promulgate a rule that establishes a plan
10 to review all claims to protect the specific chem-
11 ical identities of chemical substances on the
12 confidential portion of the list published under
13 paragraph (1) that are asserted pursuant to
14 subparagraph (B).
15 "(D) REQUIREMENTS OF REVIEW PLAN.—
16 In establishing the review plan under subpara-
17 graph (C), the Administrator shall—
18 "(i) require, at a time specified by the
19 Administrator, all manufacturers or proc-
20 essors asserting claims under subpara-
21 graph (B) to substantiate the claim, in ac-
22 cordance with section 14, unless the manu-
23 facturer or processor has substantiated the
24 claim in a submission made to the Admin-
25 istrator during the 5-year period ending on

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1 the last day of the of the time period speci-
2 fied by the Administrator; and
3 "(ii) in accordance with section 14—
4 "(I) review each substantiation—
5 "(aa) submitted pursuant to
6 clause (i) to determine if the
7 claim qualifies for protection
8 from disclosure; and
9 "(bb) submitted previously
10 by a manufacturer or processor
11 and relied on in lieu of the sub-
12 stantiation required pursuant to
13 clause (i), if the substantiation
14 has not been previously reviewed
15 by the Administrator, to deter-
16 mine if the claim warrants pro-
17 tection from disclosure;
18 "(II) approve, approve in part
19 and deny in part, or deny each claim;
20 and
21 "(III) except as provided in this
22 section and section 14, protect from
23 disclosure information for which the
24 Administrator approves such a claim

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1 for a period of 10 years, unless, prior
2 to the expiration of the period—
3 "(aa) the person notifies the
4 Administrator that the person is
5 withdrawing the claim, in which
6 case the Administrator shall not
7 protect the information from dis-
8 closure; or
9 "(bb) the Administrator oth-
10 erwise becomes aware that the
11 information does not qualify for
12 protection from disclosure, in
13 which case the Administrator
14 shall take the actions described
15 in section 14(g)(2).
16 "(E) TIMELINE FOR COMPLETION OF RE-
17 VIEWS.—
18 "(i) IN GENERAL.—The Administrator
19 shall implement the review plan so as to
20 complete reviews of all claims specified in
21 subparagraph (C) not later than 5 years
22 after the date on which the Administrator
23 compiles the initial list of active substances
24 pursuant to subparagraph (A).
25 "(ii) CONSIDERATIONS.—

1 "(I) IN GENERAL.—The Admin-
2 istrator may extend the deadline for
3 completion of the reviews for not more
4 than 2 additional years, after an ade-
5 quate public justification, if the Ad-
6 ministrator determines that the exten-
7 sion is necessary based on the number
8 of claims needing review and the
9 available resources.
10 "(II) ANNUAL REVIEW GOAL AND
11 RESULTS.—At the beginning of each
12 year, the Administrator shall publish
13 an annual goal for reviews and the
14 number of reviews completed in the
15 prior year.
16 "(5) ACTIVE AND INACTIVE SUBSTANCES.—
17 "(A) IN GENERAL.—The Administrator
18 shall keep designations of active substances and
19 inactive substances on the list published under
20 paragraph (1) current.
21 "(B) CHANGE TO ACTIVE STATUS.—
22 "(i) IN GENERAL.—Any person that
23 intends to manufacture or process for a
24 nonexempt commercial purpose a chemical
25 substance that is designated as an inactive

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1 substance shall notify the Administrator
2 before the date on which the inactive sub-
3 stance is manufactured or processed.
4 "(ii) CONFIDENTIAL CHEMICAL IDEN-
5 TITY.—If a person submitting a notice
6 under clause (i) for an inactive substance
7 on the confidential portion of the list pub-
8 lished under paragraph (1) seeks to main-
9 tain an existing claim for protection
10 against disclosure of the specific chemical
11 identity of the inactive substance as con-
12 fidential, the person shall, consistent with
13 the requirements of section 14—
14 "(I) in the notice submitted
15 under clause (i), assert the claim; and
16 "(II) by not later than 30 days
17 after providing the notice under clause
18 (i), substantiate the claim.
19 "(iii) ACTIVE STATUS.—On receiving
20 a notification under clause (i), the Admin-
21 istrator shall—
22 "(I) designate the applicable
23 chemical substance as an active sub-
24 stance;

1 "(II) pursuant to section 14,
2 promptly review any claim and associ-
3 ated substantiation submitted pursu-
4 ant to clause (ii) for protection
5 against disclosure of the specific
6 chemical identity of the chemical sub-
7 stance and approve, approve in part
8 and deny in part, or deny the claim;
9 "(III) except as provided in this
10 section and section 14, protect from
11 disclosure the specific chemical iden-
12 tity of the chemical substance for
13 which the Administrator approves a
14 claim under subclause (II) for a pe-
15 riod of 10 years, unless, prior to the
16 expiration of the period—
17 "(aa) the person notifies the
18 Administrator that the person is
19 withdrawing the claim, in which
20 case the Administrator shall not
21 protect the information from dis-
22 closure; or
23 "(bb) the Administrator oth-
24 erwise becomes aware that the
25 information does not qualify for

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1 protection from disclosure, in
2 which case the Administrator
3 shall take the actions described
4 in section 14(g)(2); and
5 "(IV) pursuant to section 6(b),
6 review the priority of the chemical
7 substance as the Administrator deter-
8 mines to be necessary.
9 "(C) CATEGORY STATUS.—The list of inac-
10 tive substances shall not be considered to be a
11 category for purposes of section 26(c).
12 "(6) INTERIM LIST OF ACTIVE SUBSTANCES.—
13 Prior to the promulgation of the rule required under
14 paragraph (4)(A), the Administrator shall designate
15 the chemical substances reported under part 711 of
16 title 40, Code of Federal Regulations (as in effect on
17 the date of enactment of the Frank R. Lautenberg
18 Chemical Safety for the 21st Century Act), during
19 the reporting period that most closely preceded the
20 date of enactment of the Frank R. Lautenberg
21 Chemical Safety for the 21st Century Act, as the in-
22 terim list of active substances for the purposes of
23 section 6(b).

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1 "(7) PUBLIC INFORMATION.—Subject to this
2 subsection and section 14, the Administrator shall
3 make available to the public—
4 "(A) each specific chemical identity on the
5 nonconfidential portion of the list published
6 under paragraph (1), along with the Adminis-
7 trator's designation of the chemical substance
8 as an active or inactive substance;
9 "(B) the unique identifier assigned under
10 section 14, accession number, generic name,
11 and, if applicable, premanufacture notice case
12 number for each chemical substance on the con-
13 fidential portion of the list published under
14 paragraph (1) for which a claim of confiden-
15 tiality was received; and
16 "(C) the specific chemical identity of any
17 active substance for which—
18 "(i) a claim for protection against dis-
19 closure of the specific chemical identity of
20 the active substance was not asserted, as
21 required under this subsection or section
22 14;
23 "(ii) all claims for protection against
24 disclosure of the specific chemical identity

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1 of the active substance have been denied
2 by the Administrator; or
3 "(iii) the time period for protection
4 against disclosure of the specific chemical
5 identity of the active substance has ex-
6 pired.
7 "(8) LIMITATION.—No person may assert a
8 new claim under this subsection or section 14 for
9 protection from disclosure of a specific chemical
10 identity of any active or inactive substance for which
11 a notice is received under paragraph (4)(A)(i) or
12 (5)(B)(i) that is not on the confidential portion of
13 the list published under paragraph (1).
14 "(9) CERTIFICATION.—Under the rules promul-
15 gated under this subsection, manufacturers and
16 processors, as applicable, shall be required—
17 "(A) to certify that each notice or substan-
18 tiation the manufacturer or processor submits
19 complies with the requirements of the rule, and
20 that any confidentiality claims are true and cor-
21 rect; and
22 "(B) to retain a record documenting com-
23 pliance with the rule and supporting confiden-
24 tiality claims for a period of 5 years beginning
25 on the last day of the submission period.".

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1 (b) MERCURY INVENTORY.—Section 8(b) of the
2 Toxic Substances Control Act (15 U.S.C. 2607(b)) (as
3 amended by subsection (a)) is further amended by adding
4 at the end the following:
5 "(10) MERCURY.—
6 "(A) DEFINITION OF MERCURY.—In this
7 paragraph, notwithstanding section 3(2)(B), the
8 term 'mercury' means—
9 "(i) elemental mercury; and
10 "(ii) a mercury compound.
11 "(B) PUBLICATION.—Not later than April
12 1, 2017, and every 3 years thereafter, the Ad-
13 ministrator shall carry out and publish in the
14 Federal Register an inventory of mercury sup-
15 ply, use, and trade in the United States.
16 "(C) PROCESS.—In carrying out the inven-
17 tory under subparagraph (B), the Adminis-
18 trator shall—
19 "(i) identify any manufacturing proc-
20 esses or products that intentionally add
21 mercury; and
22 "(ii) recommend actions, including
23 proposed revisions of Federal law or regu-
24 lations, to achieve further reductions in
25 mercury use.

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1 "(D) REPORTING.—
2 "(i) IN GENERAL.—To assist in the
3 preparation of the inventory under sub-
4 paragraph (B), any person who manufac-
5 tures mercury or mercury-added products
6 or otherwise intentionally uses mercury in
7 a manufacturing process shall make peri-
8 odic reports to the Administrator, at such
9 time and including such information as the
10 Administrator shall determine by rule pro-
11 mulgated not later than 2 years after the
12 date of enactment of this paragraph.
13 "(ii) COORDINATION.—To avoid dupli-
14 cation, the Administrator shall coordinate
15 the reporting under this subparagraph
16 with the Interstate Mercury Education and
17 Reduction Clearinghouse and any applica-
18 ble reporting requirements under the Solid
19 Waste Disposal Act.
20 "(iii) EXEMPTION.—Clause (i) shall
21 not apply to a person engaged in the gen-
22 eration, handling, or management of mer-
23 cury-containing waste, unless that person
24 manufactures or recovers mercury in the
25 management of that waste.".

1 **SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.**

2 Section 9 of the Toxic Substances Control Act (15
3 U.S.C. 2608) is amended—

4 (1) in subsection (a)—

5 (A) in paragraph (1)—

6 (i) by striking "has reasonable basis
7 to conclude" and inserting "determines";
8 and

9 (ii) by inserting ", without consider-
10 ation of costs or other nonrisk factors, in-
11 cluding an unreasonable risk to a poten-
12 tially exposed or susceptible subpopulation
13 identified as relevant by the Administrator,
14 under the conditions of use," after "or the
15 environment";

16 (B) in paragraph (2)—

17 (i) in subparagraph (A), by inserting
18 ", within the time period specified by the
19 Administrator in the report," after "issues
20 an order"; and

21 (ii) in subparagraph (B), by inserting
22 "responds within the time period specified
23 by the Administrator in the report and"
24 before "initiates, within 90";

25 (C) by redesignating paragraph (3) as
26 paragraph (6); and

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1 (D) by inserting after paragraph (2) the
2 following:
3 "(3) The Administrator shall take the actions de-
4 scribed in paragraph (4) if the Administrator makes a re-
5 port under paragraph (1) with respect to a chemical sub-
6 stance or mixture and the agency to which the report was
7 made does not—
8 "(A) issue the order described in paragraph
9 (2)(A) within the time period specified by the Ad-
10 ministrator in the report; or
11 "(B)(i) respond under paragraph (1) within the
12 timeframe specified by the Administrator in the re-
13 port; and
14 "(ii) initiate action within 90 days of publica-
15 tion in the Federal Register of the response de-
16 scribed in clause (i).
17 "(4) If an agency to which a report is submitted
18 under paragraph (1) does not take the actions described
19 in subparagraph (A) or (B) of paragraph (3), the Admin-
20 istrator shall—
21 "(A) initiate action under section 6(a) with re-
22 spect to the risk described in such report; or
23 "(B) take any action authorized or required
24 under section 7.

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1 "(5) This subsection shall not relieve the Adminis-
2 trator of any obligation to take any appropriate action
3 under section 6(a) or 7 to address risks from the manufac-
4 ture, processing, distribution in commerce, use, or disposal
5 of a chemical substance or mixture, or any combination
6 of those activities, that are not identified in a report issued
7 by the Administrator under paragraph (1).";
8 (2) in subsection (b)—
9 (A) by striking "The Administrator shall
10 coordinate" and inserting "(1) The Adminis-
11 trator shall coordinate"; and
12 (B) by adding at the end the following:
13 "(2) In making a determination under paragraph (1)
14 that it is in the public interest for the Administrator to
15 take an action under this title with respect to a chemical
16 substance or mixture rather than under another law ad-
17 ministered in whole or in part by the Administrator, the
18 Administrator shall consider, based on information rea-
19 sonably available to the Administrator, all relevant aspects
20 of the risk described in paragraph (1) and a comparison
21 of the estimated costs and efficiencies of the action to be
22 taken under this title and an action to be taken under
23 such other law to protect against such risk."; and
24 (3) by adding at the end the following:

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1 "(e) EXPOSURE INFORMATION.—In addition to the
2 requirements of subsection (a), if the Administrator ob-
3 tains information related to exposures or releases of a
4 chemical substance or mixture that may be prevented or
5 reduced under another Federal law, including a law not
6 administered by the Administrator, the Administrator
7 shall make such information available to the relevant Fed-
8 eral agency or office of the Environmental Protection
9 Agency.".

10 **SEC. 10. EXPORTS OF ELEMENTAL MERCURY.**

11 (a) PROHIBITION ON EXPORT OF CERTAIN MERCURY
12 COMPOUNDS.—Section 12(c) of the Toxic Substances
13 Control Act (15 U.S.C. 2611(c)) is amended—

14 (1) in the subsection heading, by inserting
15 "AND MERCURY COMPOUNDS" after "MERCURY";
16 and

17 (2) by adding at the end the following:

18 "(7) PROHIBITION ON EXPORT OF CERTAIN
19 MERCURY COMPOUNDS.—

20 "(A) IN GENERAL.—Effective January 1,
21 2020, the export of the following mercury com-
22 pounds is prohibited:

23 "(i) Mercury (I) chloride or calomel.

24 "(ii) Mercury (II) oxide.

25 "(iii) Mercury (II) sulfate.

1 "(iv) Mercury (II) nitrate.
2 "(v) Cinnabar or mercury sulphide.
3 "(vi) Any mercury compound that the
4 Administrator adds to the list published
5 under subparagraph (B) by rule, on deter-
6 mining that exporting that mercury com-
7 pound for the purpose of regenerating ele-
8 mental mercury is technically feasible.
9 "(B) PUBLICATION.—Not later than 90
10 days after the date of enactment of the Frank
11 R. Lautenberg Chemical Safety for the 21st
12 Century Act, and as appropriate thereafter, the
13 Administrator shall publish in the Federal Reg-
14 ister a list of the mercury compounds that are
15 prohibited from export under this paragraph.
16 "(C) PETITION.—Any person may petition
17 the Administrator to add a mercury compound
18 to the list published under subparagraph (B).
19 "(D) ENVIRONMENTALLY SOUND DIS-
20 POSAL.—This paragraph does not prohibit the
21 export of mercury compounds on the list pub-
22 lished under subparagraph (B) to member
23 countries of the Organization for Economic Co-
24 operation and Development for environmentally
25 sound disposal, on the condition that no mer-

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1 cury or mercury compounds so exported are to
2 be recovered, recycled, or reclaimed for use, or
3 directly reused, after such export.
4 "(E) REPORT.—Not later than 5 years
5 after the date of enactment of the Frank R.
6 Lautenberg Chemical Safety for the 21st Cen-
7 tury Act, the Administrator shall evaluate any
8 exports of mercury compounds on the list pub-
9 lished under subparagraph (B) for disposal that
10 occurred after such date of enactment and shall
11 submit to Congress a report that—
12 "(i) describes volumes and sources of
13 mercury compounds on the list published
14 under subparagraph (B) exported for dis-
15 posal;
16 "(ii) identifies receiving countries of
17 such exports;
18 "(iii) describes methods of disposal
19 used after such export;
20 "(iv) identifies issues, if any, pre-
21 sented by the export of mercury com-
22 pounds on the list published under sub-
23 paragraph (B);
24 "(v) includes an evaluation of man-
25 agement options in the United States for

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1 mercury compounds on the list published
2 under subparagraph (B), if any, that are
3 commercially available and comparable in
4 cost and efficacy to methods being utilized
5 in such receiving countries; and
6 "(vi) makes a recommendation re-
7 garding whether Congress should further
8 limit or prohibit the export of mercury
9 compounds on the list published under
10 subparagraph (B) for disposal.
11 "(F) EFFECT ON OTHER LAW.—Nothing
12 in this paragraph shall be construed to affect
13 the authority of the Administrator under the
14 Solid Waste Disposal Act (42 U.S.C. 6901 et
15 seq.).".
16 (b) TEMPORARY GENERATOR ACCUMULATION.—Sec-
17 tion 5 of the Mercury Export Ban Act of 2008 (42 U.S.C.
18 6939f) is amended—
19 (1) in subsection (a)(2), by striking "2013" and
20 inserting "2019";
21 (2) in subsection (b)—
22 (A) in paragraph (1)—
23 (i) by redesignating subparagraphs
24 (A), (B), and (C), as clauses (i), (ii), and

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1 (iii), respectively and indenting appro-
2 priately;
3 (ii) in the first sentence, by striking
4 "After consultation" and inserting the fol-
5 lowing:
6 "(A) ASSESSMENT AND COLLECTION.—
7 After consultation";
8 (iii) in the second sentence, by strik-
9 ing "The amount of such fees" and insert-
10 ing the following:
11 "(B) AMOUNT.—The amount of the fees
12 described in subparagraph (A)";
13 (iv) in subparagraph (B) (as so des-
14 ignated)—
15 (I) in clause (i) (as so redesig-
16 nated), by striking "publically avail-
17 able not later than October 1, 2012"
18 and inserting "publicly available not
19 later than October 1, 2018";
20 (II) in clause (ii) (as so redesig-
21 nated), by striking "and";
22 (III) in clause (iii) (as so redesig-
23 nated), by striking the period at the
24 end and inserting ", subject to clause
25 (iv); and"; and

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1 (IV) by adding at the end the fol-
2 lowing:
3 "(iv) for generators temporarily accu-
4 mulating elemental mercury in a facility
5 subject to subparagraphs (B) and (D)(iv)
6 of subsection (g)(2) if the facility des-
7 ignated in subsection (a) is not operational
8 by January 1, 2019, shall be adjusted to
9 subtract the cost of the temporary accumu-
10 lation during the period in which the facil-
11 ity designated under subsection (a) is not
12 operational."; and
13 (v) by adding at the end the following:
14 "(C) CONVEYANCE OF TITLE AND PERMIT-
15 TING.—If the facility designated in subsection
16 (a) is not operational by January 1, 2020, the
17 Secretary—
18 "(i) shall immediately accept the con-
19 veyance of title to all elemental mercury
20 that has accumulated in facilities in ac-
21 cordance with subsection (g)(2)(D), before
22 January 1, 2020, and deliver the accumu-
23 lated mercury to the facility designated
24 under subsection (a) on the date on which
25 the facility becomes operational;

1 "(ii) shall pay any applicable Federal
2 permitting costs, including the costs for
3 permits issued under section 3005(c) of
4 the Solid Waste Disposal Act (42 U.S.C.
5 6925(c)); and
6 "(iii) shall store, or pay the cost of
7 storage of, until the time at which a facil-
8 ity designated in subsection (a) is oper-
9 ational, accumulated mercury to which the
10 Secretary has title under this subpara-
11 graph in a facility that has been issued a
12 permit under section 3005(c) of the Solid
13 Waste Disposal Act (42 U.S.C. 6925(c)).";
14 and
15 (B) in paragraph (2), in the first sentence,
16 by striking "paragraph (1)(C)" and inserting
17 "paragraph (1)(B)(iii)"; and
18 (3) in subsection (g)(2)—
19 (A) in the undesignated material at the
20 end, by striking "This subparagraph" and in-
21 serting the following:
22 "(C) Subparagraph (B)";
23 (B) in subparagraph (C) (as designated by
24 subparagraph (A)), by inserting "of that sub-
25 paragraph" before the period at the end; and

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1 (C) by adding at the end the following:
2 "(D) A generator producing elemental
3 mercury incidentally from the beneficiation or
4 processing of ore or related pollution control ac-
5 tivities may accumulate the mercury produced
6 onsite that is destined for a facility designated
7 by the Secretary under subsection (a) for more
8 than 90 days without a permit issued under
9 section 3005(c) of the Solid Waste Disposal Act
10 (42 U.S.C. 6925(c)), and shall not be subject to
11 the storage prohibition of section 3004(j) of
12 that Act (42 U.S.C. 6924(j)), if—
13 "(i) the Secretary is unable to accept
14 the mercury at a facility designated by the
15 Secretary under subsection (a) for reasons
16 beyond the control of the generator;
17 "(ii) the generator certifies in writing
18 to the Secretary that the generator will
19 ship the mercury to a designated facility
20 when the Secretary is able to accept the
21 mercury;
22 "(iii) the generator certifies in writing
23 to the Secretary that the generator is stor-
24 ing only mercury the generator has pro-
25 duced or recovered onsite and will not sell,

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1 or otherwise place into commerce, the mer-
2 cury; and
3 "(iv) the generator has obtained an
4 identification number under section 262.12
5 of title 40, Code of Federal Regulations,
6 and complies with the requirements de-
7 scribed in paragraphs (1) through (4) of
8 section 262.34(a) of title 40, Code of Fed-
9 eral Regulations (as in effect on the date
10 of enactment of this subparagraph).
11 "(E) MANAGEMENT STANDARDS FOR TEM-
12 PORARY STORAGE.—Not later than January 1,
13 2017, the Secretary, after consultation with the
14 Administrator of the Environmental Protection
15 Agency and State agencies in affected States,
16 shall develop and make available guidance that
17 establishes procedures and standards for the
18 management and short-term storage of ele-
19 mental mercury at a generator covered under
20 subparagraph (D), including requirements to
21 ensure appropriate use of flasks or other suit-
22 able containers. Such procedures and standards
23 shall be protective of human health and the en-
24 vironment and shall ensure that the elemental
25 mercury is stored in a safe, secure, and effec-

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1 tive manner. A generator may accumulate mer-
2 cury in accordance with subparagraph (D) im-
3 mediately upon enactment of this subpara-
4 graph, and notwithstanding that guidance
5 called for by this paragraph has not been devel-
6 oped or made available.".
7 (c) INTERIM STATUS.—Section 5(d)(1) of the Mer-
8 cury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is
9 amended—
10 (1) in the fourth sentence, by striking "in exist-
11 ence on or before January 1, 2013,"; and
12 (2) in the last sentence, by striking "January
13 1, 2015" and inserting "January 1, 2020".
14 **SEC. 11. CONFIDENTIAL INFORMATION.**
15 Section 14 of the Toxic Substances Control Act (15
16 U.S.C. 2613) is amended to read as follows:
17 **"SEC. 14. CONFIDENTIAL INFORMATION.**
18 "(a) IN GENERAL.—Except as provided in this sec-
19 tion, the Administrator shall not disclose information that
20 is exempt from disclosure pursuant to subsection (a) of
21 section 552 of title 5, United States Code, by reason of
22 subsection (b)(4) of that section—
23 "(1) that is reported to, or otherwise obtained
24 by, the Administrator under this Act; and

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1 "(2) for which the requirements of subsection
2 (c) are met.
3 In any proceeding under section 552(a) of title 5, United
4 States Code, to obtain information the disclosure of which
5 has been denied because of the provisions of this sub-
6 section, the Administrator may not rely on section
7 552(b)(3) of such title to sustain the Administrator's ac-
8 tion.
9 "(b) INFORMATION NOT PROTECTED FROM DISCLO-
10 SURE.—
11 "(1) MIXED CONFIDENTIAL AND NONCON-
12 FIDENTIAL INFORMATION.—Information that is pro-
13 tected from disclosure under this section, and which
14 is mixed with information that is not protected from
15 disclosure under this section, does not lose its pro-
16 tection from disclosure notwithstanding that it is
17 mixed with information that is not protected from
18 disclosure.
19 "(2) INFORMATION FROM HEALTH AND SAFETY
20 STUDIES.—Subsection (a) does not prohibit the dis-
21 closure of—
22 "(A) any health and safety study which is
23 submitted under this Act with respect to—
24 "(i) any chemical substance or mix-
25 ture which, on the date on which such

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1 study is to be disclosed has been offered
2 for commercial distribution; or
3 "(ii) any chemical substance or mix-
4 ture for which testing is required under
5 section 4 or for which notification is re-
6 quired under section 5; and
7 "(B) any information reported to, or other-
8 wise obtained by, the Administrator from a
9 health and safety study which relates to a
10 chemical substance or mixture described in
11 clause (i) or (ii) of subparagraph (A).
12 This paragraph does not authorize the disclosure of
13 any information, including formulas (including mo-
14 lecular structures) of a chemical substance or mix-
15 ture, that discloses processes used in the manufac-
16 turing or processing of a chemical substance or mix-
17 ture or, in the case of a mixture, the portion of the
18 mixture comprised by any of the chemical substances
19 in the mixture.
20 "(3) OTHER INFORMATION NOT PROTECTED
21 FROM DISCLOSURE.—Subsection (a) does not pro-
22 hibit the disclosure of—
23 "(A) any general information describing
24 the manufacturing volumes, expressed as spe-
25 cific aggregated volumes or, if the Adminis-

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1 trator determines that disclosure of specific ag-
2 gregated volumes would reveal confidential in-
3 formation, expressed in ranges; or
4 "(B) a general description of a process
5 used in the manufacture or processing and in-
6 dustrial, commercial, or consumer functions and
7 uses of a chemical substance, mixture, or article
8 containing a chemical substance or mixture, in-
9 cluding information specific to an industry or
10 industry sector that customarily would be
11 shared with the general public or within an in-
12 dustry or industry sector.
13 "(4) BANS AND PHASE-OUTS.—
14 "(A) IN GENERAL.—If the Administrator
15 promulgates a rule pursuant to section 6(a)
16 that establishes a ban or phase-out of a chem-
17 ical substance or mixture, the protection from
18 disclosure of any information under this section
19 with respect to the chemical substance or mix-
20 ture shall be presumed to no longer apply, sub-
21 ject to subsection (g)(1)(E) and subparagraphs
22 (B) and (C) of this paragraph.
23 "(B) LIMITATIONS.—
24 "(i) CRITICAL USE.—In the case of a
25 chemical substance or mixture for which a

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1 specific condition of use is subject to an
2 exemption pursuant to section 6(g), if the
3 Administrator establishes a ban or phase-
4 out described in subparagraph (A) with re-
5 spect to the chemical substance or mixture,
6 the presumption against protection under
7 such subparagraph shall only apply to in-
8 formation that relates solely to any condi-
9 tions of use of the chemical substance or
10 mixture to which the exemption does not
11 apply.
12 "(ii) EXPORT.—In the case of a chem-
13 ical substance or mixture for which there is
14 manufacture, processing, or distribution in
15 commerce that meets the conditions of sec-
16 tion 12(a)(1), if the Administrator estab-
17 lishes a ban or phase-out described in sub-
18 paragraph (A) with respect to the chemical
19 substance or mixture, the presumption
20 against protection under such subpara-
21 graph shall only apply to information that
22 relates solely to any other manufacture,
23 processing, or distribution in commerce of
24 the chemical substance or mixture for the
25 conditions of use subject to the ban or

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1 phase-out, unless the Administrator makes
2 the determination in section 12(a)(2).
3 "(iii) SPECIFIC CONDITIONS OF
4 USE.—In the case of a chemical substance
5 or mixture for which the Administrator es-
6 tablishes a ban or phase-out described in
7 subparagraph (A) with respect to a specific
8 condition of use of the chemical substance
9 or mixture, the presumption against pro-
10 tection under such subparagraph shall only
11 apply to information that relates solely to
12 the condition of use of the chemical sub-
13 stance or mixture for which the ban or
14 phase-out is established.
15 "(C) REQUEST FOR NONDISCLOSURE.—
16 "(i) IN GENERAL.—A manufacturer
17 or processor of a chemical substance or
18 mixture subject to a ban or phase-out de-
19 scribed in this paragraph may submit to
20 the Administrator, within 30 days of re-
21 ceiving a notification under subsection
22 (g)(2)(A), a request, including documenta-
23 tion supporting such request, that some or
24 all of the information to which the notice
25 applies should not be disclosed or that its

1 disclosure should be delayed, and the Ad-
2 ministrator shall review the request under
3 subsection (g)(1)(E).
4 "(ii) EFFECT OF NO REQUEST OR DE-
5 NIAL.—If no request for nondisclosure or
6 delay is submitted to the Administrator
7 under this subparagraph, or the Adminis-
8 trator denies such a request under sub-
9 section (g)(1)(A), the information shall not
10 be protected from disclosure under this
11 section.
12 "(5) CERTAIN REQUESTS.—If a request is made
13 to the Administrator under section 552(a) of title 5,
14 United States Code, for information reported to or
15 otherwise obtained by the Administrator under this
16 Act that is not protected from disclosure under this
17 subsection, the Administrator may not deny the re-
18 quest on the basis of section 552(b)(4) of title 5,
19 United States Code.
20 "(c) REQUIREMENTS FOR CONFIDENTIALITY
21 CLAIMS.—
22 "(1) ASSERTION OF CLAIMS.—
23 "(A) IN GENERAL.—A person seeking to
24 protect from disclosure any information that
25 person submits under this Act (including infor-

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1 mation described in paragraph (2)) shall assert
2 to the Administrator a claim for protection
3 from disclosure concurrent with submission of
4 the information, in accordance with such rules
5 regarding a claim for protection from disclosure
6 as the Administrator has promulgated or may
7 promulgate pursuant to this title.
8 "(B) INCLUSION.—An assertion of a claim
9 under subparagraph (A) shall include a state-
10 ment that the person has—
11 "(i) taken reasonable measures to pro-
12 tect the confidentiality of the information;
13 "(ii) determined that the information
14 is not required to be disclosed or otherwise
15 made available to the public under any
16 other Federal law;
17 "(iii) a reasonable basis to conclude
18 that disclosure of the information is likely
19 to cause substantial harm to the competi-
20 tive position of the person; and
21 "(iv) a reasonable basis to believe that
22 the information is not readily discoverable
23 through reverse engineering.
24 "(C) ADDITIONAL REQUIREMENTS FOR
25 CLAIMS REGARDING CHEMICAL IDENTITY IN-

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1 FORMATION.—In the case of a claim under sub-
2 paragraph (A) for protection from disclosure of
3 a specific chemical identity, the claim shall in-
4 clude a structurally descriptive generic name for
5 the chemical substance that the Administrator
6 may disclose to the public, subject to the condi-
7 tion that such generic name shall—
8 "(i) be consistent with guidance devel-
9 oped by the Administrator under para-
10 graph (4)(A); and
11 "(ii) describe the chemical structure
12 of the chemical substance as specifically as
13 practicable while protecting those features
14 of the chemical structure—
15 "(I) that are claimed as confiden-
16 tial; and
17 "(II) the disclosure of which
18 would be likely to cause substantial
19 harm to the competitive position of
20 the person.
21 "(2) INFORMATION GENERALLY NOT SUBJECT
22 TO SUBSTANTIATION REQUIREMENTS.—Subject to
23 subsection (f), the following information shall not be
24 subject to substantiation requirements under para-
25 graph (3):

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1 "(A) Specific information describing the
2 processes used in manufacture or processing of
3 a chemical substance, mixture, or article.
4 "(B) Marketing and sales information.
5 "(C) Information identifying a supplier or
6 customer.
7 "(D) In the case of a mixture, details of
8 the full composition of the mixture and the re-
9 spective percentages of constituents.
10 "(E) Specific information regarding the
11 use, function, or application of a chemical sub-
12 stance or mixture in a process, mixture, or arti-
13 cle.
14 "(F) Specific production or import volumes
15 of the manufacturer or processor.
16 "(G) Prior to the date on which a chemical
17 substance is first offered for commercial dis-
18 tribution, the specific chemical identity of the
19 chemical substance, including the chemical
20 name, molecular formula, Chemical Abstracts
21 Service number, and other information that
22 would identify the specific chemical substance,
23 if the specific chemical identity was claimed as
24 confidential at the time it was submitted in a
25 notice under section 5.

1 "(3) SUBSTANTIATION REQUIREMENTS.—Ex-
2 cept as provided in paragraph (2), a person assert-
3 ing a claim to protect information from disclosure
4 under this section shall substantiate the claim, in ac-
5 cordance with such rules as the Administrator has
6 promulgated or may promulgate pursuant to this
7 section.
8 "(4) GUIDANCE.—The Administrator shall de-
9 velop guidance regarding—
10 "(A) the determination of structurally de-
11 scriptive generic names, in the case of claims
12 for the protection from disclosure of specific
13 chemical identity; and
14 "(B) the content and form of the state-
15 ments of need and agreements required under
16 paragraphs (4), (5), and (6) of subsection (d).
17 "(5) CERTIFICATION.—An authorized official of
18 a person described in paragraph (1)(A) shall certify
19 that the statement required to assert a claim sub-
20 mitted pursuant to paragraph (1)(B), and any infor-
21 mation required to substantiate a claim submitted
22 pursuant to paragraph (3), are true and correct.
23 "(d) EXCEPTIONS TO PROTECTION FROM DISCLO-
24 SURE.—Information described in subsection (a)—

1 "(1) shall be disclosed to an officer or employee
2 of the United States—
3 "(A) in connection with the official duties
4 of that person under any Federal law for the
5 protection of health or the environment; or
6 "(B) for a specific Federal law enforce-
7 ment purpose;
8 "(2) shall be disclosed to a contractor of the
9 United States and employees of that contractor—
10 "(A) if, in the opinion of the Adminis-
11 trator, the disclosure is necessary for the satis-
12 factory performance by the contractor of a con-
13 tract with the United States for the perform-
14 ance of work in connection with this Act; and
15 "(B) subject to such conditions as the Ad-
16 ministrator may specify;
17 "(3) shall be disclosed if the Administrator de-
18 termines that disclosure is necessary to protect
19 health or the environment against an unreasonable
20 risk of injury to health or the environment, without
21 consideration of costs or other nonrisk factors, in-
22 cluding an unreasonable risk to a potentially exposed
23 or susceptible subpopulation identified as relevant by
24 the Administrator under the conditions of use;

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1 "(4) shall be disclosed to a State, political sub-
2 division of a State, or tribal government, on written
3 request, for the purpose of administration or en-
4 forcement of a law, if such entity has 1 or more ap-
5 plicable agreements with the Administrator that are
6 consistent with the guidance developed under sub-
7 section (c)(4)(B) and ensure that the entity will take
8 appropriate measures, and has adequate authority,
9 to maintain the confidentiality of the information in
10 accordance with procedures comparable to the proce-
11 dures used by the Administrator to safeguard the in-
12 formation;
13 "(5) shall be disclosed to a health or environ-
14 mental professional employed by a Federal or State
15 agency or tribal government or a treating physician
16 or nurse in a nonemergency situation if such person
17 provides a written statement of need and agrees to
18 sign a written confidentiality agreement with the Ad-
19 ministrator, subject to the conditions that—
20 "(A) the statement of need and confiden-
21 tiality agreement are consistent with the guid-
22 ance developed under subsection (c)(4)(B);
23 "(B) the statement of need shall be a
24 statement that the person has a reasonable
25 basis to suspect that—

1 "(i) the information is necessary for,
2 or will assist in—
3 "(I) the diagnosis or treatment of
4 1 or more individuals; or
5 "(II) responding to an environ-
6 mental release or exposure; and
7 "(ii) 1 or more individuals being diag-
8 nosed or treated have been exposed to the
9 chemical substance or mixture concerned,
10 or an environmental release of or exposure
11 to the chemical substance or mixture con-
12 cerned has occurred; and
13 "(C) the person will not use the informa-
14 tion for any purpose other than the health or
15 environmental needs asserted in the statement
16 of need, except as otherwise may be authorized
17 by the terms of the agreement or by the person
18 who has a claim under this section with respect
19 to the information, except that nothing in this
20 title prohibits the disclosure of any such infor-
21 mation through discovery, subpoena, other
22 court order, or any other judicial process other-
23 wise allowed under applicable Federal or State
24 law;

1 "(6) shall be disclosed in the event of an emer-
2 gency to a treating or responding physician, nurse,
3 agent of a poison control center, public health or en-
4 vironmental official of a State, political subdivision
5 of a State, or tribal government, or first responder
6 (including any individual duly authorized by a Fed-
7 eral agency, State, political subdivision of a State, or
8 tribal government who is trained in urgent medical
9 care or other emergency procedures, including a po-
10 lice officer, firefighter, or emergency medical techni-
11 cian) if such person requests the information, sub-
12 ject to the conditions that such person shall—
13 "(A) have a reasonable basis to suspect
14 that—
15 "(i) a medical, public health, or envi-
16 ronmental emergency exists;
17 "(ii) the information is necessary for,
18 or will assist in, emergency or first-aid di-
19 agnosis or treatment; or
20 "(iii) 1 or more individuals being di-
21 agnosed or treated have likely been ex-
22 posed to the chemical substance or mixture
23 concerned, or a serious environmental re-
24 lease of or exposure to the chemical sub-

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1 stance or mixture concerned has occurred;
2 and
3 "(B) if requested by a person who has a
4 claim with respect to the information under this
5 section—
6 "(i) provide a written statement of
7 need and agree to sign a confidentiality
8 agreement, as described in paragraph (5);
9 and
10 "(ii) submit to the Administrator such
11 statement of need and confidentiality
12 agreement as soon as practicable, but not
13 necessarily before the information is dis-
14 closed;
15 "(7) may be disclosed if the Administrator de-
16 termines that disclosure is relevant in a proceeding
17 under this Act, subject to the condition that the dis-
18 closure is made in such a manner as to preserve con-
19 fidentiality to the extent practicable without impair-
20 ing the proceeding; and
21 "(8) shall be disclosed if the information is re-
22 quired to be made public under any other provision
23 of Federal law.
24 "(e) DURATION OF PROTECTION FROM DISCLO-
25 SURE.—

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1 "(1) IN GENERAL.—Subject to paragraph (2),
2 subsection (f)(3), and section 8(b), the Adminis-
3 trator shall protect from disclosure information de-
4 scribed in subsection (a)—
5 "(A) in the case of information described
6 in subsection (c)(2), until such time as—
7 "(i) the person that asserted the claim
8 notifies the Administrator that the person
9 is withdrawing the claim, in which case the
10 information shall not be protected from
11 disclosure under this section; or
12 "(ii) the Administrator becomes aware
13 that the information does not qualify for
14 protection from disclosure under this sec-
15 tion, in which case the Administrator shall
16 take any actions required under sub-
17 sections (f) and (g); and
18 "(B) in the case of information other than
19 information described in subsection (c)(2)—
20 "(i) for a period of 10 years from the
21 date on which the person asserts the claim
22 with respect to the information submitted
23 to the Administrator; or

1 "(ii) if applicable before the expiration
2 of such 10-year period, until such time
3 as—
4 "(I) the person that asserted the
5 claim notifies the Administrator that
6 the person is withdrawing the claim,
7 in which case the information shall
8 not be protected from disclosure
9 under this section; or
10 "(II) the Administrator becomes
11 aware that the information does not
12 qualify for protection from disclosure
13 under this section, in which case the
14 Administrator shall take any actions
15 required under subsections (f) and
16 (g).
17 "(2) EXTENSIONS.—
18 "(A) IN GENERAL.—In the case of infor-
19 mation other than information described in sub-
20 section (c)(2), not later than the date that is 60
21 days before the expiration of the period de-
22 scribed in paragraph (1)(B)(i), the Adminis-
23 trator shall provide to the person that asserted
24 the claim a notice of the impending expiration
25 of the period.

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1 "(B) REQUEST.—
2 "(i) IN GENERAL.—Not later than the
3 date that is 30 days before the expiration
4 of the period described in paragraph
5 (1)(B)(i), a person reasserting the relevant
6 claim shall submit to the Administrator a
7 request for extension substantiating, in ac-
8 cordance with subsection (c)(3), the need
9 to extend the period.
10 "(ii) ACTION BY ADMINISTRATOR.—
11 Not later than the date of expiration of the
12 period described in paragraph (1)(B)(i),
13 the Administrator shall, in accordance with
14 subsection (g)(1)—
15 "(I) review the request submitted
16 under clause (i);
17 "(II) make a determination re-
18 garding whether the claim for which
19 the request was submitted continues
20 to meet the relevant requirements of
21 this section; and
22 "(III)(aa) grant an extension of
23 10 years; or
24 "(bb) deny the request.

1 "(C) NO LIMIT ON NUMBER OF EXTEN-
2 SIONS.—There shall be no limit on the number
3 of extensions granted under this paragraph, if
4 the Administrator determines that the relevant
5 request under subparagraph (B)(i)—
6 "(i) establishes the need to extend the
7 period; and
8 "(ii) meets the requirements estab-
9 lished by the Administrator.
10 "(f) REVIEW AND RESUBSTANTIATION.—
11 "(1) DISCRETION OF ADMINISTRATOR.—The
12 Administrator may require any person that has
13 claimed protection for information from disclosure
14 under this section, whether before, on, or after the
15 date of enactment of the Frank R. Lautenberg
16 Chemical Safety for the 21st Century Act, to re-
17 assert and substantiate or resubstantiate the claim
18 in accordance with this section—
19 "(A) after the chemical substance is des-
20 ignated as a high-priority substance under sec-
21 tion 6(b);
22 "(B) for any chemical substance des-
23 ignated as an active substance under section
24 8(b)(5)(B)(iii); or

1 "(C) if the Administrator determines that
2 disclosure of certain information currently pro-
3 tected from disclosure would be important to
4 assist the Administrator in conducting risk
5 evaluations or promulgating rules under section
6 6.
7 "(2) REVIEW REQUIRED.—The Administrator
8 shall review a claim for protection of information
9 from disclosure under this section and require any
10 person that has claimed protection for that informa-
11 tion, whether before, on, or after the date of enact-
12 ment of the Frank R. Lautenberg Chemical Safety
13 for the 21st Century Act, to reassert and substan-
14 tiate or resubstantiate the claim in accordance with
15 this section—
16 "(A) as necessary to determine whether
17 the information qualifies for an exemption from
18 disclosure in connection with a request for in-
19 formation received by the Administrator under
20 section 552 of title 5, United States Code;
21 "(B) if the Administrator has a reasonable
22 basis to believe that the information does not
23 qualify for protection from disclosure under this
24 section; or

1 "(C) for any chemical substance the Ad-
2 ministrator determines under section 6(b)(4)(A)
3 presents an unreasonable risk of injury to
4 health or the environment.
5 "(3) PERIOD OF PROTECTION.—If the Adminis-
6 trator requires a person to reassert and substantiate
7 or resubstantiate a claim under this subsection, and
8 determines that the claim continues to meet the rel-
9 evant requirements of this section, the Administrator
10 shall protect the information subject to the claim
11 from disclosure for a period of 10 years from the
12 date of such determination, subject to any subse-
13 quent requirement by the Administrator under this
14 subsection.
15 "(g) DUTIES OF ADMINISTRATOR.—
16 "(1) DETERMINATION.—
17 "(A) IN GENERAL.—Except for claims re-
18 garding information described in subsection
19 (c)(2), the Administrator shall, subject to sub-
20 paragraph (C), not later than 90 days after the
21 receipt of a claim under subsection (c), and not
22 later than 30 days after the receipt of a request
23 for extension of a claim under subsection (e) or
24 a request under subsection (b)(4)(C), review

1 and approve, approve in part and deny in part,
2 or deny the claim or request.
3 "(B) REASONS FOR DENIAL.—If the Ad-
4 ministrator denies or denies in part a claim or
5 request under subparagraph (A) the Adminis-
6 trator shall provide to the person that asserted
7 the claim or submitted the request a written
8 statement of the reasons for the denial or de-
9 nial in part of the claim or request.
10 "(C) SUBSETS.—The Administrator
11 shall—
12 "(i) except with respect to information
13 described in subsection (c)(2)(G), review
14 all claims or requests under this section for
15 the protection from disclosure of the spe-
16 cific chemical identity of a chemical sub-
17 stance; and
18 "(ii) review a representative subset,
19 comprising at least 25 percent, of all other
20 claims or requests for protection from dis-
21 closure under this section.
22 "(D) EFFECT OF FAILURE TO ACT.—The
23 failure of the Administrator to make a decision
24 regarding a claim or request for protection from
25 disclosure or extension under this section shall

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1 not have the effect of denying or eliminating a
2 claim or request for protection from disclosure.
3 "(E) DETERMINATION OF REQUESTS
4 UNDER SUBSECTION (b)(4)(C).—With respect to
5 a request submitted under subsection (b)(4)(C),
6 the Administrator shall, with the objective of
7 ensuring that information relevant to the pro-
8 tection of health and the environment is dis-
9 closed to the extent practicable, determine
10 whether the documentation provided by the per-
11 son rebuts what shall be the presumption of the
12 Administrator that the public interest in the
13 disclosure of the information outweighs the
14 public or proprietary interest in maintaining the
15 protection for all or a portion of the informa-
16 tion that the person has requested not be dis-
17 closed or for which disclosure be delayed.
18 "(2) NOTIFICATION.—
19 "(A) IN GENERAL.—Except as provided in
20 subparagraph (B) and subsections (b), (d), and
21 (e), if the Administrator denies or denies in
22 part a claim or request under paragraph (1),
23 concludes, in accordance with this section, that
24 the information does not qualify for protection
25 from disclosure, intends to disclose information

1 pursuant to subsection (d), or promulgates a
2 rule under section 6(a) establishing a ban or
3 phase-out with respect to a chemical substance
4 or mixture, the Administrator shall notify, in
5 writing, the person that asserted the claim or
6 submitted the request of the intent of the Ad-
7 ministrator to disclose the information or not
8 protect the information from disclosure under
9 this section. The notice shall be furnished by
10 certified mail (return receipt requested), by per-
11 sonal delivery, or by other means that allows
12 verification of the fact and date of receipt.
13 "(B) DISCLOSURE OF INFORMATION.—Ex-
14 cept as provided in subparagraph (C), the Ad-
15 ministrator shall not disclose information under
16 this subsection until the date that is 30 days
17 after the date on which the person that asserted
18 the claim or submitted the request receives noti-
19 fication under subparagraph (A).
20 "(C) EXCEPTIONS.—
21 "(i) FIFTEEN DAY NOTIFICATION.—
22 For information the Administrator intends
23 to disclose under subsections (d)(3), (d)(4),
24 (d)(5), and (j), the Administrator shall not
25 disclose the information until the date that

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1 is 15 days after the date on which the per-
2 son that asserted the claim or submitted
3 the request receives notification under sub-
4 paragraph (A), except that, with respect to
5 information to be disclosed under sub-
6 section (d)(3), if the Administrator deter-
7 mines that disclosure of the information is
8 necessary to protect against an imminent
9 and substantial harm to health or the envi-
10 ronment, no prior notification shall be nec-
11 essary.
12 "(ii) NOTIFICATION AS SOON AS PRAC-
13 TICABLE.—For information the Adminis-
14 trator intends to disclose under paragraph
15 (6) of subsection (d), the Administrator
16 shall notify the person that submitted the
17 information that the information has been
18 disclosed as soon as practicable after dis-
19 closure of the information.
20 "(iii) NO NOTIFICATION REQUIRED.—
21 Notification shall not be required—
22 "(I) for the disclosure of infor-
23 mation under paragraphs (1), (2), (7),
24 or (8) of subsection (d); or

1 "(II) for the disclosure of infor-
2 mation for which—
3 "(aa) the Administrator has
4 provided to the person that as-
5 serted the claim a notice under
6 subsection (e)(2)(A); and
7 "(bb) such person does not
8 submit to the Administrator a re-
9 quest under subsection (e)(2)(B)
10 on or before the deadline estab-
11 lished in subsection (e)(2)(B)(i).
12 "(D) APPEALS.—
13 "(i) ACTION TO RESTRAIN DISCLO-
14 SURE.—If a person receives a notification
15 under this paragraph and believes the in-
16 formation is protected from disclosure
17 under this section, before the date on
18 which the information is to be disclosed
19 pursuant to subparagraph (B) or (C) the
20 person may bring an action to restrain dis-
21 closure of the information in—
22 "(I) the United States district
23 court of the district in which the com-
24 plainant resides or has the principal
25 place of business; or

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1 "(II) the United States District
2 Court for the District of Columbia.
3 "(ii) NO DISCLOSURE.—
4 "(I) IN GENERAL.—Subject to
5 subsection (d), the Administrator shall
6 not disclose information that is the
7 subject of an appeal under this para-
8 graph before the date on which the
9 applicable court rules on an action
10 under clause (i).
11 "(II) EXCEPTION.—Subclause (I)
12 shall not apply to disclosure of infor-
13 mation described under subsections
14 (d)(4) and (j).
15 "(3) REQUEST AND NOTIFICATION SYSTEM.—
16 The Administrator, in consultation with the Director
17 of the Centers for Disease Control and Prevention,
18 shall develop a request and notification system that,
19 in a format and language that is readily accessible
20 and understandable, allows for expedient and swift
21 access to information disclosed pursuant to para-
22 graphs (5) and (6) of subsection (d).
23 "(4) UNIQUE IDENTIFIER.—The Administrator
24 shall—

1 "(A)(i) develop a system to assign a
2 unique identifier to each specific chemical iden-
3 tity for which the Administrator approves a re-
4 quest for protection from disclosure, which shall
5 not be either the specific chemical identity or a
6 structurally descriptive generic term; and
7 "(ii) apply that identifier consistently to all
8 information relevant to the applicable chemical
9 substance;
10 "(B) annually publish and update a list of
11 chemical substances, referred to by their unique
12 identifiers, for which claims to protect the spe-
13 cific chemical identity from disclosure have been
14 approved, including the expiration date for each
15 such claim;
16 "(C) ensure that any nonconfidential infor-
17 mation received by the Administrator with re-
18 spect to a chemical substance included on the
19 list published under subparagraph (B) while the
20 specific chemical identity of the chemical sub-
21 stance is protected from disclosure under this
22 section identifies the chemical substance using
23 the unique identifier; and
24 "(D) for each claim for protection of a spe-
25 cific chemical identity that has been denied by

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1 the Administrator or expired, or that has been
2 withdrawn by the person who asserted the
3 claim, and for which the Administrator has
4 used a unique identifier assigned under this
5 paragraph to protect the specific chemical iden-
6 tity in information that the Administrator has
7 made public, clearly link the specific chemical
8 identity to the unique identifier in such infor-
9 mation to the extent practicable.
10 "(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-
11 SURE.—
12 "(1) INDIVIDUALS SUBJECT TO PENALTY.—
13 "(A) IN GENERAL.—Subject to subpara-
14 graph (C) and paragraph (2), an individual de-
15 scribed in subparagraph (B) shall be fined
16 under title 18, United States Code, or impris-
17 oned for not more than 1 year, or both.
18 "(B) DESCRIPTION.—An individual re-
19 ferred to in subparagraph (A) is an individual
20 who—
21 "(i) pursuant to this section, obtained
22 possession of, or has access to, information
23 protected from disclosure under this sec-
24 tion; and

1 "(ii) knowing that the information is
2 protected from disclosure under this sec-
3 tion, willfully discloses the information in
4 any manner to any person not entitled to
5 receive that information.
6 "(C) EXCEPTION.—This paragraph shall
7 not apply to any medical professional (including
8 an emergency medical technician or other first
9 responder) who discloses any information ob-
10 tained under paragraph (5) or (6) of subsection
11 (d) to a patient treated by the medical profes-
12 sional, or to a person authorized to make med-
13 ical or health care decisions on behalf of such
14 a patient, as needed for the diagnosis or treat-
15 ment of the patient.
16 "(2) OTHER LAWS.—Section 1905 of title 18,
17 United States Code, shall not apply with respect to
18 the publishing, divulging, disclosure, or making
19 known of, or making available, information reported
20 to or otherwise obtained by the Administrator under
21 this Act.
22 "(i) APPLICABILITY.—
23 "(1) IN GENERAL.—Except as otherwise pro-
24 vided in this section, section 8, or any other applica-

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1 ble Federal law, the Administrator shall have no au-
2 thority—
3 "(A) to require the substantiation or re-
4 substantiation of a claim for the protection
5 from disclosure of information reported to or
6 otherwise obtained by the Administrator under
7 this Act prior to the date of enactment of the
8 Frank R. Lautenberg Chemical Safety for the
9 21st Century Act; or
10 "(B) to impose substantiation or re-
11 substantiation requirements, with respect to the
12 protection of information described in sub-
13 section (a), under this Act that are more exten-
14 sive than those required under this section.
15 "(2) ACTIONS PRIOR TO PROMULGATION OF
16 RULES.—Nothing in this Act prevents the Adminis-
17 trator from reviewing, requiring substantiation or re-
18 substantiation of, or approving, approving in part, or
19 denying any claim for the protection from disclosure
20 of information before the effective date of such rules
21 applicable to those claims as the Administrator may
22 promulgate after the date of enactment of the Frank
23 R. Lautenberg Chemical Safety for the 21st Century
24 Act.

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1 "(j) ACCESS BY CONGRESS.—Notwithstanding any
2 limitation contained in this section or any other provision
3 of law, all information reported to or otherwise obtained
4 by the Administrator (or any representative of the Admin-
5 istrator) under this Act shall be made available, upon writ-
6 ten request of any duly authorized committee of the Con-
7 gress, to such committee.".

8 **SEC. 12. PENALTIES.**

9 Section 16 of the Toxic Substances Control Act (15
10 U.S.C. 2615) is amended—
11 (1) in subsection (a)(1), by striking "$25,000"
12 and inserting "$37,500"; and
13 (2) in subsection (b)—
14 (A) by striking "Any person" and inserting
15 the following:
16 "(1) IN GENERAL.—Any person";
17 (B) by striking "$25,000" and inserting
18 "$50,000"; and
19 (C) by adding at the end the following:
20 "(2) IMMINENT DANGER OF DEATH OR SERIOUS
21 BODILY INJURY.—
22 "(A) IN GENERAL.—Any person who
23 knowingly and willfully violates any provision of
24 section 15 or 409, and who knows at the time
25 of the violation that the violation places an indi-

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1 vidual in imminent danger of death or serious
2 bodily injury, shall be subject on conviction to
3 a fine of not more than $250,000, or imprison-
4 ment for not more than 15 years, or both.
5 "(B) ORGANIZATIONS.—Notwithstanding
6 the penalties described in subparagraph (A), an
7 organization that commits a knowing violation
8 described in subparagraph (A) shall be subject
9 on conviction to a fine of not more than
10 $1,000,000 for each violation.
11 "(C) INCORPORATION OF CORRESPONDING
12 PROVISIONS.—Subparagraphs (B) through (F)
13 of section 113(c)(5) of the Clean Air Act (42
14 U.S.C. 7413(c)(5)(B)–(F)) shall apply to the
15 prosecution of a violation under this para-
16 graph.".

17 **SEC. 13. STATE-FEDERAL RELATIONSHIP.**

18 ø¿To be determined¿

19 **SEC. 14. JUDICIAL REVIEW.**

20 Section 19(a) of the Toxic Substances Control Act
21 (15 U.S.C. 2618(a)) is amended—
22 (1) in paragraph (1), by adding at the end the
23 following:
24 "(C)(i) Not later than 60 days after the publi-
25 cation of a designation under section 6(b)(1)(B)(ii)

1 or (iii), any person may commence a civil action to
2 challenge the designation.
3 "(ii) The United States Court of Appeals for
4 the District of Columbia Circuit shall have exclusive
5 jurisdiction over a civil action filed under this sub-
6 paragraph."; and
7 (2) by striking paragraph (3).
8 ø**SEC. 15. CITIZENS' CIVIL ACTIONS.**
9 Section 20(b) of the Toxic Substances Control Act
10 (15 U.S.C. 2619(b)) is amended—¿
11 ø(1) in paragraph (1)(B), by striking "or" at
12 the end; and¿
13 ø(2) in paragraph (2), by striking the period at
14 the end and inserting the following:¿ ", except that
15 no prior notification shall be required in the case of
16 a civil action brought to compel a decision by the
17 Administrator pursuant to øsection 18(f)(3)(B)¿; or
18 ø"(3) in the case of a civil action brought to
19 compel a decision by the Administrator pursuant to
20 øsection 18(f)(3)(B)¿, after the date that is 60 days
21 after the deadline specified in øsection
22 18(f)(3)(B)¿.".¿
23 **SEC. 16. STUDIES.**
24 Section 25 of the Toxic Substances Control Act (15
25 U.S.C. 2624) is repealed.

1 **SEC. 17. ADMINISTRATION OF THE ACT.**

2 Section 26 of the Toxic Substances Control Act (15
3 U.S.C. 2625) is amended—

4 (1) in subsection (b)(1)—

5 (A) by striking "of a reasonable fee";

6 (B) by striking "data under section 4 or 5
7 to defray the cost of administering this Act"
8 and inserting "information under section 4 or a
9 notice or other information to be reviewed by
10 the Administrator under section 5, or who man-
11 ufactures or processes a chemical substance
12 that is the subject of a risk evaluation under
13 section 6(b), of a fee that is sufficient and not
14 more than reasonably necessary to defray the
15 cost related to such chemical substance of ad-
16 ministering sections 4, 5, and 6, and collecting,
17 processing, reviewing, and providing access to
18 and protecting from disclosure as appropriate
19 under section 14 information on chemical sub-
20 stances under this title, including contractor
21 costs incurred by the Administrator";

22 (C) by striking "Such rules shall not pro-
23 vide for any fee in excess of $2,500 or, in the
24 case of a small business concern, any fee in ex-
25 cess of $100."; and

1 (D) by striking "submit the data and the
2 cost to the Administrator of reviewing such
3 data" and inserting "pay such fee and the cost
4 to the Administrator of carrying out the activi-
5 ties described in this paragraph";
6 (2) by adding at the end of subsection (b) the
7 following:
8 "(3) FUND.—
9 "(A) ESTABLISHMENT.—There is established in
10 the Treasury of the United States a fund, to be
11 known as the TSCA Service Fee Fund (in this para-
12 graph referred to as the 'Fund'), consisting of such
13 amounts as are deposited in the Fund under this
14 paragraph.
15 "(B) COLLECTION AND DEPOSIT OF FEES.—
16 The Administrator shall collect the fees described in
17 this subsection and deposit those fees in the Fund.
18 "(C) CREDITING AND AVAILABILITY OF
19 FEES.—On request by the Administrator, the Sec-
20 retary of the Treasury shall transfer from the Fund
21 to the Administrator amounts appropriated to pay
22 or recover the costs incurred by the Environmental
23 Protection Agency in carrying out the activities de-
24 scribed in paragraph (1).

1 "(D) USE OF FUNDS BY ADMINISTRATOR.—
2 Fees authorized under this section shall be collected
3 and available for obligation only to the extent and in
4 the amount provided in advance in appropriations
5 Acts, and shall be available without fiscal year limi-
6 tation for use in defraying the costs of the activities
7 described in paragraph (1).
8 "(E) ACCOUNTING AND AUDITING.—
9 "(i) ACCOUNTING.—The Administrator
10 shall biennially prepare and submit to the Com-
11 mittee on Environment and Public Works of the
12 Senate and the Committee on Energy and Com-
13 merce of the House of Representatives a report
14 that includes an accounting of the fees paid to
15 the Administrator under this paragraph and
16 amounts disbursed from the Fund for the pe-
17 riod covered by the report, as reflected by fi-
18 nancial statements provided in accordance with
19 sections 3515 and 3521 of title 31, United
20 States Code.
21 "(ii) AUDITING.—
22 "(I) IN GENERAL.—For the purpose
23 of section 3515(c) of title 31, United
24 States Code, the Fund shall be considered
25 a component of a covered executive agency.

1 "(II) COMPONENTS OF AUDIT.—The
2 annual audit required in accordance with
3 sections 3515 and 3521 of title 31, United
4 States Code, of the financial statements of
5 activities carried out using amounts from
6 the Fund shall include an analysis of—
7 "(aa) the fees collected and
8 amounts disbursed under this sub-
9 section;
10 "(bb) the reasonableness of the
11 fees in place as of the date of the
12 audit to meet current and projected
13 costs of administering the provisions
14 of this title for which the fees may be
15 used; and
16 "(cc) the number of requests for
17 a risk evaluation made by manufac-
18 turers under section 6(b)(4)(C)(ii).
19 "(III) FEDERAL RESPONSIBILITY.—
20 The Inspector General of the Environ-
21 mental Protection Agency shall conduct
22 the annual audit described in subclause
23 (II) and submit to the Administrator a re-
24 port that describes the findings and any

1 recommendations of the Inspector General
2 resulting from the audit.
3 "(4) AMOUNT AND ADJUSTMENT OF FEES; RE-
4 FUNDS.—In setting fees under this section, the Adminis-
5 trator shall—
6 "(A) prescribe lower fees for small business
7 concerns, after consultation with the Administrator
8 of the Small Business Administration;
9 "(B) set the fees established under paragraph
10 (1) at levels such that the fees will, in aggregate,
11 provide a sustainable source of funds to annually de-
12 fray—
13 "(i) the lower of—
14 "(I) 25 percent of the costs to the Ad-
15 ministrator of carrying out sections 4, 5,
16 and 6, and of collecting, processing, re-
17 viewing, and providing access to and pro-
18 tecting from disclosure as appropriate
19 under section 14 information on chemical
20 substances under this title, other than the
21 costs to conduct and complete risk evalua-
22 tions under section 6(b); or
23 "(II) $25,000,000 (subject to adjust-
24 ment pursuant to subparagraph (F)); and

1 "(ii) the costs of risk evaluations specified
2 in subparagraph (D);
3 "(C) reflect an appropriate balance in the as-
4 sessment of fees between manufacturers and proc-
5 essors, and allow the payment of fees by consortia
6 of manufacturers or processors;
7 "(D) notwithstanding subparagraph (B)—
8 "(i) except as provided in clause (ii), for
9 chemical substances for which the Adminis-
10 trator has granted a request from a manufac-
11 turer pursuant to section 6(b)(4)(C)(ii), estab-
12 lish the fee at a level sufficient to defray the
13 full costs to the Administrator of conducting
14 the risk evaluation under section 6(b);
15 "(ii) for chemical substances for which the
16 Administrator has granted a request from a
17 manufacturer pursuant to section
18 6(b)(4)(C)(ii), and which are included in the
19 2014 update of the TSCA Work Plan for
20 Chemical Assessments, establish the fee at a
21 level sufficient to defray 50 percent of the costs
22 to the Administrator of conducting the risk
23 evaluation under section 6(b); and

1 "(iii) apply fees collected pursuant to
2 clauses (i) and (ii) only to defray the costs de-
3 scribed in those clauses;
4 "(E) prior to the establishment or amendment
5 of any fees under paragraph (1), consult and meet
6 with parties potentially subject to the fees or their
7 representatives, subject to the condition that no obli-
8 gation under the Federal Advisory Committee Act (5
9 U.S.C. App.) or subchapter II of chapter 5 of title
10 5, United States Code, is applicable with respect to
11 such meetings;
12 "(F) beginning with the fiscal year that is 3
13 years after the date of enactment of the Frank R.
14 Lautenberg Chemical Safety for the 21st Century
15 Act, and every 3 years thereafter, after consultation
16 with parties potentially subject to the fees and their
17 representatives pursuant to subparagraph (E), in-
18 crease or decrease the fees established under para-
19 graph (1) as necessary to adjust for inflation and to
20 ensure that funds deposited in the Fund are suffi-
21 cient to defray—
22 "(i) approximately but not more than 25
23 percent of the annual costs to the Adminis-
24 trator of carrying out sections 4, 5, and 6, and
25 of collecting, processing, reviewing, and pro-

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1 viding access to and protecting from disclosure
2 as appropriate under section 14 information on
3 chemical substances under this title, other than
4 the costs to conduct and complete risk evalua-
5 tions requested under section 6(b)(4)(C)(ii);
6 and
7 "(ii) the full annual costs and the 50-per-
8 cent portion of the annual costs of risk evalua-
9 tions specified in subparagraph (D); and
10 "(G) if a notice submitted under section 5 is
11 not reviewed or such a notice is withdrawn, refund
12 the fee or a portion of the fee if no substantial work
13 was performed on the notice.
14 "(5) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees
15 may not be assessed for a fiscal year under this section
16 unless the amount of appropriations for the Chemical Risk
17 Review and Reduction program project of the Environ-
18 mental Protection Agency for the fiscal year (excluding
19 the amount of any fees appropriated for the fiscal year)
20 are equal to or greater than the amount of appropriations
21 for that program project for fiscal year 2014.
22 "(6) TERMINATION.—The authority provided by this
23 subsection shall terminate at the conclusion of the fiscal
24 year that is 10 years after the date of enactment of the
25 Frank R. Lautenberg Chemical Safety for the 21st Cen-

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1 tury Act unless otherwise reauthorized or modified by
2 Congress."; and
3 (3) by adding at the end the following:
4 "(h) SCIENTIFIC STANDARDS.—In carrying out sec-
5 tions 4, 5, and 6, to the extent that the Administrator
6 makes a decision based on science, the Administrator shall
7 use scientific information, technical procedures, measures,
8 methods, protocols, methodologies, or models, employed in
9 a manner consistent with the best available science, and
10 shall consider as applicable—
11 "(1) the extent to which the scientific informa-
12 tion, technical procedures, measures, methods, proto-
13 cols, methodologies, or models employed to generate
14 the information are reasonable for and consistent
15 with the intended use of the information;
16 "(2) the extent to which the information is rel-
17 evant for the Administrator's use in making a deci-
18 sion about a chemical substance or mixture;
19 "(3) the degree of clarity and completeness with
20 which the data, assumptions, methods, quality assur-
21 ance, and analyses employed to generate the infor-
22 mation are documented;
23 "(4) the extent to which the variability and un-
24 certainty in the information, or in the procedures,

1 measures, methods, protocols, methodologies, or
2 models, are evaluated and characterized; and
3 "(5) the extent of independent verification or
4 peer review of the information or of the procedures,
5 measures, methods, protocols, methodologies, or
6 models.
7 "(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Ad-
8 ministrator shall make decisions under sections 4, 5, and
9 6 based on the weight of the scientific evidence.
10 "(j) AVAILABILITY OF INFORMATION.—Subject to
11 section 14, the Administrator shall make available to the
12 public—
13 "(1) all notices, determinations, findings, rules,
14 consent agreements, and orders of the Administrator
15 under this title;
16 "(2) any information required to be provided to
17 the Administrator under section 4;
18 "(3) a nontechnical summary of each risk eval-
19 uation conducted under section 6(b);
20 "(4) a list of the studies considered by the Ad-
21 ministrator in carrying out each such risk evalua-
22 tion, along with the results of those studies; and
23 "(5) each designation of a chemical substance
24 as a high-priority substance, low-priority substance,
25 or low-hazard substance, along with an identification

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1 of the information, analysis, and basis used to make
2 the designations.
3 "(k) REASONABLY AVAILABLE INFORMATION.—In
4 carrying out sections 4, 5, and 6, the Administrator shall
5 take into consideration information relating to a chemical
6 substance or mixture, including hazard and exposure in-
7 formation, under the conditions of use, that is reasonably
8 available to the Administrator.
9 "(l) POLICIES, PROCEDURES, AND GUIDANCE.—
10 "(1) DEVELOPMENT.—Not later than 2 years
11 after the date of enactment of the Frank R. Lauten-
12 berg Chemical Safety for the 21st Century Act, the
13 Administrator shall develop any policies, procedures,
14 and guidance the Administrator determines are nec-
15 essary to carry out the amendments to this Act
16 made by the Frank R. Lautenberg Chemical Safety
17 for the 21st Century Act.
18 "(2) REVIEW.—Not later than 5 years after the
19 date of enactment of the Frank R. Lautenberg
20 Chemical Safety for the 21st Century Act, and not
21 less frequently than once every 5 years thereafter,
22 the Administrator shall—
23 "(A) review the adequacy of the policies,
24 procedures, and guidance developed under para-
25 graph (1), including with respect to animal,

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1 nonanimal, and epidemiological test methods
2 and procedures for assessing and determining
3 risk under this title; and
4 "(B) revise such policies, procedures, and
5 guidance as the Administrator determines nec-
6 essary to reflect new scientific developments or
7 understandings.
8 "(3) TESTING OF CHEMICAL SUBSTANCES AND
9 MIXTURES.—The policies, procedures, and guidance
10 developed under paragraph (1) applicable to testing
11 chemical substances and mixtures shall—
12 "(A) address how and when the exposure
13 level or exposure potential of a chemical sub-
14 stance would factor into decisions to require
15 new testing, subject to the condition that the
16 Administrator shall not interpret the lack of ex-
17 posure information as a lack of exposure or ex-
18 posure potential; and
19 "(B) describe the manner in which the Ad-
20 ministrator will determine that additional infor-
21 mation is necessary to carry out this title, in-
22 cluding information relating to potentially ex-
23 posed or susceptible populations.
24 "(4) CHEMICAL SUBSTANCES WITH COMPLETED
25 RISK ASSESSMENTS.—With respect to a chemical

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1 substance listed in the 2014 update to the TSCA
2 Work Plan for Chemical Assessments for which the
3 Administrator has published a completed risk assess-
4 ment prior to the date of enactment of the Frank
5 R. Lautenberg Chemical Safety for the 21st Century
6 Act, the Administrator may publish proposed and
7 final rules under section 6(a) that are consistent
8 with the scope of the completed risk assessment for
9 the chemical substance and consistent with other ap-
10 plicable requirements of section 6.
11 "(5) GUIDANCE.—Not later than 1 year after
12 the date of enactment of the Frank R. Lautenberg
13 Chemical Safety for the 21st Century Act, the Ad-
14 ministrator shall develop guidance to assist inter-
15 ested persons in developing and submitting draft
16 risk evaluations which shall be considered by the Ad-
17 ministrator. The guidance shall, at a minimum, ad-
18 dress the quality of the information submitted and
19 the process to be followed in developing draft risk
20 evaluations for consideration by the Administrator.
21 "(m) REPORT TO CONGRESS.—
22 "(1) INITIAL REPORT.—Not later than 6
23 months after the date of enactment of the Frank R.
24 Lautenberg Chemical Safety for the 21st Century
25 Act, the Administrator shall submit to the Commit-

1 tees on Energy and Commerce and Appropriations
2 of the House of Representatives and the Committees
3 on Environment and Public Works and Appropria-
4 tions of the Senate a report containing an estimation
5 of—
6 "(A) the capacity of the Environmental
7 Protection Agency to conduct and publish risk
8 evaluations under section 6(b)(4)(C)(i) and(ii),
9 and the resources necessary to conduct the min-
10 imum number of risk evaluations required
11 under section 6(b)(2);
12 "(B) the capacity of the Environmental
13 Protection Agency to conduct and publish risk
14 evaluations under section 6(b)(4)(A)(ii), the
15 likely demand for such risk evaluations, and the
16 anticipated schedule for accommodating that
17 demand;
18 "(C) the capacity of the Environmental
19 Protection Agency to promulgate rules under
20 section 6(a) as required based on risk evalua-
21 tions conducted and published under section
22 6(b); and
23 "(D) the actual and anticipated efforts of
24 the Environmental Protection Agency to in-

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1 crease the Agency's capacity to conduct and
2 publish risk evaluations under section 6(b).
3 "(2) SUBSEQUENT REPORTS.—The Adminis-
4 trator shall update and resubmit the report de-
5 scribed in paragraph (1) not less frequently than
6 once every 5 years.
7 "(n) ANNUAL PLAN.—At the beginning of each cal-
8 endar year, the Administrator shall publish an annual plan
9 that—
10 "(1) identifies the chemical substances for
11 which risk evaluations are expected to be completed
12 that year and the resources necessary for their com-
13 pletion;
14 "(2) describes the status of each risk evaluation
15 that has been initiated but not yet completed; and
16 "(3) if the schedule for completion of a risk
17 evaluation has changed, includes an updated sched-
18 ule for that risk evaluation.
19 "(o) CONSULTATION WITH SCIENCE ADVISORY COM-
20 MITTEE ON CHEMICALS.—
21 "(1) ESTABLISHMENT.—Not later than 1 year
22 after the date of enactment of the Frank R. Lauten-
23 berg Chemical Safety for the 21st Century Act, the
24 Administrator shall establish an advisory committee,
25 to be known as the Science Advisory Committee on

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1 Chemicals (referred to in this subsection as the
2 'Committee').
3 "(2) PURPOSE.—The purpose of the Committee
4 shall be to provide independent advice and expert
5 consultation, at the request of the Administrator,
6 with respect to the scientific and technical aspects of
7 issues relating to the implementation of this title.
8 "(3) COMPOSITION.—The Committee shall be
9 composed of representatives of such science, govern-
10 ment, labor, public health, public interest, animal
11 protection, industry, and other groups as the Admin-
12 istrator determines to be advisable, including rep-
13 resentatives that have specific scientific expertise in
14 the relationship of chemical exposures to women,
15 children, and other potentially exposed or susceptible
16 subpopulations.
17 "(4) SCHEDULE.—The Administrator shall con-
18 vene the Committee in accordance with such sched-
19 ule as the Administrator determines to be appro-
20 priate, but not less frequently than once every 2
21 years.
22 "(p) PRIOR ACTIONS.—
23 "(1) RULES, ORDERS, AND EXEMPTIONS.—
24 Nothing in the Frank R. Lautenberg Chemical Safe-
25 ty for the 21st Century Act eliminates, modifies, or

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1 withdraws any rule promulgated, order issued, or ex-
2 emption established pursuant to this Act before the
3 date of enactment of the Frank R. Lautenberg
4 Chemical Safety for the 21st Century Act.
5 "(2) PRIOR-INITIATED EVALUATIONS.—Nothing
6 in this Act prevents the Administrator from initi-
7 ating a risk evaluation regarding a chemical sub-
8 stance, or from continuing or completing such risk
9 evaluation, prior to the effective date of the policies,
10 procedures, and guidance required to be developed
11 by the Administrator pursuant to the amendments
12 made by the Frank R. Lautenberg Chemical Safety
13 for the 21st Century Act.
14 "(3) ACTIONS COMPLETED PRIOR TO COMPLE-
15 TION OF POLICIES, PROCEDURES, AND GUIDANCE.—
16 Nothing in this Act requires the Administrator to re-
17 vise or withdraw a completed risk evaluation, deter-
18 mination, or rule under this Act solely because the
19 action was completed prior to the development of a
20 policy, procedure, or guidance pursuant to the
21 amendments made by the Frank R. Lautenberg
22 Chemical Safety for the 21st Century Act.".

1 **SEC. 18. STATE PROGRAMS.**

2 Section 28 of the Toxic Substances Control Act (15
3 U.S.C. 2627) is amended by striking subsections (c) and
4 (d).

5 **SEC. 19. CONFORMING AMENDMENTS.**

6 (a) TABLE OF CONTENTS.—The table of contents in
7 section 1 of the Toxic Substances Control Act is amend-
8 ed—

9 (1) by striking the item relating to section 6
10 and inserting the following:

"Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.";

11 (2) by striking the item relating to section 10
12 and inserting the following:

"Sec. 10. Research, development, collection, dissemination, and utilization of information.";

13 (3) by striking the item relating to section 14
14 and inserting the following:

"Sec. 14. Confidential information."; and

15 (4) by striking the item relating to section 25.

16 (b) SECTION 2.—Section 2(b)(1) of the Toxic Sub-
17 stances Control Act (15 U.S.C. 2601(b)(1)) is amended
18 by striking "data" both places it appears and inserting
19 "information".

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

1 (1) in paragraph (8) (as redesignated by section
2 3 of this Act), by striking "data" and inserting "in-
3 formation"; and
4 (2) in paragraph (15) (as redesignated by sec-
5 tion 3 of this Act)—
6 (A) by striking "standards" and inserting
7 "protocols and methodologies";
8 (B) by striking "test data" both places it
9 appears and inserting "information"; and
10 (C) by striking "data" each place it ap-
11 pears and inserting "information".
12 (d) SECTION 4.—Section 4 of the Toxic Substances
13 Control Act (15 U.S.C. 2603) is amended—
14 (1) in subsection (b)—
15 (A) in paragraph (1), by striking "rule"
16 each place it appears and inserting "rule, order,
17 or consent agreement";
18 (B) in paragraph (2)(B), by striking
19 "rules" and inserting "rules, orders, and con-
20 sent agreements";
21 (C) in paragraph (3)(A), by striking "rule"
22 and inserting "rule or order"; and
23 (D) in paragraph (4)—
24 (i) by striking "rule under subsection
25 (a)" each place it appears and inserting

1 "rule, order, or consent agreement under
2 subsection (a)";
3 (ii) by striking "repeals the rule" each
4 place it appears and inserting "repeals the
5 rule or order or modifies the consent
6 agreement to terminate the requirement";
7 and
8 (iii) by striking "repeals the applica-
9 tion of the rule" and inserting "repeals or
10 modifies the application of the rule, order,
11 or consent agreement";
12 (2) in subsection (c)—
13 (A) in paragraph (1), by striking "rule"
14 and inserting "rule or order";
15 (B) in paragraph (2)—
16 (i) in subparagraph (A), by striking
17 "a rule under subsection (a) or for which
18 data is being developed pursuant to such a
19 rule" and inserting "a rule, order, or con-
20 sent agreement under subsection (a) or for
21 which information is being developed pur-
22 suant to such a rule, order, or consent
23 agreement";
24 (ii) in subparagraph (B), by striking
25 "such rule or which is being developed pur-

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1 suant to such rule" and inserting "such
2 rule, order, or consent agreement or which
3 is being developed pursuant to such rule,
4 order, or consent agreement"; and
5 (iii) in the matter following subpara-
6 graph (B), by striking "the rule" and in-
7 serting "the rule or order";
8 (C) in paragraph (3)(B)(i), by striking
9 "rule promulgated" and inserting "rule, order,
10 or consent agreement"; and
11 (D) in paragraph (4)—
12 (i) by striking "rule promulgated"
13 each place it appears and inserting "rule,
14 order, or consent agreement";
15 (ii) by striking "such rule" each place
16 it appears and inserting "such rule, order,
17 or consent agreement"; and
18 (iii) in subparagraph (B), by striking
19 "the rule" and inserting "the rule, order,
20 or consent agreement";
21 (3) in subsection (d), by striking "rule" and in-
22 serting "rule, order, or consent agreement"; and
23 (4) in subsection (g), by striking "rule" and in-
24 serting "rule, order, or consent agreement".

1 (e) SECTION 5.—Section 5 of the Toxic Substances
2 Control Act (15 U.S.C. 2604) is amended—
3 (1) in subsection (b)—
4 (A) in paragraph (1)(A)—
5 (i) by striking "rule promulgated"
6 and inserting "rule, order, or consent
7 agreement"; and
8 (ii) by striking "such rule" and insert-
9 ing "such rule, order, or consent agree-
10 ment";
11 (B) in paragraph (1)(B)—
12 (i) by striking "rule promulgated"
13 and inserting "rule or order"; and
14 (ii) by striking "the date of the sub-
15 mission in accordance with such rule" and
16 inserting "the required date of submis-
17 sion"; and
18 (C) in paragraph (2)(A)(ii), by striking
19 "rule promulgated" and inserting "rule, order,
20 or consent agreement"; and
21 (2) in subsection (d)(2)(C), by striking "rule"
22 and inserting "rule, order, or consent agreement".
23 (f) SECTION 7.—Section 7(a)(1) of the Toxic Sub-
24 stances Control Act (15 U.S.C. 2606(a)(1)) is amended,
25 in the matter following subparagraph (C), by striking "a

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1 rule under section 4, 5, 6, or title IV or an order under
2 section 5 or title IV" and inserting "a determination
3 under section 5 or 6, a rule under section 4, 5, or 6 or
4 title IV, an order under section 4, 5, or 6 or title IV, or
5 a consent agreement under section 4".
6 (g) SECTION 8.—Section 8(a) of the Toxic Sub-
7 stances Control Act (15 U.S.C. 2607(a)) is amended—
8 (1) in paragraph (2)(E), by striking "data" and
9 inserting "information"; and
10 (2) in paragraph (3)(A)(ii)(I), by striking "or
11 an order in effect under section 5(e)" and inserting
12 ", an order in effect under section 4 or 5(e), or a
13 consent agreement under section 4".
14 (h) SECTION 9.—Section 9 of the Toxic Substances
15 Control Act (15 U.S.C. 2608) is amended—
16 (1) in subsection (a), by striking "section 6"
17 each place it appears and inserting "section 6(a)";
18 and
19 (2) in subsection (d), by striking "Health, Edu-
20 cation, and Welfare" and inserting "Health and
21 Human Services".
22 (i) SECTION 10.—Section 10 of the Toxic Substances
23 Control Act (15 U.S.C. 2609) is amended—
24 (1) in the section heading, by striking "**DATA**"
25 and inserting "**INFORMATION**";

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1 (2) by striking "Health, Education, and Wel-
2 fare" each place it appears and inserting "Health
3 and Human Services";
4 (3) in subsection (b)—
5 (A) in the subsection heading, by striking
6 "DATA" and inserting "INFORMATION";
7 (B) by striking "data" and inserting "in-
8 formation" in paragraph (1);
9 (C) by striking "data" and inserting "in-
10 formation" in paragraph (2)(A); and
11 (D) by striking "a data" and inserting "an
12 information" in paragraph (2)(B); and
13 (4) in subsection (g), by striking "data" and in-
14 serting "information".
15 (j) SECTION 11.—Section 11(b)(2) of the Toxic Sub-
16 stances Control Act (15 U.S.C. 2610(b)(2)) is amended—
17 (1) by striking "data" each place it appears
18 and inserting "information"; and
19 (2) in subparagraph (E), by striking "rule pro-
20 mulgated" and inserting "rule promulgated, order
21 issued, or consent agreement entered into".
22 (k) SECTION 12.—Section 12(b)(1) of the Toxic Sub-
23 stances Control Act (15 U.S.C. 2611(b)(1)) is amended
24 by striking "data" both places it appears and inserting
25 "information".

1 (l) SECTION 15.—Section 15(1) of the Toxic Sub-
2 stances Control Act (15 U.S.C. 2614(1)) is amended by
3 striking "(A) any rule" and all that follows through "or
4 (D)" and inserting "any requirement of this title or any
5 rule promulgated, order issued, or consent agreement en-
6 tered into under this title, or".
7 (m) SECTION 19.—Section 19 of the Toxic Sub-
8 stances Control Act (15 U.S.C. 2618) is amended—
9 (1) in subsection (a)—
10 (A) in paragraph (1)(A)—
11 (i) by striking "Not later than 60
12 days after the date of the promulgation of
13 a rule under section 4(a), 5(a)(2), 5(b)(4),
14 6(a), 6(e), or 8, or under title II or IV"
15 and inserting "Except as otherwise pro-
16 vided in this title, not later than 60 days
17 after the date on which a rule is promul-
18 gated under this title, title II, or title IV,
19 or the date on which an order is issued
20 under section 4, 5(e), 5(f), or 6(i)(1),";
21 (ii) by striking "such rule" and insert-
22 ing "such rule or order"; and
23 (iii) by striking "such a rule" and in-
24 serting "such a rule or order";
25 (B) in paragraph (1)(B)—

Commented [A1]: We suggest making this reference specific to 4(a). "Order" is a broad concept and would apply, eg, to exemption decisions by EPA under 4(c). We understand your intent to be provide for review under (A)(1), and for substantial evidence review in particular, only for test orders.

1 (i) by striking "Courts" and inserting
2 "Except as otherwise provided in this title,
3 courts"; and
4 (ii) by striking "subparagraph (A) or
5 (B) of section 6(b)(1)" and inserting "this
6 title, other than an order under section 4,
7 5(e), 5(f), or 6(i)(1),"; and
8 (C) in paragraph (2), by striking "rule-
9 making record" and inserting "record"; and
10 (2) in subsection (b)—
11 (A) by striking "review a rule" and insert-
12 ing "review a rule, or an order under section 4,
13 5(e), 5(f), or 6(i)(1),";
14 (B) by striking "such rule" and inserting
15 "such rule or order";
16 (C) by striking "the rule" and inserting
17 "the rule or order";
18 (D) by striking "new rule" each place it
19 appears and inserting "new rule or order"; and
20 (E) by striking "modified rule" and insert-
21 ing "modified rule or order"; and
22 (3) in subsection (c)—
23 (A) in paragraph (1)—
24 (i) in subparagraph (A)—

Commented [A2]: Suggest making this 4(a).

Commented [A3]: In addition, in paragraph (2), about 10 words after this change, you need to strike "based the rule being reviewed" and insert "based the rule or order being reviewed".

Commented [A4]: Suggest 4(a)

1 (I) by striking "a rule" and in-
2 serting "a rule or order"; and
3 (II) by striking "such rule" and
4 inserting "such rule or order";
5 (ii) in subparagraph (B)—
6 (I) in the matter preceding clause
7 (i), by striking "a rule" and inserting
8 "a rule or order";
9 (II) by amending clause (i) to
10 read as follows:
11 "(i) in the case of review of—
12 "(I) a rule under section 4(a), 5(b)(4),
13 6(a) (including review of the associated deter-
14 mination under section 6(b)(4)(A)), or 6(e), the
15 standard for review prescribed by paragraph
16 (2)(E) of such section 706 shall not apply and
17 the court shall hold unlawful and set aside such
18 rule if the court finds that the rule is not sup-
19 ported by substantial evidence in the rule-
20 making record taken as a whole; and
21 "(II) an order under section 4, 5(e), 5(f),
22 or 6(i)(1), the standard for review prescribed by
23 paragraph (2)(E) of such section 706 shall not
24 apply and the court shall hold unlawful and set
25 aside such order if the court finds that the

Commented [A5]: Suggest 4(a). That would be consistent with subclause (I).

1 order is not supported by substantial evidence
2 in the record taken as a whole; and"; and
3 (III) by striking clauses (ii) and
4 (iii) and the matter after clause (iii)
5 and inserting the following:
6 "(ii) the court may not review the contents and
7 adequacy of any statement of basis and purpose re-
8 quired by section 553(c) of title 5, United States
9 Code, to be incorporated in the rule or order, except
10 as part of the record, taken as a whole."; and
11 (iii) by striking subparagraph (C);
12 and
13 (B) in paragraph (2), by striking "any
14 rule" and inserting "any rule or order".
15 (n) SECTION 20.—Section 20(a)(1) of the Toxic Sub-
16 stances Control Act (15 U.S.C. 2619(a)(1)) is amended
17 by striking "order issued under section 5" and inserting
18 "order issued under section 4 or 5".
19 (o) SECTION 21.—Section 21 of the Toxic Substances
20 Control Act (15 U.S.C. 2620) is amended—
21 (1) in subsection (a), by striking "order under
22 section 5(e) or (6)(b)(2)" and inserting "order
23 under section 4 or 5(e) or (f)"; and
24 (2) in subsection (b)—

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1 (A) in paragraph (1), by striking "order
2 under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)"
3 and inserting "order under section 4 or 5(e)";
4 and
5 (B) in paragraph (4)(B)—
6 (i) in the matter preceding clause (i),
7 by striking "order under section 5(e) or
8 6(b)(2)" and inserting "order under sec-
9 tion 4 or 5(e)";
10 (ii) in clause (i), by striking "order
11 under section 5(e)" and inserting "order
12 under section 4 or 5(e)"; and
13 (iii) in clause (ii), by striking "or an
14 order under section 6(b)(2)".
15 (p) SECTION 24.—Section 24(b)(2)(B) of the Toxic
16 Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is
17 amended—
18 (1) by inserting "and" at the end of clause (i);
19 (2) by striking clause (ii); and
20 (3) by redesignating clause (iii) as clause (ii).
21 (q) SECTION 26.—Section 26 of the Toxic Substances
22 Control Act (15 U.S.C. 2625) is amended—
23 (1) in subsection (e), by striking "Health, Edu-
24 cation, and Welfare" each place it appears and in-
25 serting "Health and Human Services"; and

1 (2) in subsection (g)(1), by striking "data" and
2 inserting "information".
3 (r) SECTION 27.—Section 27(a) of the Toxic Sub-
4 stances Control Act (15 U.S.C. 2626(a)) is amended—
5 (1) by striking "Health, Education, and Wel-
6 fare" and inserting "Health and Human Services";
7 (2) by striking "test data" both places it ap-
8 pears and inserting "information";
9 (3) by striking "rules promulgated" and insert-
10 ing "rules, orders, or consent agreements"; and
11 (4) by striking "standards" and inserting "pro-
12 tocols and methodologies".
13 (s) SECTION 30.—Section 30(2) of the Toxic Sub-
14 stances Control Act (15 U.S.C. 2629(2)) is amended by
15 striking "rule" and inserting "rule, order, or consent
16 agreement".
17 **SEC. 20. NO RETROACTIVITY.**
18 Nothing in sections 1 through 19, or the amendments
19 made by sections 1 through 19, shall be interpreted to
20 apply retroactively to any State, Federal, or maritime legal
21 action filed before the date of enactment of this Act.
22 **SEC. 21. TREVOR'S LAW.**
23 (a) PURPOSES.—The purposes of this section are—

1 (1) to provide the appropriate Federal agencies
2 with the authority to help conduct investigations into
3 potential cancer clusters;
4 (2) to ensure that Federal agencies have the
5 authority to undertake actions to help address can-
6 cer clusters and factors that may contribute to the
7 creation of potential cancer clusters; and
8 (3) to enable Federal agencies to coordinate
9 with other Federal, State, and local agencies, insti-
10 tutes of higher education, and the public in inves-
11 tigating and addressing cancer clusters.
12 (b) DESIGNATION AND INVESTIGATION OF POTEN-
13 TIAL CANCER CLUSTERS.—Part P of title III of the Pub-
14 lic Health Service Act (42 U.S.C. 280g et seq.) is amended
15 by adding at the end the following:
16 **"SEC. 399V–6. DESIGNATION AND INVESTIGATION OF PO-**
17 **TENTIAL CANCER CLUSTERS.**
18 "(a) DEFINITIONS.—In this section:
19 "(1) CANCER CLUSTER.—The term 'cancer
20 cluster' means the incidence of a particular cancer
21 within a population group, a geographical area, and
22 a period of time that is greater than expected for
23 such group, area, and period.
24 "(2) PARTICULAR CANCER.—The term 'par-
25 ticular cancer' means one specific type of cancer or

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1 a type of cancers scientifically proven to have the
2 same cause.
3 "(3) POPULATION GROUP.—The term 'popu-
4 lation group' means a group, for purposes of calcu-
5 lating cancer rates, defined by factors such as race,
6 ethnicity, age, or gender.
7 "(b) CRITERIA FOR DESIGNATION OF POTENTIAL
8 CANCER CLUSTERS.—
9 "(1) DEVELOPMENT OF CRITERIA.—The Sec-
10 retary shall develop criteria for the designation of
11 potential cancer clusters.
12 "(2) REQUIREMENTS.—The criteria developed
13 under paragraph (1) shall consider, as appropriate—
14 "(A) a standard for cancer cluster identi-
15 fication and reporting protocols used to deter-
16 mine when cancer incidence is greater than
17 would be typically observed;
18 "(B) scientific screening standards that
19 ensure that a cluster of a particular cancer in-
20 volves the same type of cancer, or types of can-
21 cers;
22 "(C) the population in which the cluster of
23 a particular cancer occurs by factors such as
24 race, ethnicity, age, and gender, for purposes of
25 calculating cancer rates;

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1 "(D) the boundaries of a geographic area
2 in which a cluster of a particular cancer occurs
3 so as not to create or obscure a potential clus-
4 ter by selection of a specific area; and
5 "(E) the time period over which the num-
6 ber of cases of a particular cancer, or the cal-
7 culation of an expected number of cases, occurs.
8 "(c) GUIDELINES FOR INVESTIGATION OF POTEN-
9 TIAL CANCER CLUSTERS.—The Secretary, in consultation
10 with the Council of State and Territorial Epidemiologists
11 and representatives of State and local health departments,
12 shall develop, publish, and periodically update guidelines
13 for investigating potential cancer clusters. The guidelines
14 shall—
15 "(1) recommend that investigations of cancer
16 clusters—
17 "(A) use the criteria developed under sub-
18 section (b);
19 "(B) use the best available science; and
20 "(C) rely on a weight of the scientific evi-
21 dence;
22 "(2) provide standardized methods of reviewing
23 and categorizing data, including from health surveil-
24 lance systems and reports of potential cancer clus-
25 ters; and

1 "(3) provide guidance for using appropriate epi-
2 demiological and other approaches for investigations.
3 "(d) INVESTIGATION OF CANCER CLUSTERS.—
4 "(1) SECRETARY DISCRETION.—The Sec-
5 retary—
6 "(A) in consultation with representatives of
7 the relevant State and local health departments,
8 shall consider whether it is appropriate to con-
9 duct an investigation of a potential cancer clus-
10 ter; and
11 "(B) in conducting investigations shall
12 have the discretion to prioritize certain poten-
13 tial cancer clusters, based on the availability of
14 resources.
15 "(2) COORDINATION.—In investigating poten-
16 tial cancer clusters, the Secretary shall coordinate
17 with agencies within the Department of Health and
18 Human Services and other Federal agencies, such as
19 the Environmental Protection Agency.
20 "(3) BIOMONITORING.—In investigating poten-
21 tial cancer clusters, the Secretary shall rely on all
22 appropriate biomonitoring information collected
23 under other Federal programs, such as the National
24 Health and Nutrition Examination Survey. The Sec-

1 retary may provide technical assistance for relevant
2 biomonitoring studies of other Federal agencies.
3 "(e) DUTIES.—The Secretary shall—
4 "(1) ensure that appropriate staff of agencies
5 within the Department of Health and Human Serv-
6 ices are prepared to provide timely assistance, to the
7 extent practicable, upon receiving a request to inves-
8 tigate a potential cancer cluster from a State or
9 local health authority;
10 "(2) maintain staff expertise in epidemiology,
11 toxicology, data analysis, environmental health and
12 cancer surveillance, exposure assessment, pediatric
13 health, pollution control, community outreach, health
14 education, laboratory sampling and analysis, spatial
15 mapping, and informatics;
16 "(3) consult with community members as inves-
17 tigations into potential cancer clusters are con-
18 ducted, as the Secretary determines appropriate;
19 "(4) collect, store, and disseminate reports on
20 investigations of potential cancer clusters, the pos-
21 sible causes of such clusters, and the actions taken
22 to address such clusters; and
23 "(5) provide technical assistance for inves-
24 tigating cancer clusters to State and local health de-
25 partments through existing programs, such as the

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1 Epi-Aids program of the Centers for Disease Control
2 and Prevention and the Assessments of Chemical
3 Exposures Program of the Agency for Toxic Sub-
4 stances and Disease Registry.".

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/8/2016 1:44:27 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

Michal,
That helps. We can work with that and will let you know if anything else comes up. EPA team is connecting tomorrow morning to compare notes to get something back to you. Thanks,
Sven

On May 7, 2016, at 9:19 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

The first 2 are still drafted to the 4/22 version. I can pull the right references in a bit but If you have it it may be faster for you.

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: 5/26/2016 1:30:03 AM
To: 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 Legislative History
Attachments: EPA comments on Statement for the Record.docx; ATT00001.htm

Michal,
This responds to the TA request on TSCA legislative history.

EPA has some additional suggestions which are reflected in redline and comments on the attached document.

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

Statement for the Record
Motion to Concur in the House amendment to the Senate amendment to the bill H.R. 2576 entitled "An Act to modernize the Toxic Substances Control Act, and for other purposes" (hereinafter to be referred to as the Frank R. Lautenberg Chemical Safety for the 21st Century Act)
May XX, 2016
Senator Edward J. Markey

As the lead Senate Democratic negotiators on the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and in the absence of a conference report to clarify Congressional intent, we submit the following non-exhaustive list that describes the intent of the House-Senate negotiators of the final bill text that was enacted into law. The issues listed do not represent the totality of the decisions made by those involved in the bicameral negotiations; rather, they represent the decisions that we feel could most benefit from an assertion of Congressional intent.

1. **"Will Present"**

Existing TSCA as in effect before the date of enactment of Frank R. Lautenberg Chemical Safety for the 21st Century Act includes the authority, contained in several sections (see, for example, section 6(a)), for EPA to take regulatory actions related to chemical substances or mixtures if it determines that the chemical substance or mixture "presents or will present" an unreasonable risk to health or the environment.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act includes language that removes all instances of "will present" from existing TSCA and the amendments thereto.

This does not reflect an intent on the part of Congressional negotiators to remove EPA's authority to consider how a chemical substance or mixture might impact health or the environment under un-intended circumstances or in the future.

In fact, a new definition added to TSCA explicitly provides such authority and a mandate for EPA to consider the potential for an un-intended or future impact of a chemical substance under the "conditions of use":

> '(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.'';

2. **Mixtures**

In section 6(b) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA is directed to undertake risk evaluations on chemical substances in order to determine whether they pose an unreasonable risk to health or the environment. Some have questioned whether the failure to explicitly authorize risk evaluations on mixtures calls into question EPA's authority to evaluate the risks from chemical substances in mixtures.

The definition of 'conditions of use' inserted above would clearly enable EPA to evaluate the use of the chemical substance in any context that could give rise to risks of concern, including in a mixture.

3. New Chemicals

Existing TSCA provides no mandate for EPA to review new chemicals prior to market entry. While EPA has instituted a review process, the burden is wholly on EPA to find a concern; if EPA lacks needed information to conduct a meaningful review, or fails to do so, manufacture of the new chemical can automatically commence. This bill makes significant changes to this passive approach under current law: For the first time, EPA will be required to make an affirmative finding of safety as a condition for commencement of manufacture. If EPA lacks sufficient information, it must either preclude market entry or impose conditions sufficient to ensure that any potential risk is amelioriated. This affirmative approach to better ensuring the safety of new chemicals entering the market is essential to restoring the public's confidence in our chemical safety system.

4. Unreasonable Risk

TSCA as in effect before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act 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."

The Frank R. Lautenberg Chemical Safety for the 21st Century Act clearly rejects that approach to determining what "unreasonable risk of injury 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 ensured that when EPA evaluates a chemical to determine whether it poses an unreasonable risk to health or the environment, it does not apply the sort of "balancing test" described above.

[1] 947 F.2d 1201 (1991)

5. **Prioritization**

Section 6(b) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, defines high-priority chemical substances and low-priority chemical substances as follows:

> "(i) 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 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.
> "(ii) LOW-PRIORITY SUBSTANCES.— The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance."

The direction to EPA for the designation of low-priority substances is of note in that it requires such designations to be made only when there is "information sufficient to establish" that the standard for designating a substance as a high-priority substance is not met. Clear authority is provided under section 4(a)(2)(B), as created in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to enable EPA to obtain the information needed to prioritize chemicals for which information is initially insufficient. The bill text also goes on to state that if "the information available to the Administrator at the end of such an extension [for testing of a chemical substance in order to determine its priority designation] remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance."

These provisions are intended to ensure that the only chemicals to be designated low-priority are those for which EPA both has sufficient information and affirmatively does NOT conclude that the substance may present an unreasonable risk.

6. **Pace of and long-term goal for EPA safety reviews of existing chemicals**

Existing TSCA grandfathered in tens of thousands of chemicals to the inventory without requiring any review of their safety. The Frank R. Lautenberg Chemical Safety for the 21st Century Act sets in motion a process under which EPA will for the first time systematically review the safety of chemicals in active commerce. While this will take many years, the goal of the legislation is to ensure that all chemicals on the market get such a review. The initial targets for numbers of reviews are relatively low, reflecting current EPA capacity and resources. These targets represent floors, not ceilings, and Senate Democratic negotiators expect that as EPA begins to collect fees, gets procedures established and gains experience, these targets can be exceeded in furtherance of the legislation's goals.

7. **"Maximum" extent practicable**

Several sections of the Frank R. Lautenberg Chemical Safety for the 21st Century Act include direction to EPA to take certain actions to "the extent practicable", in contrast to language in S 697 as reported by the Senate that actions be taken to "the *maximum* extent practicable." During House-Senate negotiations on the bill, Senate negotiators were informed that House Legislative Counsel believed the terms "extent practicable" and "maximum extent practicable" are synonymous, and ultimately Congress agreed to include "extent practicable" in the Frank R. Lautenberg Chemical Safety for the 21st Century Act with the expectation that no change in meaning from S 697 as reported by the Senate be inferred from that agreement.

8. Cost considerations in rulemaking

Section 6(c)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act lists what is required in analysis intended to support an EPA rule for a chemical substance or mixture:

> ''(2) REQUIREMENTS FOR RULE.— ''(A) STATEMENT OF EFFECTS.—In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—
> ''(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
> ''(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
> ''(iii) the benefits of the chemical substance or mixture for various uses; and
> ''(iv) the reasonably ascertainable economic consequences of the rule, including consideration of—
> ''(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
> ''(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
> "(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

The language above specifies the manner in which EPA is to consider effects, exposures and costs associated with regulating a chemical substance. Senate Democratic negotiators further clarify that sections 6(c)(2)(A)(i) and (ii) do not require EPA to conduct a second risk evaluation-like analysis to identify the specified information, but rather, that EPA is required to consider the evaluations of health and environmental effects and exposures developed in the risk evaluation itself as it determines what regulatory actions to take.

Clauses (i)-(iv) delineate factors EPA is to consider in deciding among restrictions in a rule under subsection (a). The extent of such consideration is bounded in two important respects: first, it is to be based on information reasonably available to EPA, and hence does not require new information collection or development; and second, consideration of these factors does not in any manner negate or lessen the requirement that the restrictions EPA imposes under the rule be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified.

The provision's requirement that EPA consider costs and benefits and the cost-effectiveness of its regulatory action and 1 or more primary alternative regulatory actions is also further bounded: EPA need only consider such factors for the 1 or more "primary" alternatives it considered, not every possible alternative; and these considerations do not require EPA to demonstrate benefits outweigh costs, determine definitively the least-cost alternative, or to select an option that is demonstrably cost-effective ~~or is the least burdensome adequately protective option~~. Rather, it requires only that EPA take into account ~~the such~~ specified ~~consideration information~~ in deciding among restrictions to impose, which must be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified. The Frank R. Lautenberg Chemical Safety for the 21st Century Act clearly rejects the regulatory approach and framework that led to the failed asbestos ban and phase-out rule of 1989 in *Corrosion Proof Fittings v. EPA* 947 F.2d 1201 (5th Cir. 1991).

Commented [A1]: Suggest this addition to directly address "least burdensome".

Commented [A2]: Without this change, the sentence could be read to say that EPA must consider the least cost alternative and other factors referenced immediately preceding.

9. "Minimum" labeling requirements

Section 6(a) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, ensures that the requirements EPA can impose to address an unreasonable risk to health or the environment include requiring "clear and adequate minimum" warnings. The addition of the word "minimum" was intended to avoid the sort of litigation that was undertaken in ***Wyeth v. Levine***, 555 U.S. 555 (2009), when a plaintiff won a Supreme Court decision after alleging that the harm she suffered from a drug that had been labeled in accordance with FDA requirements had nevertheless been inadequately labeled under Vermont law. This ensures that manufacturers or processors of chemical substances and mixtures can always take additional measures, if in the interest of protecting health and the environment, it would be reasonable to do so.

10. Critical Use Exemptions

Section 6(g) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, authorizes EPA to exempt specific conditions of use from otherwise applicable section 6(a) rule requirements, if EPA makes specified findings. Section 6(g)(4) in turn requires EPA to include in such an exemption conditions that are "necessary to protect health and the environment while achieving the purposes of the exemption." It is Congress' intent that the conditions EPA imposes will protect health and the environment to the extent feasible, recognizing that, by its nature, an exemption will allow for activities that present some degree of unreasonable risk.

11. **Regulatory Compliance**

Several sections of the Frank R. Lautenberg Chemical Safety for the 21st Century Act clarify the Congressional intent that compliance with federal EPA standards, rules or other requirements shall not preclude liability in circumstances where a reasonable manufacturer or processor or distributor of a chemical substance or mixture could or should have taken additional measures or precautions in the interest of protecting public health and the environment.

12. TSCA as the Primary Statute for the Regulation of Toxic Substances

EPA's authorities and duties under section 6 of TSCA have been significantly expanded under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, now including comprehensive deadlines and throughput expectations for chemical prioritization, risk evaluation, and risk management. The interagency referral process and the intra-agency consideration process established under Section 9 of existing TSCA must now be regarded in a different light since TSCA can no longer be construed as a "gap-filler" statutory authority of last resort. Accordingly, Section 9 has been revised to ensure that once it is clear that a chemical substance presents an unreasonable risk, these processes will not conflict with the fundamental expectation that EPA ensure in a timely manner that the chemical substance no longer presents such risk.

The question of whether existing regulation of a chemical substance (either by EPA or other authorities) adequately mitigates the risks of a chemical substance is one that EPA would consider in the course of its risk evaluation under Section 6. It is not a separate factor that EPA may invoke under Section 9 to allow unreasonable risks to persist. Once EPA has identified that a chemical substance presents an unreasonable risk, Section 9(a) is not intended to supersede or modify the Agency's obligations under Sections 6(a) or 7 to address risks from activities involving the chemical substance, except as expressly identified in a section 9(a) referral for further regulation by another agency.

Regarding EPA's consideration of whether to use non-TSCA EPA authorities in order to address unreasonable chemical risks identified under TSCA, the new section 9(b)(2) merely consolidates existing language which was previously split between section 6(c) and section 9(b). It only applies where the Administrator has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities. It allows the Administrator substantial discretion to use TSCA nonetheless, and it certainly does not reflect that TSCA is an authority of last resort in such cases. Furthermore, none of these revisions were intended to alter the clear intent of Congress, reflected in the original legislative history of TSCA, that these decisions would be completely discretionary with the Administrator and not subject to judicial review in any manner.

13. **Disclosure of Confidential Business Information**

S 697 as passed by the Senate included several requirements as amendments to sections 8 and 14 of existing TSCA that direct EPA to "promptly" make confidential business information public when it determines that protections against disclosure of such information should no longer apply. The Frank R. Lautenberg Chemical Safety for the 21st Century Act instead directs EPA to remove the protections against disclosure when it determines that they should no longer apply. Because EPA informed Senate negotiators that its practice is to promptly make public information that is no longer protected against disclosure, we see no difference or distinction in meaning between the language in S 697 as passed and the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and expect EPA to continue its current practice of affirmatively making public information that is not or no longer protected from disclosure.

Subsection 14(d)(9) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, further clarifies the Congressional intent that any information required pursuant to discovery, subpoena, court order, or any other judicial process is always allowable and discoverable under State and Federal law, and not protected from disclosure.

14. 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 from disclosure of information from health and safety studies: for information where disclosure would disclose either how a chemical is manufactured or processed 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.

15. **"Requirements"**

Subsection 5(i)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA action or inaction on a chemical substance.

Subsection 6(j) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA action or inaction on a chemical substance.

16. **State-Federal Relationship**

Sections 18(a)(1)(B) and 18(b)(1) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, refer to circumstances under which a state may not establish or continue to enforce a "statute, criminal penalty, or administrative action" on a chemical substance. Section 18(b)(2) states that "this subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any statute enacted, criminal penalty ***assessed***, or administrative action taken". In an email transmitted by Senate Republican negotiators at 11:45 AM on May 23, 2016, the Senate requested that House Legislative Counsel delete the word "assessed," but this change was not made in advance of the 12 PM deadline to file the bill text with the House Rules Committee. The Senate's clear intent was *not to* change or in any way limit the meaning of the phrase "criminal penalty" in section 18(b)(2).

Section 18(d)(1) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, references "risk evaluations" on chemical substances that may be conducted by states or political subdivisions of states with the clear intent to describe the circumstances in which such efforts would not be preempted by federal action. The term "Risk Evaluation" may

not be universally utilized in every state or political subdivision of a state, but researching each analogous term used in each state or political subdivision of a state in order to explicitly list it was neither realistic nor possible. The use of this term is not intended to be in any way limiting.

Section 18(d)(1)(A)(ii) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, fully preserves the authority of states or political subdivisions of states to impose "information obligation" requirements on manufacturers or processors with respect to chemicals they produce or use. The provision cites examples of such obligations: reporting and monitoring or "other information obligations." These may include, but are not limited to, state requirements related to information, such as companies' obligations to disclose use information or to label products or chemicals with certain information.

Section 18(d)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, specifies that nothing in this section shall modify the preemptive effect of any prior rule or order by the Administrator prior to the effective date, responding to concerns that prior EPA action on substances such as polychlorinated biphenyl would be potentially immunized from liability for injury or harm.

Section 18(e) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, grandfathers existing and enacted state laws, regulatory actions, and requirements later imposed under the authority of state laws that were in effect on August 31, 2003.

Commented [A3]: There should be an "and" instead of a comma between "state laws" and "regulatory actions"; otherwise, the meaning of this is garbled.

Section 18(f) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, provides discretionary and mandatory waivers which exempt regulatory action by states and their political subdivisions from any federal preemptive effect. Subsection 18(f)(2)(B) further specifies the Congressional intent that regulatory action by states and their political subdivisions shall not be subject to any federal preemptive effect upon the enactment of any relevant statute, or the proposal or completion of a preliminary administrative action prohibiting or otherwise regulating a chemical substance or mixture, provided the enactment of the state law or the taking of the state administrative action occurs in a window of time that is the period that begins with the initiation by EPA of the prioritization process and that ends 18 months later, or the date EPA publishes the scope of the risk evaluation for a chemical substance, whichever is sooner.

Section 18(g) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, specifies that no preemption of any common law or statutory causes of action for civil relief or criminal conduct shall occur, and that nothing in this Act shall be interpreted as dispositive or otherwise limiting any civil action or other claim for relief. This section also clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA action or inaction on a chemical substance. This section further clarifies Congress' intent that no express, implied, or actual conflict exists between any federal regulatory action and any state, federal, or maritime tort action, responding to the perceived conflict contemplated in *Geier v. American Honda Motor Co.,* 529 U.S. 861 (2000) and its progeny.

17. **Fees**

Fees under section 26(b), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, are authorized to be collected so that 25% of EPA's overall costs to carry out section 4, 5, and 6, and to collect, process, review, provide access to and protect from disclosure information, are defrayed, subject to a $25,000,000 cap (that itself can be adjusted for inflation or if it no longer provides 25% of EPA's costs listed above). While the collection of fees is tied to the submission of particular information or the manufacturing or processing of a particular chemical substance undergoing a risk evaluation, in general the use of these fees is not limited to defraying the cost of the action that was the basis for the fee. The exception to this general principle is for fees to defray the cost of conducting manufacturer requested risk evaluations. These must be spent on the particular risk evaluation that was the basis for the fee. This limitation applies only to the fee collected for purpose of conducting the risk evaluation and does not prevent EPA from collecting further fees from such persons for other uses for which fees are authorized under the section. For example, if that risk evaluation later leads to risk management action, EPA may assign further fees to manufacturers and processors of that substance, subject to the $25,000,000 cap and the requirement to not exceed 25% of overall program costs for carrying out sections 4, 5, and 6.

We also note that some have raised the possibility that section 26(b)(4)(B)(i)(I), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, could be read to exclude the cost of risk evaluations, other than industry-requested risk evaluations, from the costs that can be covered by fees. This was not the intent. As clearly indicated in section 26(b)(1), Congress intends that manufacturers and processors of chemicals subject to risk evaluations be subject to fees, and that fees be collected to defray the cost of administering sections 4, 5, and 6, and of collecting, processing, reviewing and providing access to and protecting from disclosure information. Risk evaluations are a central element of section 6. And as demonstrated by section 6(b)(4)(F)(i), the intent of the bill is that the EPA-initiated risk evaluations be defrayed at the 25% level (subject to the $25,000,000 cap), in contrast to the industry-initiated evaluations, which are funded at the 50% or 100% level. The final citation in section 26(b)(4)(B)(i) should be read as section 6(b)(4)(C)(ii), as it is in section 6(b)(4)(F)(i), not to section 6(b) generally.

18. **Partial Risk Evaluations**

Section 26(l)(4) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, states

> "(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."

EPA has completed risk assessments on TCE, NMP, and MC, but has not yet proposed or finalized section 6(a) rules to address the risks that were identified. During the bicameral negotiations, EPA conveyed its concern that these risk assessments were not conducted across all conditions of use of these chemical substances, because existing TSCA does not require this to

be done. EPA was concerned that if it proposed 6(a) rules to regulate these substances after the Frank R. Lautenberg Chemical Safety for the 21st Century Act was enacted, the rules could be invalidated through litigation because the risk assessments did not consider all conditions of use, and additionally noted the concern that, if EPA delayed its rules for these substances in order to conduct a full risk evaluation across all conditions of use, the imposition of important public health protections that are known to be needed would also be delayed. Congress shared these concerns. The language House-Senate negotiators included above is intended to allow EPA to proceed with the regulation of these substances if the scope of the proposed and final rules is consistent with the scope of the risk assessments conducted on these substances (even where the risk assessments did not include a consideration of all conditions of use).

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/5/2016 10:03:34 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]; 'McCarthy, David' [David.McCarthy@mail.house.gov]; 'Richards, Tina' [Tina.Richards@mail.house.gov]
Subject: HEC TSCA TA request on mixtures in HLC (5-4)

Jerry –
This TA responds to the request on references to mixtures in HLC (5-4) version.

1. Page 5, line 4 – there are mixtures described in that subparagraph as well; should these new orders & consent agreements apply to them as well?

Response: We think that it would be helpful to add references to mixtures at page 5 line 4.

2. Page 14, lines 18-23. Is this also necessary for mixtures?

Response: EPA does not believe an edit is necessary here because nothing in the bill precludes EPA from encouraging the grouping of 2 or more mixtures into categories. But if your intent is to require EPA to encourage the grouping of 2 or more mixtures into categories for testing purposes, then it would probably make sense to add references to mixtures here.

3. Page 16, lines 1-2. Is this also necessary for mixtures?

Response: Reference to mixtures is not necessary here. This is a purely illustrative list and it is generally clear that the intent of this provision is to reduce the use of vertebrate animals in the testing of chemical substances or mixtures. But if you wanted to more clearly signal your intent here, we have no concern with adding "or mixtures" following chemical substances"

4. Throughout the new fee language that's going into section 26(b) (beginning on page 125, line 8), are there necessary costs associated exclusively with mixtures that need to be added?

Response: We do not think that it is necessary to add references to mixtures here to cover fees associated with work that would be done on mixtures. Testing of mixtures under section 4 would trigger a requirement to submit "information under section 4," which is a fee trigger. Mixtures are not subject to PMN or SNUN requirements under section 5, so they should not be referenced as fee triggers in that respect. Mixtures are not individually subject to risk evaluations under section 6(b), so, similarly, they should not be referenced as fee triggers in that respect. Under current drafting, EPA can set fees to carry out the work of administering sections 4, 5, and 6, including the review of tested mixtures and the evaluation of the risks that chemical substances pose when they exist in mixtures with other chemical substances.

5. Page 136, lines 12-18. Mixtures are in the lead-in, and they can be subject to testing; do they need to be added here?

Response: If your intent is to ensure that the policies cover mixtures in the respect described in paragraph (A), it seems reasonable to add "or mixture" at page 136 line 14.

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

From: "Couri, Jerry" <JerryCouri@mail.house.gov>
Date: May 5, 2016 at 3:12:35 PM EDT
To: "Sven-Erik Kaiser (kaiser.sven-erik@epa.gov)" <kaiser.sven-erik@epa.gov>
Cc: "McCarthy, David" <David.McCarthy@mail.house.gov>, "Richards, Tina" <Tina.Richards@mail.house.gov>
Subject: TA request on whether not making these changes damages implementation

we came across some provisions of the bill that might need to refer to mixtures:

1. Page 5, line 4 – there are mixtures described in that subparagraph as well; should these new orders & consent agreements apply to them as well?
2. Page 14, lines 18-23. Is this also necessary for mixtures?
3. Page 16, lines 1-2. Is this also necessary for mixtures?
4. Throughout the new fee language that's going into section 26(b) (beginning on page 125, line 8), are there necessary costs associated exclusively with mixtures that need to be added?
5. Page 136, lines 12-18. Mixtures are in the lead-in, and they can be subject to testing; do they need to be added here?

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/26/2016 1:25:21 AM
To: Bettina_Poirier@epw.senate.gov; jason_albritton@epw.senate.gov; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]
Subject: Sen. Boxer TSCA TA request on Legislative History
Attachments: EPA comments on Statement for the Record.docx; ATT00001.htm

This responds to the TA request on TSCA legislative history.

While EPA was not the originator of this document we de believe there is value in clarifying legislative intent for many of these issues. For example, members during the House debate on Tuesday opined that changes made to TSCA section 9 signal an intent that TSCA be used only as a last resort, and they called into question the need for ongoing EPA section 6 rulemakings. We believe that characterization of the changes to section 9, and the interpretation of section 9 as modified, are incorrect and see value in providing an alternative viewpoint. As another important example, section 26(b)(4)(B)(i)(I) could be interpreted to preclude EPA from collecting fees to cover EPA-initiated risk evaluations. We see significant value in having this point addressed.

EPA did review an earlier version of this document and provided input that is reflected in it. However, EPA has some additional suggestions on language that we had not previously seen, which are reflected in redline and comments on the attached document.

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) [mailto:Jason_Albritton@epw.senate.gov]
Sent: Wednesday, May 25, 2016 6:04 PM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Cc: Poirier, Bettina (EPW) <Bettina_Poirier@epw.senate.gov>
Subject: TSCA Legislative History

Nichole,

I understand EPA has provided input on the attached document. Can you let us know if you have reviewed this version and if you have any additional comments?

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: 5/5/2016 9:17:45 PM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]; Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: HEC TSCA TA section 21 followup (HLC 5-4)
Attachments: HEC.TSCA TA.HLC 5-4.section 21.docx; 2016_03_xml.pdf

Dave and Jackie,
This TA responds to the followup request on section 21. Page and line citations refer back to HLC 5-4 (attached PDF).

To resolve [A4] by adding 5(f) to 21(b)(4)(B)(ii):

Page 153 lines 13-14: <<(iii) in clause (ii), by striking "or an order under section 6(b)(2)" and inserting "or an order under section 5(f)".>>

To address [A5] by making the Section 21 petitioner's demonstration parallel to EPA's determination under 6(b)(4)(A) and furthermore requiring a demonstration that the requested chemical merits being moved ahead of other priorities:

Following lines 13-14 on Page 153, add additional language to the bill , striking in clause (ii): "there is a reasonable basis to conclude" and all that follows through "injury to health or the environment" and inserting "the chemical substance presents an unreasonable risk in accordance with section 6(b)(4)(A) and such risk is of greater magnitude than the risk presented by chemicals substances currently undergoing risk evaluation under section 6(b)(4)(A)."

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

From: "McCarthy, David" <David.McCarthy@mail.house.gov>
Date: May 5, 2016 at 2:53:01 PM EDT
To: "'Kaiser.Sven-Erik@epa.gov'" <Kaiser.Sven-Erik@epa.gov>
Subject: section 21

Sven - could you guys also send us the specific instructions to carry out the changes in the May 4 PDF for bubbles A4 and A5 in section 21? Thanks!

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, May 05, 2016 01:07 PM
To: McCarthy, David; Cohen, Jacqueline
Subject: HEC TSCA TA on section 21 (HLC 5-4 version)

Dave and Jackie,
Additional TA on section 21 of the HLC 5-4 version. Again, this is a version that compares HLC 5-4 to HLC 4-22. EPA's comments are only in the comment bubbles.

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

[DISCUSSION DRAFT]

114TH CONGRESS
2D SESSION

H. R. _____

To modernize the Toxic Substances Control Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To modernize the Toxic Substances Control 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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings, policy, and intent.
Sec. 3. Definitions.

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)—

(A) by striking "If the Administrator finds" and inserting "(1) If the Administrator finds";

(B) in paragraph (1), as so designated—

(i) by striking "(1)(A)(i)" and inserting "(A)(i)(I)";

(ii) by striking "(ii)" each place it appears and inserting "(II)";

(iii) by striking "are insufficient data" and inserting "is insufficient information" each place it appears;

(iv) by striking "(iii)" each place it appears and inserting "(III)";

(v) by striking "such data" and inserting "such information" each place it appears;

(vi) by striking "(B)(i)" and inserting "(ii)(I)";

(vii) by striking "(I)" and inserting "(aa)";

(viii) by striking "(II)" and inserting "(bb)";

(ix) by striking "(2)" and inserting "(B)"; and

(x) in the matter following subparagraph (B), as so redesignated—

(I) by inserting ", or, in the case of a chemical substance described in subparagraph (A)(i), by rule, order, or consent agreement," after "rule";

(II) by striking "data" each place it appears and inserting "information"; and

(III) by striking "and which are relevant" and inserting "and which is relevant"; and

(C) by adding at the end the following:

"(2) ADDITIONAL TESTING AUTHORITY.—In addition to the authority provided under paragraph (1), the Administrator may, by rule, order, or consent agreement—

"(A) require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary—

"(i) to review a notice under section 5 or to perform a risk evaluation under section 6(b);

"(ii) to implement a requirement imposed in a rule, order, or consent agreement under subsection (e) or (f) of section 5 or under a rule promulgated under section 6(a);

"(iii) at the request of a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure; or

"(iv) pursuant to section 12(a)(2); and

"(B) require the development of new information for the purposes of prioritizing a chemical substance under section 6(b) only if the Administrator determines that such information is necessary to establish the priority of the substance, subject to the limitations that—

"(i) not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, order, or consent agreement under this subparagraph, the Administrator shall designate the chemical substance as a high-

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

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

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 subsection (a)(2) may re-
22 quire the development of information by any person who
23 manufactures or processes, or intends to manufacture or
24 process, a chemical substance or mixture subject to the
25 rule or order.";

(D) in paragraph (4)—

(i) by striking "of data" each place it appears and inserting "of information"; and

(ii) by striking "test data" each place it appears and inserting "information"; and

(E) by striking paragraph (5);

(4) in subsection (c)—

(A) in paragraph (1), by striking "data" and inserting "information";

(B) in paragraph (2), by striking "data" each place it appears and inserting "information";

(C) in paragraph (3)—

(i) by striking "test data" each place it appears and inserting "information"; and

(ii) by striking "such data" each place it appears and inserting "such information"; and

(D) in paragraph (4) by striking "test data" each place it appears and inserting "information";

(5) in subsection (d)—

(A) by striking "test data" each place it appears and inserting "information";

(B) by striking "such data" each place it appears and inserting "such information"; and

(C) by striking "for which data have" and inserting "for which information has";

(6) in subsection (e)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "promulgation of a rule" and inserting "development of information"; and

(II) by striking "data" each place it appears and inserting "information"; and

(ii) in subparagraph (B), by striking "either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding" and insert "issue an order, enter into a consent agreement, or initiate a rulemaking proceeding under subsection (a), or, if such an order or consent agree-

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'';

(iii) by striking "appropriate" and inserting "applicable"; and

(iv) by inserting ", made without consideration of costs or other nonrisk factors," after "publish in the Federal Register a finding";

(8) in subsection (g)—

(A) by amending the subsection heading to read as follows:"PETITION FOR PROTOCOLS AND METHODOLOGIES FOR THE DEVELOPMENT OF INFORMATION";

(B) by striking "test data" each place it appears and inserting "information"; and

(C) by striking "submit data" and inserting "submit information"; and

(9) by adding at the end the following:

"(h) REDUCTION OF TESTING ON VERTEBRATES.—

"(1) IN GENERAL.—The Administrator shall reduce, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures under this title by—

"(A) when making a request or adopting a requirement for testing using vertebrate animals, and in accordance with subsection (a)(3),

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

"(iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests, provided that such consortia make data from such testing available to the Administrator.

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

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures through, for example—

"(i) computational toxicology and bioinformatics;

"(ii) high-throughput screening methods;

1 "(iii) testing of categories of chemical
2 substances;
3 "(iv) tiered testing methods;
4 "(v) in vitro studies;
5 "(vi) systems biology;
6 "(vii) new or revised methods identi-
7 fied by validation bodies such as the Inter-
8 agency Coordinating Committee on the
9 Validation of Alternative Methods or the
10 Organization for Economic Co-operation
11 and Development; or
12 "(viii) industry consortia that develop
13 information submitted under this title;
14 "(B) as practicable, ensure that the stra-
15 tegic plan developed under subparagraph (A) is
16 reflected in the development of requirements for
17 testing under this section;
18 "(C) include in the strategic plan devel-
19 oped under subparagraph (A) a list, which the
20 Administrator shall update on a regular basis,
21 of particular alternative test methods or strate-
22 gies the Administrator has identified that do
23 not require new vertebrate animal testing and
24 are scientifically reliable, relevant, and capable
25 of providing information of equivalent or better

1 scientific reliability and quality to that which
2 would be obtained from vertebrate animal test-
3 ing for specific health and environmental
4 endpoints;
5 "(D) provide an opportunity for public no-
6 tice and comment on the contents of the plan
7 developed under subparagraph (A), including
8 the criteria for considering scientific relevance
9 and value for risk assessment purposes of the
10 test methods and strategies that may be identi-
11 fied pursuant to subparagraph (C);
12 "(E) beginning on the date that is 5 years
13 after the date of enactment of the Frank R.
14 Lautenberg Chemical Safety for the 21st Cen-
15 tury Act, and every 5 years thereafter, submit
16 to Congress a report that describes the progress
17 made in implementing the plan developed under
18 subparagraph (A) and goals for future alter-
19 native test methods and strategies implementa-
20 tion; and
21 "(F) prioritize and, to the extent con-
22 sistent with available resources and the Admin-
23 istrator's other responsibilities under this title,
24 carry out performance assessment, validation,
25 and translational studies to accelerate the devel-

opment of scientifically valid test methods and strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this title.".

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "Except as provided in" and inserting "(A) Except as provided in subparagraph (B) of this paragraph and";

(ii) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(iii) by striking all that follows "significant new use" and inserting a period; and

(iv) by adding at the end the following:

"(B) A person may take the actions described in subparagraph (A) if—

"(i) such person submits to the Administrator, at least 90 days before such manufac-

1 ture or processing, a notice, in accordance with
2 subsection (d), of such person's intention to
3 manufacture or process such substance and
4 such person complies with any applicable re-
5 quirement imposed under subsection (b); and
6 "(ii) the Administrator—
7 "(I) conducts a review of the notice;
8 and
9 "(II) makes a determination under
10 subparagraph (A), (B), (C), or (D) of
11 paragraph (3) and takes the actions re-
12 quired in association with that determina-
13 tion under such subparagraph within the
14 applicable review period."; and
15 (B) by adding at the end the following new
16 paragraphs:
17 "(3) REVIEW AND DETERMINATION.—Within
18 the applicable review period, subject to section 18,
19 the Administrator shall review such notice and de-
20 termine—
21 "(A) that the relevant chemical substance
22 or significant new use presents or will present
23 an unreasonable risk of injury to health or the
24 environment, without consideration of costs or
25 other nonrisk factors, including an unreason-

able risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

"(B) that—

"(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; 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, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

"(II) such substance is or will be produced in substantial quantities, and such

1 substance either enters or may reasonably
2 be anticipated to enter the environment in
3 substantial quantities or there is or may be
4 significant or substantial human exposure
5 to the substance,
6 in which case the Administrator shall take the actions re-
7 quired under subsection (e);
8 "(C) that the relevant chemical substance
9 or significant new use is likely not to present an
10 unreasonable risk of injury to health or the en-
11 vironment, without consideration of costs or
12 other nonrisk factors, including an unreason-
13 able risk to a potentially exposed or susceptible
14 subpopulation identified as relevant by the Ad-
15 ministrator under the conditions of use, in
16 which case the Administrator shall publish such
17 determination and the submitter of the notice
18 may commence manufacture of the chemical
19 substance or manufacture or processing for a
20 significant new use; or
21 "(D) that the relevant chemical substance
22 is a low-hazard substance, in which case the
23 Administrator shall publish such determination
24 and the submitter of the notice may commence
25 manufacture of the chemical substance or man-

1 ufacture or processing of the chemical sub-
2 stance for 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 period of review.
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.

"(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

"(5) ARTICLE CONSIDERATION.—In promulgating a rule under paragraph (2), the Administrator may consider whether there is a likely potential for exposure to a chemical substance through an article or category of articles, and if the Administrator finds such a likely potential, the Administrator shall require notification under this section for the import or processing of a chemical substance as part of the article or category of articles.";

(2) in subsection (b)—

(A) in the subsection heading, by striking "TEST DATA" and inserting "INFORMATION";

(B) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information"; and

(II) by striking "such data" and inserting "such information"; and

(ii) in subparagraph (B)—

(I) by striking "test data" and inserting "information";

(II) by striking "subsection (a)(1)(A)" and inserting "subsection (a)(1)(A)(i)"; and

(III) by striking "subsection (a)(1)(B)" and inserting "subsection (a)(1)(A)(ii)";

(C) in paragraph (2)—

(i) in subparagraph (A)—

(I) by striking "test data" in clause (ii) and inserting "information";

(II) by striking "shall" and inserting "may"; and

(III) by striking "data prescribed" and inserting "information prescribed"; and

(ii) in subparagraph (B)—

(I) by striking "Data" and inserting "Information";

(II) by striking "data" both places it appears and inserting "information";

(III) by striking "show" and inserting "shows";

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";

(4) in subsection (d)—

(A) by striking "test data" in paragraph (1)(B) and inserting "information";

(B) by striking "data" each place it appears in paragraph (1)(C) and paragraph (2) and inserting "information";

(C) in paragraph (2)(B), by striking "uses or intended uses of such substance" and inserting "uses of such substance identified in the notice by the Administrator"; and

(D) in paragraph (3)—

(i) by striking "for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "for which the applicable review period"; and

(ii) by striking "such notification period" and inserting "such period";

(5) in subsection (e)—

(A) in paragraph (1)(A)—

(i) in clause (ii)(I), by inserting "without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator

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''; and
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'';
21 (C) by striking paragraph (1)(C); and
22 (D) by striking paragraph (2);
23 (6) in subsection (f)—
24 (A) in paragraph (1)—

(i) by striking "finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with" and inserting "determines that a chemical substance or significant new use with";

(ii) by striking ", or that any combination of such activities,";

(iii) by inserting ", without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use," after "health or environment"; and

(iv) by striking "notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance" and inserting "applicable review period";

(B) in paragraph (3)—

(i) in subparagraph (A)—

(I) by striking "Administrator may" and all that follows through

"issue a proposed order to prohibit the" and inserting "Administrator may issue an order to prohibit or limit the"; and

(II) by striking "under paragraph (1)" and all that follows through "processing of such substance." and inserting "under paragraph (1). Such order shall take effect on the expiration of the applicable review period.";

(ii) by striking subparagraph (B) and redesignating subparagraph (C) as subparagraph (B);

(iii) in subparagraph (B), as so redesignated—

(I) by striking "subparagraphs (B) and (C)" and inserting "subparagraph (B)";

(II) by striking "clause (i) of"; and

(III) by striking "; and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect

1 to an injunction issued under sub-
2 paragraph (B)''; and
3 (iv) by striking subparagraph (D);
4 and
5 (C) by adding at the end the following:
6 ''(4) TREATMENT OF NONCONFORMING USES.—
7 Not later than 90 days after taking an action under
8 paragraph (2) or (3) or issuing an order under sub-
9 section (e) relating to a chemical substance with re-
10 spect to which the Administrator has made a deter-
11 mination under subsection (a)(3)(A) or (B), the Ad-
12 ministrator shall consider whether to promulgate a
13 rule pursuant to subsection (a)(2) that identifies as
14 a significant new use any manufacturing, processing,
15 use, distribution in commerce, or disposal of the
16 chemical substance that does not conform to the re-
17 strictions imposed by the action or order, and, as ap-
18 plicable, initiate such a rulemaking or publish a
19 statement describing the reasons of the Adminis-
20 trator for not initiating such a rulemaking.
21 ''(5) WORKPLACE EXPOSURES.—To the extent
22 practicable, the Administrator shall consult with the
23 Assistant Secretary of Labor for Occupational Safe-
24 ty and Health prior to adopting any prohibition or
25 other restriction relating to a chemical substance

with respect to which the Administrator has made a determination under subsection (a)(3)(A) to address workplace exposures.";

(7) by amending subsection (g) to read as follows:

"(g) STATEMENT ON ADMINISTRATOR FINDING.—If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is likely not to present an unreasonable risk of injury to health or the environment, or in accordance with subsection (a)(3)(D) that the chemical substance is a low-hazard substance, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.";

(8) in subsection (h)—

(A) in paragraph (1)(A), by inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific uses identified in the application" after "health or the environment";

(B) in paragraph (2), by striking "data" each place it appears and inserting "information"; and

(C) in paragraph (4), by striking ". A rule promulgated" and all that follows through "section 6(c)" and inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use"; and

(9) by amending subsection (i) to read as follows:

"(i) DEFINITIONS.—(1) For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.

"(2) For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.

"(3) For purposes of this section, the term 'applicable review period' means the period starting on the date the

1 Administrator receives a notice under subsection (a)(1)
2 and ending 90 days after that date, or on such date as
3 is provided for in subsection (b)(1) or (c).".

4 **SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULA-**
5 **TION OF CHEMICAL SUBSTANCES AND MIX-**
6 **TURES.**

7 Section 6 of the Toxic Substances Control Act (15
8 U.S.C. 2605) is amended—

9 (1) by striking the section heading and insert-
10 ing "**PRIORITIZATION, RISK EVALUATION, AND**
11 **REGULATION OF CHEMICAL SUBSTANCES AND**
12 **MIXTURES**";

13 (2) in subsection (a)—

14 (A) by striking "finds that there is a rea-
15 sonable basis to conclude that" and inserting
16 "determines in accordance with subsection
17 (b)(4)(A)";

18 (B) by inserting "and subject to section
19 18, and in accordance with subsection (c)(2),"
20 after "shall by rule";

21 (C) by striking "to protect adequately
22 against such risk using the least burdensome
23 requirements" and inserting "so that the chem-
24 ical substance or mixture no longer presents
25 such risk";

(D) by inserting "or otherwise restricting" after "prohibiting" in paragraph (2)(A);

(E) by inserting "minimum" before "warnings" both places it appears in paragraph (3);

(F) by striking "and monitor or conduct tests" and inserting "or monitor or conduct tests" in paragraph (4); and

(G) in paragraph (7)—

(i) by striking "such unreasonable risk of injury" and inserting "such determination"; and

(ii) by striking "such risk of injury" and inserting "such determination";

(3) by amending subsection (b) to read as follows:

"(b) RISK EVALUATIONS.—

"(1) PRIORITIZATION FOR RISK EVALUATIONS.—

"(A) ESTABLISHMENT OF PROCESS.—

"(i) IN GENERAL.—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

1 designating chemical substances as high-
2 priority substances for risk evaluations or
3 low-priority substances for which risk eval-
4 uations are not warranted at the time. The
5 process to designate the priority of chem-
6 ical substances, which shall not take longer
7 than one year, shall include a consideration
8 of the hazard and exposure potential of a
9 chemical substance or a category of chem-
10 ical substances (including consideration of
11 persistence and bioaccumulation, poten-
12 tially exposed or susceptible subpopulations
13 and storage near significant sources of
14 drinking water), the conditions of use or
15 significant changes in the conditions of use
16 of the chemical substance, and the volume
17 or significant changes in the volume of the
18 chemical substance manufactured or proc-
19 essed.
20 "(ii) PUBLIC NOTICE AND COM-
21 MENT.—The process established under
22 clause (i) shall require the Administrator
23 to notify the public when prioritization be-
24 gins and allow for notice and comment
25 which shall be completed along with the

1 rest of the process within the one year
2 deadline.
3 "(B) IDENTIFICATION OF PRIORITIES FOR
4 RISK EVALUATION.—
5 "(i) HIGH-PRIORITY SUBSTANCES.—
6 The Administrator shall designate as a
7 high-priority substance a chemical sub-
8 stance that the Administrator concludes,
9 without consideration of costs or other
10 nonrisk factors, may present an unreason-
11 able risk of injury to health or the environ-
12 ment because of potential hazard and a po-
13 tential route of exposure under the condi-
14 tions of use, including an unreasonable
15 risk to a potentially exposed or susceptible
16 subpopulation identified as relevant by the
17 Administrator.
18 "(ii) LOW-PRIORITY SUBSTANCES.—
19 Except as provided in clause (iii), the Ad-
20 ministrator shall designate a chemical sub-
21 stance as a low-priority substance if the
22 Administrator concludes, based on infor-
23 mation sufficient to establish, without con-
24 sideration of costs or other nonrisk factors,
25 that such substance does not meet the

1 standard identified in clause (i) for desig-
2 nating a chemical substance a high-priority
3 substance.
4 "(iii) LOW-HAZARD SUBSTANCES.—
5 The Administrator may designate a chem-
6 ical substance as a low-hazard substance if
7 the Administrator concludes, based on in-
8 formation sufficient to establish, without
9 consideration of costs or other nonrisk fac-
10 tors or exposure, that the chemical sub-
11 stance—
12 "(I) poses no or low hazard to
13 human health or the environment, in-
14 cluding any hazard to a potentially ex-
15 posed or susceptible subpopulation
16 identified as relevant by the Adminis-
17 trator; and
18 "(II) does not meet the standard
19 identified in clause (i) for designating
20 a chemical substance a high-priority
21 substance.
22 "(C) EXTENSION OF DEADLINE.—The Ad-
23 ministrator shall, in the rulemaking required
24 under subparagraph (A), provide for a process
25 to extend the one year deadline under subpara-

1 graph (A) for up to six months in order to re-
2 ceive or evaluate information required to be
3 submitted in accordance with section
4 4(a)(2)(B), subject to the limitation that if the
5 information available to the Administrator at
6 the end of such an extension remains insuffi-
7 cient to enable the designation of the chemical
8 substance as a low-priority substance, the Ad-
9 ministrator shall designate the substance as
10 high-priority substance.

11 "(2) INITIAL RISK EVALUATIONS AND SUBSE-
12 QUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY
13 SUBSTANCES.—

14 "(A) INITIAL RISK EVALUATIONS.—Not
15 later than 180 days after the date of enactment
16 of the Frank R. Lautenberg Chemical Safety
17 for the 21st Century Act, the Administrator
18 shall ensure that risk evaluations are being con-
19 ducted on at least 10 chemical substances
20 drawn from the 2014 update of the TSCA
21 Work Plan for Chemical Assessments.

22 "(B) ADDITIONAL RISK EVALUATIONS.—
23 Not later than three and one half years after
24 the date of enactment of the Frank R. Lauten-
25 berg Chemical Safety for the 21st Century Act,

1 the Administrator shall ensure that risk evalua-
2 tions are being conducted on at least 20 high-
3 priority substances and that at least 20 chem-
4 ical substances have been designated as low-pri-
5 ority or low-hazard substances, subject to the
6 limitation that at least 50 percent of all chem-
7 ical substances on which risk evaluations are
8 being conducted by the Administrator are
9 drawn from the 2014 update of the TSCA
10 Work Plan for Chemical Assessments.
11 "(C) CONTINUING DESIGNATIONS AND
12 RISK EVALUATIONS.—The Administrator shall
13 continue to designate priority substances and
14 conduct risk evaluations in accordance with this
15 subsection.
16 "(D) PREFERENCE.—In designating high-
17 priority substances, the Administrator shall give
18 preference to—
19 "(i) chemical substances that are list-
20 ed in the 2014 update of the TSCA Work
21 Plan for Chemical Assessments as having a
22 Persistence and Bioaccumulation Score of
23 3; and
24 "(ii) chemical substances that are list-
25 ed in the 2014 update of the TSCA Work

1 Plan for Chemical Assessments that are
2 known human carcinogens and have high
3 acute and chronic toxicity.
4 "(E) METALS AND METAL COMPOUNDS.—
5 In identifying priorities for risk evaluation and
6 conducting risk evaluations of metals and metal
7 compounds, the Administrator shall use the
8 Framework for Metals Risk Assessment of the
9 Office of the Science Advisor, Risk Assessment
10 Forum, and dated March 2007, or a successor
11 document that addresses metals risk assessment
12 and is peer reviewed by the Science Advisory
13 Board.
14 "(3) INITIATION OF RISK EVALUATIONS; DES-
15 IGNATIONS.—
16 "(A) RISK EVALUATION INITIATION.—
17 Upon designating a chemical substance as a
18 high-priority substance, the Administrator shall
19 initiate a risk evaluation on the substance.
20 "(B) REVISION.—The Administrator may
21 revise the designation of a low-priority sub-
22 stance or a low-hazard substance based on in-
23 formation made available to the Administrator.
24 "(C) ONGOING DESIGNATIONS.—The Ad-
25 ministrator shall designate at least one high-

1 priority substance upon the completion of each
2 risk evaluation (other than risk evaluations for
3 chemical substances designated under para-
4 graph (4)(C)(ii)).
5 "(4) RISK EVALUATION PROCESS AND DEAD-
6 LINES.—
7 "(A) IN GENERAL.—The Administrator
8 shall conduct risk evaluations pursuant to this
9 paragraph to determine whether a chemical
10 substance presents an unreasonable risk of in-
11 jury to health or the environment, without con-
12 sideration of costs or other nonrisk factors, in-
13 cluding an unreasonable risk to a potentially ex-
14 posed or susceptible subpopulation identified as
15 relevant to the risk evaluation by the Adminis-
16 trator, under the conditions of use.
17 "(B) ESTABLISHMENT OF PROCESS.—Not
18 later than 1 year after the date of enactment of
19 the Frank R. Lautenberg Chemical Safety for
20 the 21st Century Act, the Administrator shall
21 establish, by rule, a process to conduct risk
22 evaluations in accordance with subparagraph
23 (A).
24 "(C) REQUIREMENT.—The Administrator
25 shall conduct and publish risk evaluations, in

1 accordance with the rule promulgated under
2 subparagraph (B), for a chemical substance—
3 "(i) that has been identified under
4 paragraph (2)(A) or designated under
5 paragraph (1)(B)(i); and
6 "(ii) subject to subparagraph (E),
7 that a manufacturer of the chemical sub-
8 stance has requested, in a form and man-
9 ner and using the criteria prescribed by
10 the Administrator in the rule promulgated
11 under subparagraph (B), be subjected to a
12 risk evaluation.
13 "(D) SCOPE.—The Administrator shall, as
14 soon as practicable and not later than 6 months
15 after each designation of a high-priority sub-
16 stance, publish the scope of the risk evaluation
17 to be conducted, including the hazards, expo-
18 sures, conditions of use, and the potentially ex-
19 posed or susceptible subpopulations the Admin-
20 istrator expects to consider.
21 "(E) LIMITATION AND CRITERIA.—
22 "(i) PERCENTAGE REQUIREMENTS.—
23 The Administrator shall ensure that, of the
24 number of chemical substances that under-
25 go a risk evaluation under clause (i) of

1 subparagraph (C), the number of chemical
2 substances undergoing a risk evaluation
3 under clause (ii) of subparagraph (C) is—
4 "(I) not less than 25 percent, if
5 sufficient requests are made under
6 clause (ii) of subparagraph (C); and
7 "(II) not more than 50 percent.
8 "(ii) REQUESTED RISK EVALUA-
9 TIONS.—Requests for risk evaluations
10 under subparagraph (C)(ii) shall be subject
11 to the payment of fees pursuant to section
12 26(b)(3), and the Administrator shall not
13 expedite or otherwise provide special treat-
14 ment to such risk evaluations.
15 "(iii) EXCEPTIONS.—(I) Chemical
16 substances for which requests have been
17 granted under subparagraph (C)(ii) and
18 that are not drawn from the 2014 update
19 of the TSCA Work Plan for Chemical As-
20 sessments shall not be subject to section
21 18(b).
22 "(II) Requests for risk evaluations on
23 chemical substances which are made under
24 subparagraph (C)(ii) and that are drawn
25 from the 2014 update of the TSCA Work

1 Plan for Chemical Assessments shall be
2 granted at the discretion of the Adminis-
3 trator and not be subject to clause (i)(II).
4 "(F) REQUIREMENTS.—In conducting a
5 risk evaluation under this subsection, the Ad-
6 ministrator shall—
7 "(i) integrate and assess available in-
8 formation on hazards and exposures for
9 the conditions of use of the chemical sub-
10 stance, including information that is rel-
11 evant to specific risks of injury to health or
12 the environment and information on poten-
13 tially exposed or susceptible subpopulations
14 identified as relevant by the Administrator;
15 "(ii) describe whether aggregate or
16 sentinel exposures to a chemical substance
17 under the conditions of use were consid-
18 ered, and the basis for that consideration;
19 "(iii) not consider costs or other
20 nonrisk factors;
21 "(iv) take into account, where rel-
22 evant, the likely duration, intensity, fre-
23 quency, and number of exposures under
24 the conditions of use of the chemical sub-
25 stance; and

1 "(v) describe the weight of the sci-
2 entific evidence for the identified hazard
3 and exposure.
4 "(G) DEADLINES.—The Administrator—
5 "(i) shall complete a risk evaluation
6 for a chemical substance as soon as prac-
7 ticable, but not later than 3 years after the
8 date on which the Administrator initiates
9 the risk evaluation under subparagraph
10 (C); and
11 "(ii) may extend the deadline for a
12 risk evaluation for not more than 1 year,
13 if information relating to the chemical sub-
14 stance is required to be developed in a
15 rule, order, or consent agreement under
16 section 4 and has not yet been submitted
17 to the Administrator, or if such informa-
18 tion has been submitted to the Adminis-
19 trator within the time specified in the rule,
20 order, or consent agreement and on or
21 after the date that is 120 days before the
22 expiration of the deadline described in
23 clause (i).
24 "(H) NOTICE AND COMMENT.—The Ad-
25 ministrator shall provide no less than 30 days

public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.";

(4) by amending subsection (c) to read as follows:

"(c) PROMULGATION OF SUBSECTION (a) RULES.—

"(1) DEADLINES.—If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator—

"(A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

"(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

"(C) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed two years,

1 and subject to the limitation that the Adminis-
2 trator may not extend a deadline for the publi-
3 cation of a proposed or final rule regarding a
4 chemical substance drawn from the 2014 up-
5 date of the TSCA Work Plan for Chemical As-
6 sessments or a chemical substance that, with
7 respect to persistence and bioaccumulation,
8 scores high for 1 and either high or moderate
9 for the other, pursuant to the TSCA Work Plan
10 Chemicals Methods Document published by the
11 Administrator in February 2012 (or a successor
12 scoring system), without adequate public jus-
13 tification that demonstrates, following a review
14 of the information reasonably available to the
15 Administrator, that the Administrator cannot
16 complete the proposed or final rule without ad-
17 ditional information regarding the chemical
18 substance.
19 "(2) REQUIREMENTS FOR RULE.—
20 "(A) STATEMENT OF EFFECTS.—In pro-
21 posing and promulgating a rule under sub-
22 section (a) with respect to a chemical substance
23 or mixture, the Administrator shall consider
24 and publish a statement based on reasonably
25 available information with respect to—

1 "(i) the effects of the chemical sub-
2 stance or mixture on health and the mag-
3 nitude of the exposure of human beings to
4 the chemical substance or mixture;
5 "(ii) the effects of the chemical sub-
6 stance or mixture on the environment and
7 the magnitude of the exposure of the envi-
8 ronment to such substance or mixture;
9 "(iii) the benefits of the chemical sub-
10 stance or mixture for various uses; and
11 "(iv) the reasonably ascertainable eco-
12 nomic consequences of the rule, including
13 consideration of—
14 "(I) the likely effect of the rule
15 on the national economy, small busi-
16 ness, technological innovation, the en-
17 vironment, and public health;
18 "(II) the costs and benefits of
19 the proposed and final regulatory ac-
20 tion and of the 1 or more primary al-
21 ternative regulatory actions considered
22 by the Administrator; and
23 "(III) the cost effectiveness of
24 the proposed regulatory action and of
25 the 1 or more primary alternative reg-

1 ulatory actions considered by the Ad-
2 ministrator.
3 "(B) SELECTING REQUIREMENTS.—In se-
4 lecting among prohibitions and other restric-
5 tions, the Administrator shall factor in, to the
6 extent practicable, the considerations under
7 subparagraph (A) in accordance with subsection
8 (a).
9 "(C) CONSIDERATION OF ALTER-
10 NATIVES.—Based on the information published
11 under subparagraph (A), in deciding whether to
12 prohibit or restrict in a manner that substan-
13 tially prevents a specific use of a chemical sub-
14 stance or mixture, and in setting an appropriate
15 transition period for such action, the Adminis-
16 trator shall consider, to the extent practicable,
17 whether technically and economically feasible al-
18 ternatives that benefit health or the environ-
19 ment, compared to the use so proposed to be
20 prohibited or restricted, will be reasonably
21 available as a substitute when the proposed pro-
22 hibition or other restriction takes effect.
23 "(D) REPLACEMENT PARTS.—
24 "(i) IN GENERAL.—For complex dura-
25 ble goods and complex consumer goods, the

1 Administrator shall exempt replacement
2 parts that are designed prior to the date of
3 publication in the Federal Register of the
4 rule under subsection (a), unless the Ad-
5 ministrator finds that such replacement
6 parts contribute significantly to the risk,
7 identified in a risk evaluation conducted
8 under subsection (b)(4)(A), to the general
9 population or to an identified potentially
10 exposed or susceptible subpopulation.
11 "(ii) DEFINITIONS.—In this subpara-
12 graph—
13 "(I) the term 'complex consumer
14 goods' means electronic or mechanical
15 devices composed of multiple manu-
16 factured components, with an in-
17 tended useful life of 3 or more years,
18 where the product is typically not con-
19 sumed, destroyed, or discarded after a
20 single use, and the components of
21 which would be impracticable to rede-
22 sign or replace; and
23 "(II) the term 'complex durable
24 goods' means manufactured goods
25 composed of 100 or more manufac-

1 tured components, with an intended
2 useful life of 5 or more years, where
3 the product is typically not consumed,
4 destroyed, or discarded after a single
5 use.

6 "(E) ARTICLES.—In selecting among pro-
7 hibitions and other restrictions, the Adminis-
8 trator shall apply such prohibitions or other re-
9 strictions to an article or category of articles
10 containing the chemical substance or mixture
11 only to the extent necessary to address the
12 identified risks from exposure to the chemical
13 substance or mixture, so that the substance or
14 mixture does not present an unreasonable risk
15 of injury to health or the environment identified
16 in the risk evaluation conducted in accordance
17 with subsection (b)(4)(A).

18 "(3) PROCEDURES.—When prescribing a rule
19 under subsection (a) the Administrator shall proceed
20 in accordance with section 553 of title 5, United
21 States Code (without regard to any reference in such
22 section to sections 556 and 557 of such title), and
23 shall also—

1 "(A) publish a notice of proposed rule-
2 making stating with particularity the reason for
3 the proposed rule;
4 "(B) allow interested persons to submit
5 written data, views, and arguments, and make
6 all such submissions publicly available;
7 "(C) promulgate a final rule based on the
8 matter in the rulemaking record; and
9 "(D) make and publish with the rule the
10 determination described in subsection (a).";
11 (5) in subsection (d)—
12 (A) by redesignating paragraph (2) as
13 paragraph (3);
14 (B) by striking paragraph (1) and insert-
15 ing the following:
16 "(1) IN GENERAL.—In any rule under sub-
17 section (a), the Administrator shall—
18 "(A) specify the date on which it shall take
19 effect, which date shall be as soon as prac-
20 ticable;
21 "(B) except as provided in subparagraph
22 (D), specify mandatory compliance dates for all
23 of the requirements under a rule under sub-
24 section (a), which shall be as soon as prac-
25 ticable, but not later than 5 years after the date