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.

"(i) CHEMICAL SUBSTANCES DESCRIBED BY CATEGORIES.—

Notwithstanding subparagraph (A), a chemical substance that is described by a category listed in subparagraph (A)(iii) ~~shall be subject to section 5~~ is a new chemical substance if the chemical substance was~~is~~ not ~~included as an individual chemical substance~~listed individually on the list published under paragraph (1) as of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and has not since been listed individually on the list published under paragraph (1), following review pursuant to section 5.

Commented [A4]: EPA TA: This is more precise. It removes potential for debate about what "included as an individual" means.

"(ii) CHEMICAL SUBSTANCES GROUPED BY CAS NUMBER.—

Nothing in~~withstanding~~ subparagraph (B)(ii), nor any action of the Administrator pursuant to subparagraph (B)(ii), shall be construed as a basis to conclude that~~,~~ any chemical substance is not a new chemical substance ~~that is not included as an individual chemical substance on the list published under paragraph (1) as of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act shall be subject to section 5.~~

Commented [A5]: EPA TA: As we understand your drafting instructions, you only want to cover (B)(ii) with this savings clause. Note, however, that (B)(i) raises very similar concerns, and there is currently no savings clause to counter them.

The problems with (B)(i) can be addressed by the edits suggested earlier or by broadening this savings clause to cover (B)(i).

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.

"(i) CHEMICAL SUBSTANCES DESCRIBED BY CATEGORIES.—

Notwithstanding subparagraph (A), a chemical substance that is described by a category listed in subparagraph (A)(iii) is a new chemical substance ~~shall be subject to section 5~~ if the chemical substance, as that term is defined in section 3(2), is manufactured for the first time after ~~is not included as an individual chemical substance on the list published under paragraph (1) as of~~ the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and has not after that date been listed individually on the list published under paragraph (1), following review pursuant to section 5.

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Commented [A1]: Added to avoid argument that the substance was actually manufactured prior to the date by virtue of being included in the category. This is intended to say that if a substance of the same molecular identity was not previously manufactured, it's new.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 1:17:59 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request on revised House section 5 (4-18)
Attachments: Comments on HLC sec 5 April 18.docx; ATT00001.htm

Michal- the attached TA responds to the request on revised House 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
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Comments on HLC sec 5 April 18

Overall, this looks like draft Senate language we saw one or two iterations ago – ie, it does not contain changes made to that language where noted below. Other than that, the only difference is the first item noted below. Note that we are not re-making TA we provided on the latest senate version we saw.

P 1 line 13: The latest senate version struck "all that follows "significant new use", but this HLV version strikes "significant new use and all that follows". That is wrong and the Senate version is right.

P 2 lines 9-11: the phrase "to restrict such manufacturing or processing" should be stricken, or added in subclause II immediately following.

P 2 lines 17-21: the text added to the "(3) review and determination" paragraph in the senate bill defining the review period has not been added here. That should be added so that the period is defined and consistently referenced. The same issue arises at p 3 lines 14-15, p 3 lines 19-21, p 7 line 13 (a paragraph (E) was added to the senate bill that does not appear in the HLC version), p 8 lines 18-20, p 11 lines 3-4, and p 13 line 24 through p 14 line 1.

P 8 lines 1-16 does not contain the changes made to the Senate version to ensure the review period is extended so that determinations made based on new data do not occur outside the review period, nor does it contain further changes to the language discussed with Dmitri to simplify the provision and reduce EPA discretion to unilaterally extend the period.

P 12 lines 12-20: This (f) text was stricken from the Senate bill following EPA comments that it may not capture all of the restrictions available under section 6 and that (e) lacked a corresponding menu of restrictions.

P 14 line 4: "for commercial purposes" was not added to modify manufacture and processing for a significant new use, as it was in the latest Senate version to conform with the description of manufacture of a new chemical substance. (Actually, the better approach would probably be to drop "for commercial purposes" from where it appears at lines 2-3, rather than to add it to line 4, since 5(i) defines manufacture and processing as meaning only for commercial purposes.)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/7/2016 10:54:19 PM
To: Michal_Freedhoff@markey.senate.gov; dimitri_karakitsos@epw.senate.gov; Adrian_Deveny@merkley.senate.gov; Jonathan_Black@tomudall.senate.gov
Subject: SEPW TSCA TA on section 5
Attachments: 5-04-07-16-TOEPA -- next draft BG.doc; ATT00001.htm

Attached please find the requested TA on the revised 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

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

Internal x-refs where existing TSCA lettering/numbering changed have not been conformed pending review of text

Commented [A1]: EPA TA Note: we are not re-making comments that we made on previous iterations and that have not been addressed here.

(a) IN GENERAL.—(1) Except as provided in subsection (h), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless—

(i) 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 subsections (b), (e) or (f); and

(ii) the Administrator conducts a review of the notice and either

(I) ,makes a determination under paragraph (3)(A) and, as necessary, issues an order to restrict such manufacturing or processing under subsection (f)(1), or

(II) makes a determination under paragraph (3)(B) and takes the actions required ~~, as necessary, issues an order to restrict such manufacturing or processing~~ issues an order under subsection (e)(1)(B).

Commented [A2]: EPA TA: As drafted, the "actions required under subsection (e)," to allow manufacture to proceed in the absence of necessary information, could apparently be as limited as taking action under (e)(1)(A)(i) (provide an opportunity for the submitter to submit the additional information).

This is because (e)(1)(A) and (e)(1)(B) are now presented as alternate paths, either of which would apparently qualify as taking the "actions required" under (e).

To restore the functionality of the prior draft, please see our in-line drafting suggestions, here and in (e)(1).

(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) Before the end of the applicable period for review under paragraph (1), and -subject to section 18, the Administrator shall review a notice received under paragraph (1) and—

(A) determine whether -the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use., and take applicable action under subsection (f) or (g); or

(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (e)(b)(3).

(4) Failure to Render Determination.—

(A) In General.—The Administrator shall complete a review of a notice required by this section within the review period provided in subsections (a) and (c).

(B) 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, including an extension pursuant to subsection (c), 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.

(C) Limitations.—

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

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

(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)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(b) SUBMISSION OF ~~TEST DATA~~INFORMATION.—

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit ~~test data~~information 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 ~~data~~ information 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 date of the submission in accordance with

Commented [A3]: Note to House: the way this was originally drafted in your Section 5 conforming changes, it allows manufacture 90 days after the date the information was required to be submitted, whether the information was submitted or not. Changed back to existing TSCA which keys off the date the information was actually submitted to EPA.

such rule or order of the information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

(2)(A) If a person—

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (5~~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 ~~test data~~information for such substance,

such person ~~shall~~ may submit to the Administrator ~~data~~ information 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 ~~data~~ information believes show that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

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

~~(3) If the Administrator determines under subsection (a)(3)(B) that additional information is necessary to make the determination under subsection (a)(3)(A), the Administrator—~~

~~(A) shall provide an opportunity for the submitter of the notice to submit the additional information;~~

~~(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;~~

~~(C) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information;~~

~~(D) on receipt of the additional information the Administrator finds supports the determination under subsection (a)(3)(A), shall promptly make the determination; and~~

~~(E) may take the actions specified in subsection (e).~~

(3~~4~~3) ~~Data~~ Information submitted under paragraph (1) or , ~~or~~ (2) of this subsection or under subsection (e)~~(3)~~ shall be made available, subject to section 14, for examination by interested persons.

(4~~5~~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

Commented [A4]: Moved and integrated into subsection (e).

health or the environment, without consideration of costs or other non-risk 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.

Commented [A5]: Note to House: per EPA, there could be other factors that go into an unreasonable risk finding and they suggest deleting the limitation on what they can consider, which is why we edited your Section 5 change here.

(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 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, subject to any necessary requirements under subsection (e) or (f), begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—(1) The notice required by subsection (a) shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and

(B) in such form and manner as the Administrator may prescribe, any ~~test data~~information 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 of such substance identified in the notice and any additional uses of such substance that are reasonably foreseeable by the Administrator~~'s or intended uses of such substance~~; 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 ~~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 WHEN AVAILABLE INFORMATION IS INSUFFICIENT.—(1)~~(A)~~ If the Administrator determines that—

~~(i)~~ the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)~~(A) permit a reasoned evaluation of the health and environmental effects of~~ for a chemical substance or significant new use with respect to which notice is required by subsection (a)~~, either—~~

~~; and~~

~~(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,~~

(A) the Administrator—

(i) shall provide an opportunity for the submitter of the notice to submit the additional information;

(ii) may, by agreement with the submitter, extend the review period for a reasonable time to allow the

Commented [A6]: Note to House- we think the 5 day timeframe is probably a tough timeframe for EPA to have to satisfy the full "conditions of use" definition which is why we have made this change.

development and submission of the additional information;

(iii) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and

(iv) on receipt of the additional information the Administrator finds supports the determination under subsection (a)(3)(A), shall make the determination within 90 days of receipt of the information; ~~and~~

(B) ~~may~~ the Administrator ~~may~~shall issue ~~an proposed~~an order to take effect on the expiration of the applicable notification and review period ~~applicable to the manufacturing or processing of such substance~~ under subsection (a), (b), or (c), to prohibit or ~~or limit~~ otherwise ~~-~~restrict the manufacture, processing, distribution in commerce, use, or disposal of ~~such~~ the chemical substance, or manufacture or processing of the chemical substance for a significant new use, or any combination of such activities, sufficient to allay the Administrator's initial concern that, in the absence of sufficient information, the substance or significant new use may present an unreasonable risk.

(2~~B~~) In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under subparagraph (1A), the Administrator shall consider, to the extent practicable based on reasonably available information, costs and other non-risk factors.

(3~~C~~) If the Administrator issues an order under paragraph (1), no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use pursuant to this paragraph except in compliance with the restrictions specified in the order).

(4) Not later than 90 days after issuing an order under paragraph (1), 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 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) An ~~proposed~~ order may not be issued under paragraph (1) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the ~~proposed~~ order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

~~(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the~~

Commented [A7]: The relationship of (A)(i-iii) and (B) is different from the relationship of the analogous provisions in the version that went to the House yesterday. Translating all the references into the current paragraph numbering system for purposes of comparison:

Yesterday, EPA *always* had to do (A)(i) and (A)(iv) and *always* could (A)(ii) and (iii), following a determination made under 5(a)(3)(B) that necessary data are lacking. Whether or not EPA issued an order under 5(e)(1)(B) didn't affect EPA's duties and powers under (A). But if EPA elected not to issue an order under 5(e)(1)(B), then manufacture couldn't proceed in the interim.

Today, EPA is given a choice to *either* take steps to resolve the 5(a)(3)(B) determination that it lacks data *or* to impose a risk management order under 5(e)(1)(B). As long as EPA does one or the other, manufacture can proceed (except insofar as EPA blocks it through an order issued under 5(e)(1)(B)).

Note also that it is unclear whether EPA is authorized to switch tracks and issue an order under 5(e)(1)(B) if it provides an opportunity for the submitter to supply additional information under 5(e)(1)(A)(i) but the data aren't supplied.

To restore the functionality of the prior draft, please see the in-line edits here, and in the discussion above for 5(a)(1).

~~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~~

~~(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 non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population 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.~~

~~(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 information 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 information 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 POTENTIAL UNREASONABLE RISKS.—(1) If the Administrator ~~finds~~ determines that ~~there is a reasonable basis to conclude that~~ the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may ~~presents or will~~ present an unreasonable risk of injury to health or environment in accordance with subsection (a)(3)(A), ~~before a rule promulgated under section 6 can protect against such risk,—~~

(A) the Administrator shall issue an order, to take effect on or before the expiration of the applicable notification and review period under subsection (a), (b), or (c) ~~to the manufacturing or processing of such substance, or to the significant new use,~~ to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or of the chemical substance for a significant new use, sufficient to allay the Administrator's initial concern that the substance or significant new use may present an unreasonable risk.

(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection except in compliance with the restrictions specified in the order; and

(C) not later than 90 days after issuing an order under subparagraph (A), 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 order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(2) 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), the Administrator shall, to the extent practicable based on reasonably available information, consider costs and other non-risk factors, and such an order may include~~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)(2)(B) shall apply with respect to such rule.~~

(3) 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 ~~to the extent thatin selecting among further prohibitions and other restrictions beyond those required~~ under paragraph (1) are practicable that the Administrator determines are ~~sufficient to enable the Administrator to conclude that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A)~~, ~~also establish those restrictions to~~ reduce the potential for exposure to the substance to the maximum extent practicable.

Commented [A8]: This could give rise to arguments that the maximum extent practicable standard is actually a lesser standard of protection than "sufficient to allay," and that new PBT chemicals should be less restricted than other new chemicals that may present an unreasonable risk.

To foreclose these sorts of arguments, you would need to make clear that maximum extent practicable only applies to the extent that further restrictions, beyond those "sufficient to allay," are still practicable.

Please see the in-line comments, which suggest a way to make this clarification.

(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

~~(3)(A) The Administrator may—~~

~~(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or~~

~~(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.~~

~~A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification~~

~~period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.~~

~~(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use, before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.~~

~~(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).~~

~~(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use.~~

(g) STATEMENT ~~OF REASONS FOR NOT TAKING ACTION~~ON ADMINISTRATOR FINDING.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment is not warranted, then notwithstanding any remaining portion of the period for review under subsection (a), (b), or (c) applicable to the manufacturing or processing of such substance or of such substance for a significant new use, the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use, and ~~has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance,~~ the Administrator shall make public ~~publish~~ a statement of the Administrator's ~~determination~~finding ~~reasons for not initiating such action~~. Such a statement shall be submitted for ~~published~~ 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.

(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, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator for the specific uses 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 ~~data~~information 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

Commented [A9]: Leg counsel to conform internal X-refs here if needed

(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, without consideration of costs or other non-risk factors, ~~. 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).~~ including an unreasonable risk to a potentially

exposed or susceptible population identified by the Administrator under the conditions of use.

(~~5~~4) 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~~5) Immediately upon receipt of an application under paragraph (1) or (~~5~~4) 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) 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.

[15 U.S.C. 2604]

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 5:54:23 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA follow up on section 6/26

Michal,
This TA responds to the followup request on section 6/26.

Question 1:
If we move the section 6 guidance for how manufacturers do their own RES to EPA into section 26, have we solved the problem?

Response:

Yes, if that is indeed the only guidance, policy or procedure provision left in sec 6. We note, though, that section 6(b)(8) of the sec 6 version you sent yesterday requires EPA to establish, by rule, a screening process (analogous to 6(b)(1) of the Senate offer). That would likely be viewed as part of the "policies, procedures and guidance" referenced in sec 26(q) that are required to be established. Our previous TA was based on the 3 section 6 guidance provisions you identified yesterday. Also, we note that the section 26(q) provisions allow EPA to proceed with risk evaluation in advance of the 26(k) guidance, but they do not mention screening. To ensure that screening is not held up, it would be best to move 6(b)(8) to 26(k) and add screening to 26(q). We have not thoroughly reviewed the sec 6 you circulated yesterday to see if there are any other provisions we think would likely be viewed as policies, procedures or guidance.

Question 2:

And then I guess associated question is if you're ok w the language in House 26 in this section and the way HLC wrote what used to say "this section"

Response:

We understand that the question refers principally to this text:

Alternate from 4/8/House offer

> Nothing in this Act, or the amendments made by this Act, prevents the Administrator of the Environmental Protection Agency from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator under section 26(k) of the Toxic Substances Control Act, as added by subsection (a) of this section.

If so, this basically looks ok, although it is not clear why "of the EPA" is added after Administrator here and nowhere else. Beyond that, recall that we sent TA yesterday on this version of sec 26, which included TA on this subsection (eg, pointing out that it leaves final risk evaluations, and maybe rules, potentially subject to challenge on the ground that they do not conform with later issued guidance).

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: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 10, 2016 at 11:32:18 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

The version you commented on yesterday. If we move the guidance in 6 on industry RES into 26, does that solve the problem and are you ok w the language in the prior initiated RE section if that move is made

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 11:29 AM
To: Freedhoff, Michal (Markey)
Subject: Fwd: Sen. Markey TSCA TA follow up on section 6/26

Michal - we have a version on this. See Brian's question below.
Thanks,
Sven

From: "Grant, Brian" <Grant.Brian@epa.gov>
Date: April 10, 2016 at 11:21:15 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Hey Sven. I don't know what version of the House language she is referring to, with an HLC formulation. Can you please forward to me if you know or ask Michal to forward the version she would like us to look at? thx.
From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 10, 2016 at 9:29:57 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

And then I guess associated question is if you're ok w the language in House 26 in this section and the way HLC wrote what used to say "this section"

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 9:28 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Michal- got it- checking. Thanks,
Sven

On Apr 10, 2016, at 9:28 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

If we move the section 6 guidance for how manufacturers do their own RES to EPA into section 26, have we solved the problem?

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 9:24 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA follow up on section 6/26

Michal,
This TA responds to the request on section 6 and 26.

We'd need to see the full current draft of Section 6 and 26 to give definitive TA, but it seems that (3) is unproblematic. It is not referring to any procedures that EPA needs to develop. Similarly, (4) is unproblematic, assuming that neither (1) nor (2) is referring to policies, procedures, or guidance that EPA needs to develop.

If the language in section 26 is only preserving EPA's ability to proceed in advance of any policies/procedures/guidance developed pursuant to section 26, then the retention of a direction to develop a guidance document pursuant to section 6 (i.e., regarding how outside parties should develop draft risk assessments) is potentially problematic. By specifically not mentioning this guidance document generation obligation, Section 26 could be the basis of an argument that Congress believed that a failure to timely prepare this specific type of guidance document might indeed be grounds to defer work on safety evaluations.

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: "Freedhoff, Michal (Markey)"
<Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 7:06:01 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)"
<Kaiser.Sven-Erik@epamail.epa.gov>
Subject: follow up on section 6/26

This is the only guidance/policies/practices language that is left in section 6. Is your section 26 Act vs section concern resolved knowing this
GUIDANCE.—
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 develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator, The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

(3) PROCEDURES.—When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) promulgate a final rule based on the matter in the rulemaking record and (D) make and publish with the rule the determination described in subsection (a).

4) APPLICATION.—Paragraphs (1), (2) and (3) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 8:43:02 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal – please see the requested followup TA on CBI and health and safety studies.

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

Response: EPA would interpret the highlighted language to effect no changes in either EPA practice or the Senate passed bill. EPA has always addressed the mix of CBI and non-CBI information in a particular document, assessing what needs to be protected and what does not, which is what the second highlighted text appears to require.

That said, others may argue that the *new* highlighted text does effectuate a change in both the bill and practice. EPA would not interpret (c)(2) as a condition or limitation on (c)(1), because it merely provides that information that is protectable remains protectable even if mixed with non-protectable information, a position EPA already takes. However, the new highlighted text might be argued to indicate that (c)(2) in some way limits or conditions the scope of information releasable pursuant to (c)(1).

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, March 15, 2016 1:16 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on CBI - health and safety studies

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

(c) Information Not Protected From Disclosure.—
(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:
(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
(i) IN GENERAL.—Subject to clause (ii)—
(I) any health and safety study that is submitted under this Act with respect to—
(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or
(bb) any chemical substance or mixture for which—

(AA) testing is required under section 4; or

(BB) a notification is required under section 5; or

(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

(ii) A safety assessment developed, or a safety determination made, under section 6.

(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

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> <image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 1:13 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal,
This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

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, March 15, 2016 10:32 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

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: 4/15/2016 1:55:43 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request on PBTs

Michal - got it. Thanks,
Sven

On Apr 14, 2016, at 9:46 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Something like this

(a) SCOPE OF REGULATION. If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, [or, for a chemical substance designated under subsection PBT, the risk posed by the substance as evaluated under subsection (exposure assessment)], the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk.:

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
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 14, 2016 5:47 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on PBTs

TSCA team – please see Michal's request on PBTs. Thoughts? 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, April 14, 2016 5:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Pbts again

Dimitri doesn't like the para 4 and 5 stuff on fixing the unreasonable risk piece. He says can't do a UR finding w"o an RE. Proposes that the text in 6(a) that used to just say "identified under the PBT section" could instead say "or, in the case of a PBT identified in the PBT section, the risk posed by the PBT " or something like that? I am in w them now and can't talk by phone but figured you can start people thinking.

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: 4/23/2016 8:08:03 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA request on house section 6 (4-23)

Michal- got it- passing along for review. Will call when ready on section 6. Thanks,
Sven

On Apr 23, 2016, at 4:03 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

For when you get through the sections you're currently working, I'm attaching Section 6 (my line edits/observations on today's draft) and what was sent to HLC on 4/21, in case that helps your review. I'd appreciate it if you could call me at my desk before you get started on any section 6 review.

Thanks
Michal
<Section 6.docx>
<Section 6 (HLC 4-21).docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 12:16:16 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Market TSCA TA request- Senate section 5

Got it

On Mar 1, 2016, at 7:15 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Quick follow up - what if the section 4 reference in the language was retained but the section 5 consent agreement reference was removed?
Thanks
M

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

From: Kaiser, Sven-Erik
Sent: Tuesday, March 1, 2016 7:08 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Market TSCA TA request- Senate section 5

Michal - this responds to your request on sect 5. Please let me know if any questions. Thanks,
Sven

The proviso under discussion is unnecessary. A section 5 consent agreement generally does not impose testing requirements. See the sample at: http://www.epa.gov/sites/production/files/2016-01/documents/co_all_purpose_preamble_and_consent_order_combined_1-5-2016.pdf at page 6. The order imposes restrictions on the manufacturing, processing, distribution in commerce, use, and disposal of a chemical substance, which continue until such time as EPA receives particular test data. If manufacture never commences in the first place, then there would generally be no testing obligations under the consent agreement. In the event that testing obligations *were* directly incorporated into a section 5 consent agreement, the parties to the agreement would not need statutory authorization to negotiate mutually agreeable terms for the termination of such testing obligations (in the event that manufacture never commences), as part of the original development of the consent agreement.The proviso under discussion could also be harmful. It would entitle a prospective manufacturer to renegotiate or litigate the terms of an existing consent agreement at any point prior to the commencement of manufacture, simply by withdrawing the PMN that was the basis for the consent agreement and then resubmitting the PMN for a fresh 90-day review. Consent agreements would not provide the same assurance of repose for EPA, at least until such time as EPA had made the key terms of the consent agreement generally binding by incorporating them into a Significant New Use Rule.

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 29, 2016 at 2:24:31 PM ES
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: TA request- Senate section 5

Sven
Last week I asked you what would happen to a test order/consent agreement under section 5 in the event that a PMN was withdrawn, and your response was that there would be no reason for it to continue in effect and EPA had authority to withdraw it.

The same question has now arisen about an instance in which EPA has entered into a section 5 consent agreement with the PMN submitter and the submitter then withdraws the PMN before submitting a NOC. The question is whether to add a "cease in effect" provision to capture both the section 4 and the section 5 consent agreement scenarios. Is there any circumstance EPA can think of that would make it wish to keep a section 5 consent agreement in effect on a PMN submitter even after the PMN is withdrawn?

Pasting the relevant language below in case it is helpful.
Michal

(e) Notice of Commencement.—

(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

(A) the name of the manufacturer; and

(B) the initial date of nonexempt commercial manufacture.

(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice. A consent agreement or order issued pursuant to Section 4 [and subsection (d)(3)(A)(i)(I)] shall cease to have legal effect on the date the notice is withdrawn.

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/4/2016 9:01:55 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA TA call on CBI

Got it - 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: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, April 04, 2016 5:01 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: SEPW TSCA TA call on CBI

Sven – just wanted to send this to you to confirm from the call that this works and would be consistent with previous TA as well as TA from the call. Thanks

(1) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE Subsection (a) does not prohibit the disclosure of

(A) A risk evaluation conducted under section 6.
(B) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.
(C) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section, that is not information described in subsections (c)(1) or (c)(2) or information required to be disclosed through subsection (c)(4) and is submitted with or contained in information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 04, 2016 3:39 PM
To: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA TA call on CBI

Dimitri – 4 is the earliest we can do it -- please call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy Thanks, Sven

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

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, April 04, 2016 3:31 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: can we do a quick

Yup that should be fine, if you all want to call and can any earlier I will be here.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 04, 2016 3:31 PM
To: Karakitsos, Dimitri (EPW)
Subject: RE: can we do a quick

Dimitri - Checking – I think we can do 4pm – ok?

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

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, April 04, 2016 3:29 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: can we do a quick

5 min call on this cbi paragraph when you get a chance please? I am available now if your folks are and can be reached at my desk – 224-9705

> (1) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section, that is not information described in subsections (c)(1) or (c)(2) or information described in subsection (c)(4) for which the protection from disclosure is presumed to no longer apply, and is submitted with or contained in information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/12/2016 11:06:01 PM
To: 'Fruci, Jean' [Jean.Fruci@mail.house.gov]; Wright, Tuley [Tuley.Wright@mail.house.gov]; Kessler, Rick [Rick.Kessler@mail.house.gov]; Crisp, Timia [Timia.Crisp@mail.house.gov]
Subject: HEC Min TSCA TA Request on Nomenclature
Attachments: HEC min. TSCA TA.Nomenclature.docx

Jean,
Please see the attached technical assistance responding to your request. 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: Fruci, Jean [mailto:Jean.Fruci@mail.house.gov]
Sent: Monday, February 08, 2016 6:24 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Wright, Tuley <Tuley.Wright@mail.house.gov>; Kessler, Rick <Rick.Kessler@mail.house.gov>; Crisp, Timia <Timia.Crisp@mail.house.gov>
Subject: TA request on Nomenclature

Sven:

I am trying to understand the impact of the Senate's language on Nomenclature [amendment to Section 8, subsection (b)]. The language as drafted is difficult to understand. In particular, I have highlighted several phrases and/or paragraphs. I would like to know how the Agency would interpret this language.

Does the paragraph (bb) provide a means for a manufacturer to avoid: 1) meeting reporting requirements of Section 8; 2) having to submit a pre-manufacturing notice under Sec. 5?

Also, if there were a savings clause that allowed the Administrator to separately list a chemical notwithstanding the mandate to use these nomenclature conventions IF the Administrator determines the chemical may present a risk to health or the environment would the Administrator have information to make such a determination?

I'll give you a call tomorrow in case you have questions for me about the assistance I am seeking. Thanks.

Jean

Jean Fruci, Ph.D.
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515
202 225-4407
jean.fruci@mail.house.gov

7 *''(3) NOMENCLATURE.—*

8 *''(A) IN GENERAL.—In carrying out para-*

9 *graph (1), the Administrator shall—*

10 *''(i) maintain the use of Class 2 no-*

11 *menclature in use on the date of enactment*

12 *of the Frank R. Lautenberg Chemical Safe-*

13 *ty for the 21st Century Act;*

14 *''(ii) maintain the use of the Soap and*

15 *Detergent Association Nomenclature Sys-*

16 *tem, published in March 1978 by the Ad-*

17 *ministrator in section 1 of addendum III of*

18 *the document entitled 'Candidate List of*

19 *Chemical Substances', and further described*

20 *in the appendix A of volume I of the 1985*

21 *edition of the Toxic Substances Control Act*

22 *Substances Inventory (EPA Document No.*

23 *EPA–560/7–85–002a); and*

24 *''(iii) treat all components of categories*

25 *that are considered to be statutory mixtures*

1 *under this Act as being included on the list*

2 *published under paragraph (1) under the*

3 *Chemical Abstracts Service numbers for the*

4 *respective categories, including, without*

5 *limitation—*

6 *''(I) cement, Portland, chemicals,*

7 *CAS No. 65997–15–1;*

8 *''(II) cement, alumina, chemicals,*
9 *CAS No. 65997–16–2;*
10 *''(III) glass, oxide, chemicals,*
11 *CAS No. 65997–17–3;*
12 *''(IV) frits, chemicals, CAS No.*
13 *65997–18–4;*
14 *''(V) steel manufacture, chemicals,*
15 *CAS No. 65997–19–5; and*
16 *''(VI) ceramic materials and*
17 *wares, chemicals, CAS No. 66402–68–*
18 *4.*
19 *''(B) MULTIPLE NOMENCLATURE CONVEN-*
20 *TIONS.—*
21 *''(i) IN GENERAL.—If an existing guid-*
22 *ance* **[what document is being referred to here?]** *allows for multiple nomenclature con-*
23 *ventions, the Administrator shall—*
24 *''(I) maintain the nomenclature*
25 *conventions for substances; and*

1 *''(II) develop new guidance that—*
2 *''(aa) establishes equivalency*
3 *between the nomenclature conven-*
4 *tions for chemical substances on*
5 *the list published under para-*
6 *graph (1); and*
7 *''(bb) permits persons to rely*
8 *on the new guidance for purposes*
9 *of determining whether a chemical*

10 *substance is on the list published*
11 *under paragraph (1).*
12 *''(ii) MULTIPLE CAS NUMBERS.—For*
13 *any chemical substance appearing multiple*
14 *times on the list under different Chemical*
15 *Abstracts Service numbers, the Adminis-*
16 *trator shall develop guidance recognizing*
17 *the multiple listings as a single chemical*
18 *substance.*

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.

I am trying to understand the impact of the Senate's language on Nomenclature [amendment to Section 8, subsection (b)]. The language as drafted is difficult to understand. In particular, I have highlighted several phrases and/or paragraphs. I would like to know how the Agency would interpret this language.

Does the paragraph (bb) provide a means for a manufacturer to avoid: 1) meeting reporting requirements of Section 8; 2) having to submit a pre-manufacturing notice under Sec. 5?

Section 8(b)(3)(A)(iii)

Section 8(b)(3)(A)(iii) relates to the definitions of certain chemical substances listed on the TSCA Inventory (sometimes referred to as "statutory mixtures," largely for historical reasons). The TSCA Inventory contains detailed descriptions of exactly what sort of substances fall within the scope of each the Inventory listings. In general terms, whether these definitions cover a substance depends on both the constituents of the substance and on whether the substance was manufactured in the course of making cements, glasses, frits, steel, or ceramics. EPA interprets section 8(b)(3)(A)(iii) as a statutory ratification of the scopes of these particular Inventory listings, as listed in the TSCA Inventory, in a manner consistent with appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a).

The drafting of this section could be improved in certain respects. First, it could be written to provide that the list of (I) through (VI) is an exclusive list, unless there is intent to ratify the scope of some other (unstated) descriptions found on the TSCA Inventory or elsewhere.

While EPA can interpret the phrase "all components of categories that are considered to be statutory mixtures under this Act," the phrasing is awkward and it could be improved to reduce the chance of confusion. The following would be clearer: "all chemical substances described by the following category listings, when manufactured as described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a)."

Section 8(b)(3)(B)(i) and (II)(bb) and

The scope of this provision is determined by the extent of existing guidance allowing for multiple nomenclature conventions. EPA would interpret the reference to "guidance" as referring only to EPA guidance, although others may argue for a different interpretation. EPA is not aware of any such existing EPA guidance that would trigger the obligation in the bill to "develop new guidance that . . . permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the [TSCA Inventory]."

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With respect to section 8 reporting, the Chemical Data Reporting under TSCA Section 8(a)(1) is based on the fact that a particular chemical substance is, in fact, listed on the TSCA Inventory. A guidance document taking the position that a particular chemical substance is already listed on the TSCA Inventory would therefore not be a mechanism to avoid reporting under this regulation.

With respect to new chemical reporting, EPA has, in the recent past, construed potentially similar requests to "rely on" particular TSCA Inventory entries as requests "to limit the circumstances in which manufacturers would be deemed to be manufacturing a new chemical substance, and thus be subject to the requirements of TSCA Section 5(a)(1)(A) [new chemicals review]" 81 FR 1366 (2016). If EPA were to agree that a substance A described by one naming convention is actually the same substance as a substance B listed on the Inventory using a different convention, then a person wishing to manufacture substance A would not need to submit a section 5 notice.

Also, if there were a savings clause that allowed the Administrator to separately list a chemical notwithstanding the mandate to use these nomenclature conventions IF the Administrator determines the chemical may present a risk to health or the environment would the Administrator have information to make such a determination?

We assume that, when you refer to a determination that a chemical substance may present a risk, you are referring to a different risk from that presented by a particular substance already on the Inventory. In this regard, we note that EPA has not generally looked at the risk a chemical may present in determining its Inventory status. This is in keeping with TSCA's definition of "chemical substance" as any substance with "a particular molecular identity (TSCA section 3(2)(A)). The Inventory functions as a list of chemical substances in commerce, both to aid in risk management and for informational purposes; risk management itself is addressed by other provisions of TSCA. It would be a policy judgment whether to depart from this long-standing approach to the Inventory; a decision to do so would likely raise significant implementation issues.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 7:34:45 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on Chem ID

I'll pass that along

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, April 12, 2016 3:34 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Chem ID

Thanks – this is exactly what I hoped you'd say. ☺

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, April 12, 2016 2:18 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Chem ID

Michal,
This TA responds to the request on CBI and Chem ID.

As a general note, the ideas you are exploring on this issue would likely result in less transparency of chemical information as compared to current law. This is something that the Administration has flagged in its 2009 Principles: TSCA reform should include "stricter requirements" for a manufacturer's claim of CBI and "data relevant to health and safety should not be claimed or otherwise treated as CBI." Outside of the limited circumstances mentioned, EPA does not typically consider chemical identity in a health and safety study to be entitled to confidential treatment. Any expansion of these circumstances could be viewed as contradictory to the Principles.

That being said, we have attached some information on the statistics you requested, as well as an additional drafting suggestion that would improve (but not eliminate) the transparency issues.

(2) (A) Subject to (2)(B), the specific identity of a chemical substance that is the subject of a health and safety study that satisfies the conditions of (1)(A) shall not be disclosed, if such chemical identity is otherwise eligible for protection under this section, unless the Administrator initiates a risk evaluation on the substance under Section 6(b), the Administrator determines under section 6 that a chemical substance presents or will present an unreasonable risk of injury to health or the environment, or the Administrator initiates an action with respect to the chemical substance under section 7(a).

(B)(i) The duration of protection for the specific identity of a chemical substance described in (2)(A) and the renewal of such protection shall be governed by section 14(e), except that the duration of protection shall be 5 years.

(ii) The Administrator may, in limited circumstances, review a claim for protection of the identity of a chemical described in (2)(A) if the Administrator determines that disclosure of such specific chemical identity would assist with the identification or remediation of an environmental hazard or exposure, or the diagnosis or treatment of an adverse health effect, that might be caused by the chemical substance.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

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

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 11, 2016 at 9:23:03 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Chem ID

Sven

Getting back to this question from a different direction – your TA below says that there is a 3rd basis for withholding chemID from HS: "where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study."

We have the pre-NOC exclusion in current senate 14

(i) The specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5.

I am wondering if "if the specific identity is not necessary to interpret the HS study" is something that I should be exploring in addition to the other ideas for inclusion alongside process and concentration/proportion. To that end, is there an easy way that you could provide me with some statistics/#s along the following lines (approximate #s ok)

1- How many chemID CBI claims are there generally? Per year?
2- How many chem IDs are withheld (both generally and per year) from HS studies because releasing would reveal
    a. Process
    b. Concentration/proportion
    c. Pre-NOC AND info not necessary

If this is impossible to figure out in a quick timeframe let me know and maybe we can figure out some other way to answer my question, which is, generally, "what is the actual impact of adding the specific identity is not necessary to interpret the health and safety study" under this EPA's practice.

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: Saturday, April 09, 2016 12:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Chem ID

Michal,
This TA responds to the request on chem ID.

Your two emails seem to be asking questions in different directions: the first seems to be asking whether another basis could be added for allowing the withholding of chem id *in health and safety studies* (presumably something industry would want), and the second seems to be asking the very different question of whether there should be more stringent expiration or voiding conditions for chem id *outside the context of health and safety studies* than for other CBI (presumably something the NGOs would want).

Re your first question: although the statute allows for withholding of chem ID (or other info) in health and safety studies only on two bases (reveals process information of proportions of a mixture), EPA regulations allow withholding of specific chem ID on a third basis: where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study. That kind of provision could be codified in the bill.

Re your second question: The idea sounds like a beefing up of sec 14(c)(3) of the Senate offer, which presumptively voids CBI claims for chem ID and other information elements following a ban of a chemical. The triggering event for that provision could be moved up to the finding of unreasonable risk.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 11:20:40 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on ChemID

As part of your thought process here, and perhaps as an alternative option, let's think about a way where if chemID is kept CBI it goes public if a) epa makes a section 6 or 7 unreasonable risk finding about it and b) it has to be re-substantiated every 5/10 years with reasonable potential of an unreasonable risk being one of the things EPA has to consider.

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

On Apr 9, 2016, at 5:40 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:
Good morning

We increasingly hear that "molecular structure" is a huge threshold issue for the House. It is for us too. I'm trying to learn more about the history here and also see if there exists middle ground - something akin to a 3rd condition for when chemID is withheld, like "keep molecular structures secret if X or Y, or unless X or Y". I'm not sure if a space like this exists for either side, but thought perhaps looking towards the recent decisions by EPA on why it did or did not release molecular structure could be useful.

Can you put together background materials or suggestions if you have any? Doesn't have to be before 1, but would be helpful if it was before 5 or 6 pm so I can review tonight as part of some of the other prep work I'm planning.

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: 2/2/2016 10:16:10 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on definition of processor
Attachments: Markey.TSCA TA.Definition of Process.docx

Michal,
The attachment provides TA responding to your request. 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: Thursday, January 28, 2016 3:09 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - definition of processor

Hi Sven

I have a couple questions about the definition of process/processor that have been raised by stakeholders.

1) First, there is a question about whether EPA could treat someone who took 10 gallon containers of a chemical substance and transferred the substance into smaller containers for sale as a processor? My read of the current statute is that YES, 10(A) would seem to allow this. Is that EPA's read as well and is there regulatory text that may further elaborate on the plain reading?
2) Second, what about companies who assemble things – ie install steering wheels in cars, or put furniture together? Could THEY be considered processors? My read is that 10(B) would NOT allow this, because if the chemical substance was already incorporated into the article, as it would be in the examples I used, (B) would make no sense in a reading that allowed these types of people to be treated as processors. Again, am I wrong on this, and is there any further regulatory or other elaboration on this point anywhere?

Thanks
michal

(10) The term ''process'' means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—
(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or
(B) as part of an article containing the chemical substance or mixture.
(11) The term ''processor'' means any person who processes a chemical substance or mixture.

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

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.

Current TSCA Definition of "Process"

(10) The term ''process'' means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—

> (A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or
>
> (B) as part of an article containing the chemical substance or mixture.

Requests for TA

1) First, there is a question about whether EPA could treat someone who took 10 gallon containers of a chemical substance and transferred the substance into smaller containers for sale as a processor? My read of the current statute is that YES, 10(A) would seem to allow this. Is that EPA's read as well and is there regulatory text that may further elaborate on the plain reading?

- Yes, EPA has taken the view under current TSCA that the repackaging of a chemical substance (e.g., transferring from larger to smaller container) to prepare the chemical substance for sale may be viewed as "process[ing]" under § 3(10). The chemical substance is being prepared, after its manufacture, for distribution in commerce. See for example:
  - "Such mixing or repackaging of fibers is considered primary processing of bulk asbestos for the purpose of this rule." 47 FR 33198 (July 30, 1982)
  - "A processor is, among other things, one who prepares a chemical substance or mixture for distribution in commerce, after its manufacture, in the same or different form of physical state from that in which it was received by the processor (see TSCA section 3(10)). One who mixes, reacts, purifies, separates, repackages, or otherwise "prepares" a chemical substance or mixture for distribution in commerce is a processor." 50 FR 37182 (September 12, 1985)
  - "Processing—repackaging" among the reporting codes for the current Chemical Data Reporting rule. 40 CFR 711.15, Table 6.

2) Second, what about companies who assemble things – i.e., install steering wheels in cars, or put furniture together? Could THEY be considered processors? My read is that 10(B) would NOT allow this, because if the chemical substance was already incorporated into the article, as it would be in the examples I used, (B) would make no sense in a reading that allowed these types of people to be treated as processors. Again, am I wrong on this, and is there any further regulatory or other elaboration on this point anywhere?

- Regarding this second scenario, EPA has taken the view that a person who incorporates an article into other equipment, for distribution in commerce, may also be viewed as "process[ing]" the chemical substances in the articles, as that term is defined under TSCA. The assembly prepares the article for distribution in commerce, the chemical substances are themselves present "as part of an article," TSCA § 3(10)(B), and thus the chemical substances in the article are being prepared for distribution in commerce. See, for example, 40 CFR 750.31(a)(7) and (8) (regarding the assembly of equipment using PCB Articles).

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/30/2016 9:51:22 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: heads up

Okay- will alert folks

On Mar 30, 2016, at 5:48 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Will be sending you a new section 5 that re-drafts to base tsca in next day or 2. Will need fast but careful turnaround please. 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>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2016 5:49:01 PM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]; 'Couri, Jerry' [JerryCouri@mail.house.gov]; 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]; 'Fruci, Jean' [Jean.Fruci@mail.house.gov]
Subject: RE: HEC TSCA TA on Nomenclature (4-26 version)

HEC TSCA Team,
Sorry about this, but upon further discussion, we think the TA on the first of the two savings clauses should be revised. Shortly we will send language that we think better conforms with the drafting direction we got from staff, which was to ensure that chemicals first manufactured post-FRL go through PMN review, even if they otherwise might be included in one of the stat mixture listings.

Our apologies for the correction. The TA on 5 is also close and should be coming over shortly. Thanks,
Sven

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

From: Kaiser, Sven-Erik
Sent: Wednesday, April 27, 2016 11:47 AM
To: McCarthy, David <David.McCarthy@mail.house.gov>; 'Couri, Jerry' <JerryCouri@mail.house.gov>; 'Cohen, Jacqueline' <jackie.cohen@mail.house.gov>; 'Fruci, Jean' <Jean.Fruci@mail.house.gov>
Subject: HEC TSCA TA on Nomenclature (4-26 version)

HEC TSCA team – The attached TA responds to the request on section 8 nomenclature provisions. We are also working on the section 5 request.

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
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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: 4/7/2016 7:47:40 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on PCBs

Michal,
This is followup TA on the PCB questions.

You asked two follow up questions regarding PCBs. Here are our responses.

Question: I'm confused about this – appreciate the inactive substance reminder. But I thought enclosed uses of PCBS were still allowed? Are the rules EPA is considering for PCBs just about disposal (and thus about the inactive substance PCBS) or are they also about the enclosed uses that I thought were still allowed?

Response: We are not sure we understand the question. Your original question, which we were responding to in Sven's 2:24 email, was whether EPA could confirm that PCBs will never be subject to pause preemption. As we indicated in our response, we cannot confirm that, because the bill does not preclude prioritization of PCBs. The rules EPA is considering for PCBs are not just about disposal – they deal mostly with certain uses that are not totally enclosed but that EPA nonetheless found do not present unreasonable risk and therefore authorized by regulation. (EPA can allow and has allowed uses to continue on two bases: that the uses are totally enclosed, and that the uses are not totally enclosed but do not present unreasonable risk.) But, we do not understand how the issue of the specific rules we are contemplating relates to the question of whether PCBs could be subject to prioritization and therefore pause preemption under the Senate bill and offer.

Question: And, as another follow up – if your 6(e) authority stands on its own as you told me last night, why would you have to subject them to prioritization prior to regulation, whether they were active or inactive or related to disposal? If they are not subject to prioritization, how would pause apply?

EPA would not have to subject PCBs to prioritization prior to regulation. As you say, EPA has fully adequate authority to regulate PCBs under section 6(e), and that is what EPA would almost certainly do. However, while EPA has authority to regulate PCBs under 6(e), and has always used that authority, nothing in TSCA precludes EPA from regulating them under 6(a), and nothing in the bill would preclude EPA from regulating PCBs under the new chemical regulation authorities. Thus, per the above response, we cannot confirm that PCBs would never be subjEct to pause preemption.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/18/2016 10:33:45 PM
To: Adrian_Deveny@merkley.senate.gov
Subject: Sen. Merkley TSCA TA Request on section 6 cost language

Adrian,
This responds to the TA request on section 6.

First, based on the latest version of 6(c)(2)(A)(i) and (ii) (discussed on Saturday), does it need to be clarified that these be explicitly linked to the results of the risk evaluation published in (b)(4)(B)? Without that link, could (i) and (ii) be read to require a new analysis? Would adding the following language at the end of (i) and (ii) solve this issue: "based on the results of the risk assessment published in (b)(4)(B)"?

EPA agrees that, under current drafting, (i) and (ii) could theoretically require analysis of the effects of a chemical beyond the analysis in the (b)(4) risk evaluation. That said, this would arise only where new information on such effects becomes reasonably available in the time between completion of the risk evaluation and completion of the proposed and final rulemakings. Given that the risk evaluation process is fairly rigorous, and requires among other things notice and comment, we think that situation is not likely to arise often. The issue could be addressed, though, by adding, at the end of (i) and (ii), ", as identified by the Administrator in the risk evaluation under subsection (b)(4)". That formulation seems preferable to "based on", since the latter could suggest some further analysis using the evaluation as the starting point.

In (iv)(III), "the cost-effectiveness of the proposed regulatory action" is not currently explicitly based on the info in (II). Given that cost-effectiveness is not defined anywhere, if the intent is that we want the cost effectiveness analysis to be based on (II) so that it looks at both the costs and the benefits of the proposed regulatory action, does that need to be made explicit in the language? Would this be corrected by inserting "based on the information in (II)," at the beginning of subclause (III)?

If, as you say, your intent is that the cost effectiveness analysis to be based on the information in (II), then adding the phrase you suggest would accomplish that result. We are not sure how much difference the addition of the language would make, since the analysis for both (II) and (III) is based on reasonably available information, and EPA is probably unlikely to generate new or different cost or benefit information for the purposes of (II) and (III).

Finally, on (C), how does EPA interpret "substantially prevents"?

EPA has not interpreted the phrase "substantially prevents" in the past. As written, the provision gives the decision maker significant discretion to interpret broadly or narrowly, and EPA cannot predict which way the Agency might interpret this language in the future.

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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202-566-2753

From: Deveny, Adrian (Merkley) [mailto:Adrian_Deveny@merkley.senate.gov]
Sent: Monday, April 18, 2016 2:25 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: remedy language

Sven
Can your team take a look at the follow questions?

First, based on the latest version of 6(c)(2)(A)(i) and (ii) (discussed on Saturday), does it need to be clarified that these be explicitly linked to the results of the risk evaluation published in (b)(4)(B)? Without that link, could (i) and (ii) be read to require a new analysis? Would adding the following language at the end of (i) and (ii) solve this issue: "based on the results of the risk assessment published in (b)(4)(B)"?

In (iv)(III), "the cost-effectiveness of the proposed regulatory action" is not currently explicitly based on the info in (II). Given that cost-effectiveness is not defined anywhere, if the intent is that we want the cost effectiveness analysis to be based on (II) so that it looks at both the costs and the benefits of the proposed regulatory action, does that need to be made explicit in the language? Would this be corrected by inserting "based on the information in (II)," at the beginning of subclause (III)?

Finally, on (C), how does EPA interpret "substantially prevents"?

ADRIAN DEVENY
Director of Energy and Environmental Policy
OFFICE OF SENATOR JEFF MERKLEY
313 Hart Senate Office Bldg.
Washington, DC 20510 | (202) 224.3753
Sign up for Senator Merkley's E-newsletter
Become a Supporter on Facebook
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 5:39:00 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request on PBTs 04-09-16PBT (Conf Proposal)
Attachments: 04-09-16PBT (Conf Proposal) -- BG.docx; ATT00001.htm

Michal- see attached TA requested on PBTs.

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: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 12:31:01 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)"

<Kaiser.Sven-Erik@epamail.epa.gov>

Subject: 04-09-16PBT (Conf Proposal).docx

Sven

Could you please review paragraphs 1-3 of this document to make sure it does what it is intended to do? I tried to be specific based on your TA about the 3 PBTs but may not have used the right

terminology. Anytime today if possible, but if I am overloading you, mid-AM tomorrow should also be ok.

Thanks

michal

<04-09-16PBT (Conf Proposal).docx>

<04-09-16PBT (Conf Proposal) -- wch.docx>

<04-09-16PBT (Conf Proposal) -- BG.docx>

( ) Chemicals That Are Persistent, Bioaccumulative, and Toxic.--

(1) Expedited Action.--Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose a rule under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments —

(A) that the Administrator has a reasonable basis to conclude are toxic and with respect to persistence and bioaccumulation, scores high for one 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), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation under section 6, initiated a risk assessment under section 5, or entered into a consent agreement under section 4; and

(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, on the basis of an exposure and use assessment conducted by the Administrator.

(2) Final Rule.--Notwithstanding subsection (__), ~~subject to the availability of appropriations~~ and subsections __ and __ , not later than 2 years after proposing a rule under paragraph (1), the Administrator shall promulgate a rule under subsection (a) with respect to each chemical substance for which a rule is proposed under paragraph (1) to reduce likely exposure to the extent practicable.

(3) Relationship to subsection (b).--If, at any time prior to the date that is 90 days after the date on which the Administrator proposes the rule under paragraph (1), the Administrator makes a finding under subsection (__), or a manufacturer requests a risk evaluation under subsection (__), with respect to a chemical substance, such chemical substance shall not be subject to this subsection, except that any proposed and final rule shall reduce likely exposure to the extent practicable.

(4) OTHER CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC OR CARCINOGENS.—

(A) In designating high priority substances pursuant to subsection (b), the Administrator shall give preference to—

(i) chemical substances that, with respect to persistence and bioaccumulation, score 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) ;and

(ii) chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

Commented [A1]: EPA TA: Per earlier TA to House, there is some awkwardness in proceeding directly to the risk management rule without having made the negative safety determination. Per comments below, it's not clear if the intent is that EPA meet that (a) standard AND reduce exposure as practicable for these PBTs, or just reduce exposure to extent practicable. That should be clarified. If it's the former, then there could be some awkwardness in being directed to eliminate an unreasonable risk that EPA has not found exists.

Commented [A2]: EPA TA: Note that, because these chemical go directly to rulemaking without risk evaluation, the rulemaking work will not be covered by fees, if the fee trigger is for chemical subject to risk evaluation.

Commented [A3]: EPA TA: This will be a challenging deadline to meet for the 9 or so chemicals that would be subject to it.

Commented [A4]: **EPA TA:** As currently drafted, a PBT can get out of this rule if EPA completes a problem formulation, section 5 analysis, or consent agreement under section 4 **at any point prior to the proposal of the rule.** If your intent was to cut this off at the point of enactment, you would need to revise the language here.

Commented [A5]: **EPA TA:** EPA is unsure whether this text refers to specific provisions in section 5 or 6 that EPA has not seen, since there is no reference in versions of sec 6 we have seen that refer to problem formulation, and no version of section 5 that refers to risk assessments. If those are not terms that will appear in those sections, then, with respect to section 6: the concept of a "Work Plan Problem Formulation" is not a defined concept. Under current TSCA, this sort of prioritization and planning work is prior to action under section 6. EPA knows what a Work Plan Problem Formulation is, though. The drafting solution may be to simply delete "under section 6." ...

Commented [A6]: Is this specific enough and could it capture any PBT other than the ones we have discussed?

Commented [A7R6]: **EPA TA:** If we are talking about actions taken prior to enactment, if a bill is enacted this summer it would likely also capture some of the other flame retardants beyond HBCD, for which we have issued problem formulations.

Commented [A8]: **EPA TA:** If the intent is to capture all relevant exposure, we suggest modifying to include environmental exposure, since PBTs are often toxic to aquatic organisms and wildlife.

Commented [A9]: What does this entail and how long does it take?

Commented [A10R9]: **EPA TA:** Generally, for a use and exposure assessment, EPA would need to do research to identify uses and use scenarios, then estimate routes, duration, extent of exposure, etc. for those various use scenarios, as well as the ...

Commented [A11]: X-ref to provision requiring risk management rules on the basis of a risk evaluation

Commented [A12]: Need to cross-reference language on 50% discount for Work Plans, ensure numerical limitation does not apply, ensure cost-benefit analysis applies to selected risk ...

Commented [A13]: EPA TA: Per comment above, is this in addition to or in lieu of the (a) standard?

Commented [A14]: **EPA TA:** You probably mean to say: "any proposed or final rule for such chemical substance shall . . ."

Commented [A15]: EPA TA: Same question re rule objective

(B) In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

(C) For a chemical substance subject to subsection (a) and 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 promulgated in a rule pursuant to subsection (c), reduce exposure to the substance to the extent practicable.

Commented [A16]: EPA TA: Would be clearer if "and" were changed to "that,"

Commented [A17]: EPA TA: Is there a reason this language does not appear in (2) and (3)? Is this intended to mean that, for these chemicals, we meet both the (a) standard and the "reduce" standard?

Retain expedited action provision in 6(c)

(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 paragraph and subsection (b)(4)(G) does not exceed two years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, 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), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 2:37:04 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
CC: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: RE: House discussion draft
Attachments: Udall.TSCA TA on House Additions.docx

Jonathan,
The attached TA responds to your request on the House discussion draft. Please let me know if any questions.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, March 04, 2016 3:04 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: House discussion draft

Sven, wondering if your crew could take a look at the attached House discussion draft and answer the following questions.

- Did anything in this offer address the specific concerns raised in EPA's January 20th letter? And if so, how?
- Do any of the additions raise workability or implementation concerns?
- Does the House discussion draft address the major concerns from the EPA Jan. 20th letter to ensure that safety decisions are made absent consideration of costs?
- Does the House draft ensure an affirmative safety finding for new chemicals?
- Do the changes require EPA to review substantiation for past CBI claims?
- Do the changes ensure that industry-requested chemicals will not be expedited relative to chemicals that EPA selects itself?

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.

- **Did anything in this offer address the specific concerns raised in EPA's January 20th letter? And if so, how?**

Yes, the offer appears to partially address certain concerns. First, the offer appears to partially address the concern that manufacturer priorities could overrun those of the Agency by confining the number of manufacturer-initiated risk evaluations to 25-50% of the total number of ongoing risk evaluations. EPA still has specific concerns on this point, as described in a later response. Second, the offer would seem to partially address the concern regarding funding by adding fee collection authority for EPA-initiated risk evaluations. However, the bill still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims.

- **Do any of the additions raise workability or implementation concerns?**

Yes. First, the additions reclassify a particular subset of industry requests under § 6(b)(3)(A)(ii) (relating to new chemical substances that have not yet been manufactured) as requests under § 5(i). This change makes these requests no longer subject to deadline adjustment under § 6(b)(5). Nor would such requests be subject to the new caps under § 6(b)(3)(C). Furthermore, EPA would not be able to collect fees for such requests if manufacture had not yet commenced (there would not yet be any manufacturer to against whom to assess risk evaluation fees under § 26(b)(1), and the authority to collect fees for the PMN review would not extend to cover voluntary risk evaluations. These provisions could create circumstances in which unfunded requests for voluntary risk evaluations overwhelm EPA's review capacity.

Second, the additions will require a very significant and resource-intensive implementation effort: (1) to sift through every CBI claim ever received under TSCA since the enactment of the statute; (2) to make a provisional adjudication of the qualifications of every claim; (3) to request and review re-substantiation packages where deemed warranted; (4) to notify all parties for which re-substantiation was inadequate, of pending release; and (5) to defend litigation arising from the required determinations. The implementation concerns raised by these provisions are rendered even more serious by the lack of funding for CBI review activities, and by the 5-7 year time frame specified for completing the specified CBI reviews, which could be enforced by deadline suits. Note that the Senate bill is considerably narrower in scope (only certain Chem ID claims), and it allows EPA to directly obligate CBI claimants to bring their claims (and re-substantiation) to EPA's attention, rather than creating the two-step process envisioned here. Note also that the Senate bill provides fee funding for these activities.

Third, specifying that alternative test protocols that avoid animal testing must be validated has the potential to significantly delay EPA's use of such protocols and divert EPA resources towards validation efforts. Validation as is currently implemented through Federal processes such as ICCVAM may not always be necessary depending on the context in which the alternative test method/data will be applied. While validation is recognized as an important process needed to accept an alternative method as a replacement for a whole animal test, there are circumstances under which alternative methods and the data derived from them may be valuable prior to completion of a full validation process. For

example, data from an alternative method may provide information or insights useful as part of a weight of evidence evaluation even when the method has not been fully validated as a replacement test.

- **Does the House discussion draft address the major concerns from the EPA Jan. 20th letter to ensure that safety decisions are made absent consideration of costs?**

Please note, as an initial matter, that EPA's letter did not articulate concerns that the House bill, as passed, would allow consideration of costs to factor into risk evaluations under section 6. In fact, EPA believes that the House bill – as passed and as modified recently - very clearly *excludes* consideration of costs from the both the risk evaluation and risk management triggering phases.

Rather, EPA's views letter pointed out potential inconsistencies in the application of the "unreasonable risk" safety standard elsewhere in the bill (in the risk management portions of section 6 and other sections of TSCA) which left ambiguity about the role of cost considerations in those contexts.

The bill does not attempt to address EPA's concerns on this point. For example, the bill does not provide an upfront safety standard definition or redefine "unreasonable risk" in each instance it appears. As such, there remains uncertainty as to what safety standard would apply for EPA actions under provisions of TSCA, outside of Section 6, that reference "unreasonable risk." The potential inconsistencies in risk management standards within Section 6 also remain (e.g., the standard for cost-effective v. non-cost effective requirements, and standards for regulating articles, replacement parts and PBTs).

- **Does the House draft ensure an affirmative safety finding for new chemicals?**

No, the new subsection 5(i) does not ensure that all new chemicals will receive an affirmative safety finding before the commencement of manufacture. It only applies if the person submitting the pre-manufacture notice for a chemical substance requests a risk evaluation of such substance. Subsection 5(i) is furthermore unnecessary to allow for this possibility. Such requests are already provided for under § 6(b)(3)(A)(ii).

- **Do the changes require EPA to review substantiation for past CBI claims?**

As described above, the changes require EPA to review all past CBI claims. EPA would then identify a particular subset of past CBI claims for which re-substantiation would be required and then EPA would request and review those re-substantiation packages.

With respect to the remaining CBI claims (i.e., those for which EPA did not require re-substantiation as an outcome of its initial review) the bill provides that such claims are automatically waived 10 years after enactment if re-substantiation is not sent to EPA by that time. The bill does not require that EPA review such re-substantiation, however.

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.

- **Do the changes ensure that industry-requested chemicals will not be expedited relative to chemicals that EPA selects itself?**

While the changes are in some respects helpful in addressing this issue, they do not ensure that the volume of industry-requested risk evaluations will be appropriately balanced against the volume of EPA-initiated risk evaluations. This is because:

- Section 6(b)(5)((B)(i) still appears to allow EPA to delay both EPA-initiated and industry-requested risk evaluations if the volume of industry-requested risk evaluations is excessive.
- Section 6(b)(7) still subjects the minimum number of EPA-initiated assessments to available appropriations.
- There is still no mechanism for industry fees to fund the development of risk management actions that EPA might be obligated to undertake as a consequence of industry-requested risk evaluations.
- As described above, a subset of industry-requested risk evaluations are now removed from caps and deadline adjustment (those accompanying a PMN).

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 7:06:40 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA priorities

Michal,
Thanks - will share with the team. Please let me know if any additional questions. Best,
Sven

On Apr 23, 2016, at 3:03 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

4 does not need review as they have not taken any changes since last draft. Definitely prioritize 14.
Attached what we sent to HLC on 26 and 19. It is possible that the 19 I am attaching may have been further updated and I know there was some back and forth with the House on it after it was sent.

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: Saturday, April 23, 2016 3:00 PM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Re: Sen. Markey TSCA TA on House "Draft in progress" section 5 (4-23)

Michal - We can divide up sections if needed to speed things up. Priorities helpful. Thanks,
Sven

On Apr 23, 2016, at 2:49 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

in case it is useful I'm attaching the page/line edits that were sent to HLC on the last version of 14. If you have the ability to have your team work on more than one section at once, and would like some prioritization, let us know.

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

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 2:43 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA on House "Draft in progress" section 5 (4-23)

Michal,
The attached TA responds to the request for big picture review of House section 5 (4-23). Please let me know next steps on 5; we are also reviewing section 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 additional questions. Thanks,

Sven

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

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Saturday, April 23, 2016 12:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Fw: Draft in progress

Sven

See attached.

Please start your review with section 5, which we believe may have been rewritten again. Specifically, we'd like you to pull together your "big picture" comments on section 5 in the way you did the last time. We can decide from there whether it makes sense for you to focus on more granular review of 5 or not.

From there, pls go next to specific edits on 14. When I get in I can send you the line edits on the last HLC 14 that were sent to the House if you feel they would help your review - let me know.

Once we have a chance to look at this we may have different direction, but for now, we think that order makes the most sense.

thanks

M

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

From: McCarthy, David <David.McCarthy@mail.house.gov>

Sent: Saturday, April 23, 2016 12:37 PM

To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)

Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick; Fruci, Jean

Subject: Draft in progress

Attached is the most current draft. We have not yet finished reading it and have not begun discussing it on our side, as several of us are not available to work on it this weekend. Also, it still has some bracketed words and a few questions about provision interactions. Language to amend section 18 is, as the draft says, "to be determined."

<Section 14 (HLC 4-20).docx>
<Section 26 (HLC 4-20).docx>
<Section 19 HLC (4-20)V2.docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/12/2016 10:34:56 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - Section 4, parties to testing

Michal – got it. Thanks,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, February 12, 2016 5:32 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - Section 4, parties to testing

Sven

This is in reference to the EPA TA that pointed out that Section 4(b)(2) in what I sent you doesn't work with Senate 4(a).

Would it make sense to strike "order or CA" and then leave the provision related to rule authority? Is it necessary to specify who EPA can direct to test things at all (ie should we strike the whole thing)?

(2)(A) A rule, order, or consent agreement under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule, order, or consent agreement under subsection (a):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding de-scribed in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/22/2016 2:10:43 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request - section 5 determinations
Attachments: 03-21-16section5determinationswithEPATA.doc; ATT00001.htm

Michal,
Please see TA responding to the request on section 5 determinations. Thanks,
Sven

Attached are EPA's technical comments on the language you've provided. With respect to the two different formulations of the "(3) Restrictions," EPA believes both would effectively remove cost considerations from the Section 5 risk management trigger. However, we'd note that the second formulation is more aligned with the structure of section 6 (i.e., reference back to an "unreasonable risk" determination – 5(d)(2)(A) and 6(b)(4)(A) - where costs are explicitly excluded). Whatever the resolution, EPA recommends parallel construction in both sections 5 and 6 to avoid arguments that some different substantive meaning was intended.

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 21, 2016 11:09 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - section 5 determinations

Sven

Can you please take a look at this? This incorporates your TA but includes 2 different formulations for the (3) restrictions text. I'd like your take generally, but on the second formulation, I'd like to know whether it addresses the various 'unreasonable risk' questions adequately by referring back to (2)(A) instead of typing the entire text string again.

Thanks

michal

(2) DETERMINATIONS.—

(A) the Administrator shall determine~~, without consideration of costs or other non-risk factors,~~ whether the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, from potential exposure to ~~a~~the chemical substance under the conditions of use, ~~identified in the notice~~ to the general population or to a potentially exposed or susceptible population identified as relevant by the Administrator, and take applicable action under paragraph (3).

(B) If the Administrator determines that information available to the Administrator is insufficient to make a determination under subparagraph (A), the Administrator shall take applicable action under paragraph (3) and—

(i) shall provide an opportunity for the submitter of the notice to submit the information, and may extend the review period for a reasonable amount of time by agreement with the submitter to allow the development and submission of the information;

(ii) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and

(iii) shall, on receipt of information the Administrator finds sufficient to support a determination under subparagraph (A), promptly make the determination, and take action under paragraph (3) as applicable.

(3) RESTRICTIONS.—

(A) DETERMINATION BY THE ADMINISTRATOR.—

(i) IN GENERAL.—If the Administrator makes a determination that a chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, from potential exposure to a chemical substance under the conditions of use to the general population or to a potentially exposed or susceptible population identified as relevant by the Administrator ~~under paragraphs (2)(A)~~ or makes a determination under subparagraph (2)(B~~C~~) with respect to a notice submitted under subsection (b) —

(i) OR

(3) RESTRICTIONS.—

(B) DETERMINATION BY THE ADMINISTRATOR.—

(i) IN GENERAL.—If the Administrator makes a determination that a chemical substance or significant new use may present an unreasonable risk of injury to health or the environment in accordance with paragraph (2)(A) or makes a determination under subparagraph (2)(B~~C~~) with respect to a notice submitted under subsection (b) —

Commented [A1]: Struck "a" and replaced with "the." Change seems important, to leave no doubt that the relevant exposure and risk factors are those relating to the chemical itself, and do not consider exposure and risk from other chemicals (eg, off-setting risks).

Commented [A2]: Added a comma, which seems to marginally improve clarity.

Commented [A3]: Would need conforming changes, per comments above.

Formatted: No bullets or numbering

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 7:30:16 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on section 26 fees
Attachments: Markey.TSCA TA.section 26 fees.4-12.docx

Michal,
The attached TA responds to the request on the revised section 26. Note that the comments are in RLSO and might not show up on a phone.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 7:38 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: section 26 of TSCA (WEI16246)

Pls review and make comments in the word doc. SLC version which hopefully reflects all that it needs to. If you could turn around by 12/1 that would be great.

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

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SEC. __. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) FEES ALLOWED.—

"(A) IN GENERAL.—The Administrator may, by rule, require the payment from any person required to submit information under section 4 or a notice or other information to be reviewed by the Administrator under section 5, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b), of a fee that is sufficient and not more than reasonably necessary to defray the cost of administering sections 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, including contractor costs incurred by the Administrator.

"(B) CONSIDERATIONS.—In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to pay the fee and the cost to the Administrator of reviewing the information or notice or conducting the risk evaluation, as applicable.

Commented [A1]: EPA TA: This should be the cost of carrying out all the activities covered by (A), not just the costs of the fee triggers.

"(C) FEE SHARING.—A rule issued under this paragraph may provide for sharing the fee in any case in which the expenses of testing are shared under section 4 or 5.

"(2) STANDARDS.—The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons that qualify as small business concerns for purposes of paragraph (1).

Commented [A2]: EPA TA: Paragarph (1) doesn't describe any special treatment for small businesses. It comes up in Paragraph (4), though.

"(3) FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Service Fee Fund' (referred to in this paragraph as the 'Fund'), consisting of such amounts as are deposited in the Fund under this paragraph.

"(B) COLLECTION AND DEPOSIT OF FEES.—The Administrator shall collect the fees described in this subsection and deposit the fees in the Fund.

"(C) CREDITING AND AVAILABILITY OF FEES.—On request by the Administrator, the Secretary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the full costs incurred by the Environmental Protection Agency, including contractor costs, for use in defraying the costs of the activities described in paragraph (1).

Commented [A3]: EPA TA: Here you say full cost recovery; but in (4) you say 25% cost recovery. This is an inconsistency.

"(D) USE OF FUNDS BY ADMINISTRATOR.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in

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advance in appropriations Acts, and shall be available without fiscal year limitation for use in defraying the costs of the activities described in paragraph (1).

"(E) ACCOUNTING AND AUDITING.—

"(i) ACCOUNTING.—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

"(ii) AUDITING.—

"(I) IN GENERAL.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

"(II) COMPONENTS OF AUDIT.—The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

"(aa) the fees collected and amounts disbursed under this subsection;

"(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of this title for which the fees may be used; and

"(cc) the number of requests for a risk evaluation made by manufacturers under [section 6(b)(4)(C)(ii)].

"(III) FEDERAL RESPONSIBILITY.—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

"(4) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this subsection, the Administrator shall—

"(A) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(B) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray—

"(i) the lower of—

"(I) 25 percent of the costs to the Administrator of carrying out sections 4,

Commented [A4]: EPA TA: This is inconsistent with the language about full cost recovery.

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5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, other than the costs to conduct and complete risk evaluations for chemical substances identified pursuant to [section 6(b)(4)(C)(ii)]; or

"(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and

"(ii) the full costs and the 50-percent portion of the costs of risk evaluations specified in subparagraph (D);

"(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(D) notwithstanding subparagraph (B)—

"(i) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to [section 6(b)(4)(C)(ii)], establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 6(b);

Commented [A5]: EPA TA: This should begin "except as provided in (D)(ii),". That proviso was not in the senate bill, but it was not needed there because requests for chemicals on the work plan were granted under a different clause.

"(ii) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to [section 6(b)(4)(C)(ii)], and which are included in the 2014 update of the TSCA Work Plan for Chemical Assessments, establish the fee at a level sufficient to defray 50 percent of the costs to the Administrator of conducting the risk evaluation under section 6(b); and

"(iii) apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses;

Commented [A6]: EPA TA: This seems to mean that EPA cannot apply fees from these manufacturers to cover the cost of the risk management rules, or any other activities of the program, because this provides that "the fee" collected these provision can't go to anything else. The intent presumably is to establish a separate set of rules for how much fee can be levied for the risk evaluation portion of what the fee covers, but the wording seems to comprehensively limit use of the fee.

"(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or representatives of those parties, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

"(F) beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and representatives of those parties pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray—

"(i) approximately but not more than 25 percent of the annual costs to the Administrator of carrying out sections 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, other than

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the costs to conduct and complete risk evaluations under section 6 for chemical substances under [section 6(b)(4)(C)(ii)]; and

"(ii) the full annual costs and the 50-percent portion of the annual costs of risk evaluations specified in subparagraph (D); and

"(G) if a notice submitted under section 5 is not reviewed or such a notice is withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(5) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for the Chemical Risk Review and Reduction program project of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for that program project for fiscal year 2014.

"(6) TERMINATION.—The authority provided by this subsection shall terminate on the last day of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act."; and

(2) by adding at the end the following:

"(h) Scientific Standards.—In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed in a manner consistent with the best available science, and consider, as applicable—

"(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

"(2) the extent to which the information is relevant for the use of the Administrator in making a decision about a chemical substance or mixture;

"(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

"(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

"(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

"(i) Weight of Scientific Evidence.—The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.

"(j) Availability of Information.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, findings, rules, consent agreements, and orders of the

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Administrator under this title;

"(2) any information required to be provided to the Administrator under section 4;

"(3) a nontechnical summary of each risk evaluation conducted under section 6; and

"(4) the studies considered by the Administrator in carrying out each risk evaluation conducted under section 6.

"(k) Reasonably Available Information.—In carrying out sections 4, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

"(l) Policies, Procedures, and Guidance.—

"(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, including policies, procedures, and guidance related to the use of scientific information described in subsection (h), and for the purpose of making the basis of decisions under sections 4, 5, and 6 clear to the public.

"(2) REVIEW.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this title; and

"(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

"(3) TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.—The policies, procedures, and guidance developed under paragraph (1) applicable to testing of chemical substances and mixtures shall—

"(A) address how and when the Administrator will consider the exposure level or exposure potential of a chemical substance or mixture in making a decision to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; and

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

"(4) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As relevant policies and procedures under this subsection are developed, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing risk evaluations.

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"(5) 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 final 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 final risk assessment for the chemical substance and consistent with other applicable requirements of section 6.

"(6) NOTICE OF EXISTING INFORMATION.—The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure made public by other Federal agencies and the National Academies and incorporate the information into risk evaluations, to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable, with the objective of increasing the efficiency of the risk evaluations.

"(7) GUIDANCE.—

"(A) 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 develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator.

"(B) REQUIREMENTS.—Guidance under this paragraph shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

"(m) Report to Congress.—

"(1) INITIAL REPORT.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of—

"(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under [section 6(b)(4)(C)], and the resources necessary to be conducting the minimum number of risk evaluations specified in [section 6(b)(2)(B)];

"(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under [section 6(b)(4)(C)(ii)], the likely demand for those risk evaluations, and the anticipated schedule for accommodating that demand;

"(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

"(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the capacity of the Agency to conduct and publish risk evaluations under section 6(b).

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"(2) SUBSEQUENT REPORTS.—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

"(n) Annual Plan.—At the beginning of each calendar year, the Administrator shall publish an annual plan that—

"(1) identifies the chemical substances for which risk evaluations are expected to be completed that year and the resources necessary for the completion of the risk evaluations;

"(2) describes the status of each risk evaluation that has been initiated but not yet completed; and

"(3) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

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

"(1) ESTABLISHMENT.—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 an advisory committee to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

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

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

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

"(p) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(q) Prior Actions and Notice of Existing Information.—

"(1) PRIOR-INITIATED EVALUATIONS.—Nothing in this Act, or the amendments made by this Act, prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such a risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under this section or section 6.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES, PROCEDURES, AND GUIDANCE.—Nothing in this Act, or the amendments made by this Act, requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule

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 solely because the action was completed prior to the completion of a new policy, procedure,
2 or guidance established under this section or section 6.".
3

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/30/2016 9:22:18 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on partial risk evaluations

Michal – how about 10am, Thurs, Mar 31? Can call Ex. 6 - Personal Privacy, code Ex. 6 - Personal Privacy Thanks, Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 30, 2016 3:12 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on partial risk evaluations

I think I need a call on this! tomorrow AM slots?

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

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 25, 2016 8:50 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA on partial risk evaluations

Michal- The 5 referenced partial risk evaluations were TCE, NMP, MC, ATO and HHCB. EPA found no concern for ATO (Antimony Trioxide) and HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[γ]-2-benzopyran). 1-BP is a draft risk assessment, and was not included in the count. See EPA's website on TSCA Work Plan Assessments:

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.

Please let me know if any additional questions. Thanks,

Sven

On Mar 25, 2016, at 7:51 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sorry, one last thing on this - you originally listed these chemicals as the subjects of these RES. But I thought in other TA you said there were 5. What is the 5th?

TCE, NMP, MC, and 1-BP.

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

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 6:48 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,
The attached TA responds to the request on partial risk evaluations. 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)" <Michal_Freedhoff@markey.senate.gov>
Date: March 22, 2016 at 10:02:12 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on partial risk evaluations

Would this do it for you? I don't think a discussion about what you add below re cost considerations would be a constructive one. I am not sure that this works to address your concern re rules/deadlines though.

(3) (A) PRIOR-INITIATED EVALUATIONS[A1] —

(i) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation or partial risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under this Act[A2] .

(ii) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As relevant policies and procedures under this Act are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing risk evaluations.

(B) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation or partial risk evaluation, determination or rule solely because the action was completed prior to the completion of a policy or procedure established under this Act.

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
<image002.png><image003.png><image004.png><image005.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, March 21, 2016 6:25 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,
This TA responds to your request on partial risk evaluations. Please let me know if any questions. Thanks, Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Response: EPA has completed risk assessments for 5 chemicals under the TSCA Workplan process. Those assessments only consider risk. There is no cost consideration. 3 of the chemicals have high risk and are moving to the risk management phase. We are developing proposed rules. As required by TSCA we will balance costs and benefits (the value of risk reduction) and identify the least burdensome means to reduce the risk. We are scheduled to propose rules for these three chemicals later this year.

The risk assessments for all three of these chemicals had narrow scopes. We did not look at all uses of the chemicals as would be required under both House and Senate passed bills. We assume that if a bill passes

before we finalize these rules we would need to finalize them using the new rulemaking standard in the law. But because the risk assessments were done without consideration of costs, we would not need to redo the work for the uses which have already been assessed.

The issue we are flagging is that meeting the scoping intent of either bill would require a significant amount of additional work on these three chemicals to assess the uses that were not included in our final assessments. That could delay regulation of the uses with known risks. Modification of the cost considerations would take a little time but much less as the cost considerations under the current law are more onerous than either the House or Senate bills. If the Senate or House bill passed as drafted we would likely call these three chemicals high priority and make an argument that we can go forward with the narrower scoped regulations using the new standard. There is some legal vulnerability that we'd be prevented from doing so. Because the rulemaking deadlines in 6(c)(1) begin to run once EPA deems a chemical unsafe, EPA would be on a tighter time clock (4 years, as opposed to 3 years + 4 years) to both complete the risk evaluations AND any associated rulemakings with respect to other uses not part of the original evaluation. It is not clear to us whether those additional uses have risk. In the alternative, we could identify these three chemicals as high priority and then assess the additional uses before moving to risk management. The down side is that we would know there was risk for certain uses of these chemicals but we would be waiting to assess the remaining uses before doing any risk management.

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, March 20, 2016 11:16 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Questions on partial risk evaluations

Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Thanks - just trying to figure out what to do with this and how to draft it etc. Not a weekend thing for you guys!

M

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

EPA TA – needs clarifying to ensure section 6 activities can proceed as intended

EPA TA here and below

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/18/2016 6:26:31 PM
To: 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Merkley TSCA TA Request on section 6 cost language

Adrian – got it - checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Deveny, Adrian (Merkley) [mailto:Adrian_Deveny@merkley.senate.gov]
Sent: Monday, April 18, 2016 2:25 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: remedy language

Sven
Can your team take a look at the follow questions?

First, based on the latest version of 6(c)(2)(A)(i) and (ii) (discussed on Saturday), does it need to be clarified that these be explicitly linked to the results of the risk evaluation published in (b)(4)(B)? Without that link, could (i) and (ii) be read to require a new analysis? Would adding the following language at the end of (i) and (ii) solve this issue: "based on the results of the risk assessment published in (b)(4)(B)"?

In (iv)(III), "the cost-effectiveness of the proposed regulatory action" is not currently explicitly based on the info in (II). Given that cost-effectiveness is not defined anywhere, if the intent is that we want the cost effectiveness analysis to be based on (II) so that it looks at both the costs and the benefits of the proposed regulatory action, does that need to be made explicit in the language? Would this be corrected by inserting "based on the information in (II)," at the beginning of subclause (III)?

Finally, on (C), how does EPA interpret "substantially prevents"?

ADRIAN DEVENY
Director of Energy and Environmental Policy
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Washington, DC 20510 | (202) 224.3753
Sign up for Senator Merkley's E-newsletter
Become a Supporter on Facebook
Follow Jeff on Twitter

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/26/2016 6:13:22 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: RE: EPA Notification: TSCA New Chemicals Update

Jerry – I'll check on that and get back to you. 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: Wednesday, October 26, 2016 2:10 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: EPA Notification: TSCA New Chemicals Update

ALL the interims agreed to an suspension/extension? How many is that? Seems a bit odd....

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, October 26, 2016 2:03 PM
Subject: EPA Notification: TSCA New Chemicals Update

Heads up that EPA updated the TSCA FAQs to add information on new chemical reviews. The new FAQ (#23) is included below, the full FAQs are available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-0#newchems.

EPA will continue to update the FAQs as TSCA reform implementation progresses. 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)
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202-566-2753

Q23. What's the status of new chemical reviews now that the first 90 days has passed?

The Frank R. Lautenberg Chemical Safety for the 21st Century Act went into effect immediately upon signature by the President on June 22, 2016. The New Chemicals Program was the most immediately affected part of the EPA's TSCA program. Amended TSCA, section 5, requires the EPA to review a new chemical or new use notice, make a determination, and to take actions required in association with that determination. In implementing this new provision, EPA is working diligently to make decisions in a time frame that comes as close as possible to that experienced prior to the new law.

EPA receives new chemical submissions totaling about 1,000 per year. As a result, on June 22, several hundred chemicals were at different stages in the review process. Section 5 submissions were considered resubmitted, thus restarting the 90-day clock for EPA's review of those chemicals. The EPA then faced a number of challenges, including:

- Doubling effort on review processes to reconsider pre-enactment decisions in light of the new standard for resubmitted PMNs, while keeping pace with new submissions.
- Developing and implementing a process for implementing the "not likely to present an unreasonable risk" finding, including new documentation and publication requirements.
- Implementing the provision of the new law which requires that EPA make an affirmative determination for both intended and reasonably foreseen uses of new chemicals.
- Implementing the new finding of "insufficient information to make a reasoned evaluation."

With the 90-day clock running on several hundred submissions, it took the EPA several weeks to put these components into place, including adding staff to review new chemicals, scheduling additional reviews, developing affirmative finding documents which meet legal requirements and provide useful information on EPA's reviews.

By the end of September 2016, EPA reached interim or final determinations for most of the new chemical submissions which were resubmitted when the new law was enacted. All submitters with interim determinations have requested, and EPA has granted, a suspension of the 90-day review period.

- On June 22, 2016, there were about 200 chemicals in the process for which EPA had previously made decisions to develop orders or to seek additional information from submitters, based on a finding that each chemical "may present an unreasonable risk". The review period for these chemicals had been voluntarily suspended by the submitters. EPA determined that the decisions on these chemicals would remain the same under the new law. Submitters have agreed to re-suspend the review period while orders are being developed or negotiated.
- That left about 115 valid submissions within the 90-day review period on June 22. EPA re-reviewed these chemicals in light of the new requirements and made decisions prior to day 90.
- New chemical submissions received after June 22 are being reviewed and will receive final or interim determinations within a 90-day review period.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/7/2016 6:41:35 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on PCBs and partial REs

Got it - 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: Thursday, April 07, 2016 2:35 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on PCBs and partial REs

I'm confused about this – appreciate the inactive substance reminder. But I thought enclosed uses of PCBS were still allowed? Are the rules EPA is considering for PCBs just about disposal (and thus about the inactive substance PCBS) or are they also about the enclosed uses that I thought were still allowed?

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, April 07, 2016 2:24 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on PCBs and partial REs

Michal – this responds to the followup TA request on PCBs and partial risk evaluations.

Question: Senate 18 says old preemption applies to chemical substances that have already been regulated under section 6 UNLESS EPA puts them through prioritization. What you're telling me below is that PCBS will never be subjected to pause preemption. Can you confirm?

Response: EPA cannot say for certain that PCBs would never by subjected to pause preemption. PCBs would be inactive chemical substances, unless we received a notice under section 8 that someone was continuing to process PCBs for a non-exempt commercial purpose (we do not believe there is any ongoing manufacture for a non-exempt commercial purpose).

Under TSCA, EPA would view the processing for commercial purposes of a material containing PCBs (for example, plastic residue from the shredding of automobiles known as "fluff") as processing for commercial purposes of the PCBs.

Under section 8 of the Senate bill and offer, processors may, but are not required to, identify as active chemical substances they have processed in the preceding 10 years. If PCBs are inactive chemical substances for which EPA found there was a potential for residual high hazards or widespread exposures, notwithstanding the statutory ban and 6(e) regulations (or if PCBs are active chemical substances) then EPA could prioritize them for a safety evaluation under section 6(a), in which case they would be subject to pause preemption. Under both the bill and offer, such preemption would apply only to new state requirements and only to conditions of use identified as subject to review in the safety assessment.

In addition, under the Senate bill, such preemption could not last for more than four years (the timing is less clear in the Senate offer due to cross-reference issues, but the intent appears to be the same).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 06, 2016 8:46 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA request on PCBs and partial REs

Senate 18 says old preemption applies to chemical substances that have already been regulated under section 6 UNLESS EPA puts them through prioritization. What you're telling me below is that PCBS will never be subjected to pause preemption. Can you confirm?

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

From: Kaiser, Sven-Erik
Sent: Wednesday, April 6, 2016 7:49 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on PCBs and partial REs

Michal,
This TA responds to the request on PCBs and partial REs. Please let me know if any questions. Thanks,
Sven

> We agree that section 6(e) provides sufficient authority for EPA to revise existing PCB regulations without going through the new process.

With respect to other chemicals, we are not sure there is a clear answer. We believe EPA has the authority to make relatively minor updates or adjustments to existing section 6(a) rules without going through the new section 6 processes, based on the implied authority to amend rules already promulgated. That said, we are doubtful EPA could, as you suggest, add new hazards, uses or restrictions (at least significant ones) without going through the new process. The dividing line might be whether EPA is updating or making corrections or other minor adjustments to an existing rule on one hand, or expanding the scope of an existing rule on the other. That said, we have not done legal research on this and do not know the answer definitively.

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 6, 2016 at 5:28:49 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Another question in the partial RE space

Sven

I'm not sure if this is addressable no matter your response, but wanted your team's take (after section 4 and 14).

You've regulated a number of things under section 6. Other than PCBS which has its own subsection, is it your read that if you wanted to revise regulations for any of those chemicals, you'd need to designate them a high priority and go through a new RE? Or do you read the bill and EPA's general authority as being sufficient to allow you to amend existing regulations to add new hazards, uses, restrictions, etc? Do you also agree that the PCB subsection should provide you with sufficient authority to revise the PCB regs without going through the new process?

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: 4/10/2016 4:28:09 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Re: Chem ID idea

Michal,
Thanks for the additional info. Checking,
Sven

On Apr 10, 2016, at 12:26 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks.

I find this entire section confusingly drafted so I'm not entirely surprised that you found what I did to it to be confusing too! ☺

House bill protects molecular structure in H&S studies. This has been flagged for us as a MAJOR red line for them. I'm trying to come up with something that could help bridge the divide.

What I meant to do was say:
Protect chemID in H&S studies unless

1) <!--[if !supportLists]--><!--[endif]-->EPA makes a UR determination under section 6
2) <!--[if !supportLists]--><!--[endif]-->EPA makes a significant widespread determination under section 7

AND
chemID that is protected In H&S studies should be substantiated every 5 years instead of every 10
AND
Allow EPA, in limited circumstances, to review such claims at other times if the Administrator determines that disclosure of information described in subsection (b)(1)(A)(ii) that is protected from disclosure would assist with the identification or remediation of an environmental hazard or exposure, or the diagnosis or treatment of an adverse health effect, that might be caused by the chemical substance.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
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Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 11:33 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Re: Chem ID idea

Michal,
This responds to the TA request on Chem ID.

We have reviewed only the new b1Aii and e1Aii. We did not see other new language re chem id, but please let us know if we missed something.

The language you suggest is confusing for several reasons. The new b1Aii does not work grammatically (it provides that (a) does not protect "any health and safety study which is submitted under this Act with respect to. . . subject to subsection (e)(1)(A)(ii), formulas (including molecular structures)," We assume you do not mean to refer to H&S studies about formulas, but rather formulas contained in HS studies.

More fundamentally, the drafting seems to conflate two very different issues: 1. To what extent is chem id protectable if in an HS study (currently, under TSCA, if it contains process info or discloses proportions of a mixture, which in EPA's view it relatively rarely does); 2. and to what extent is chem id protectable in other contexts (currently, under TSCA, if it meets the general CBI standard -- which it often does). Your suggested drafting would probably be best read as saying that chem id in an HS study is protectable so long as it meets the standard in e1Aii (ie, a considerable increase in the protectability of chem ids in HS studies). Is that your intention?

If you can give more guidance about what you are trying to accomplish, we can provide more specific drafting suggestions.

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: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 9:56:07 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: Chem ID idea

Sven

Pls have your team review the added text as per our earlier discussion for workability, omissions, clarifications, other ideas, etc. Sometime tomorrow would be good.

Thanks
Michal

<14-04-09-16with CBI.docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 12:13:44 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Sen. Markey TSCA TA request - House fees

Michal- got it. Thanks,
Sven

On Mar 11, 2016, at 5:05 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Quick follow up question for you Sven

Would changing "defray the cost of administering the provision for which suhc fee is collected" to

"Defray the cost of administering the provision and any other activities under the act related to the chemical substance or mixture for which such fee is collected" address one of the points you make below?

Would this change above allow you to protect or decide to release CBI that was included in a risk evaluation or test data, for example? Would it allow you to use the results of the test when conducting the risk evaluation or doing risk management?

I recognize that the solution above probably does not address the core resubstantiation obligations provided in the senate bill in section 8. But could it address the question of industry-requested RES and whether the fees for the RE could then be used for rulemaking?

Quick turnaround needed - mtg on this is at 1:30. Feel free to suggest alternatives if what I wrote makes no sense. :-)

Thx
M

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

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 5:45 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - House fees

Michal,
This responds to your TA request on House fees language and section 4.

Under either the House bill or the House offer, section 26(b)(1) provides that fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected." In general, it will be difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with

recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.

Constraining the use of fees in this manner will likely lead to other sorts of implementation problems. For example, it appears that fees collected for data submitted under section 4 could only be used to cover the cost of collecting the information, not of using the information to perform risk evaluations. This is because the fee collection authority would be categorized under section 4, yet the use of the information in a risk evaluation would be under section 6(b). Furthermore, because CBI review obligations are undertaken under section 14, EPA could not use these fees to defray the cost of reviewing and otherwise processing CBI claims. Finally, a manufacturer's decision to request a risk evaluation may eventually result in EPA being subject to a legal obligation to undertake risk management rulemaking, but EPA could not use industry fees to defray the cost of that rulemaking.

The House offer partially addresses these implementation concerns regarding funding by adding fee collection authority for EPA initiated risk evaluations (the House bill only provides for fees to defray risk evaluation when industry requests the risk evaluation). However, the House offer still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims. This is especially problematic in combination with the House offer's introduction of a new and very resource intensive program for the review of older CBI claims.

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, March 10, 2016 3:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - House fees

Sven

House fees language basically says that a fee collected under section 4 can only be used for section 4 activities, and so forth. Does EPA have any workability or other concern associated with this provision?

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: 4/23/2016 6:59:37 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Sen. Markey TSCA TA on House "Draft in progress" section 5 (4-23)

Michal - We can divide up sections if needed to speed things up. Priorities helpful. Thanks,
Sven

On Apr 23, 2016, at 2:49 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

in case it is useful I'm attaching the page/line edits that were sent to HLC on the last version of 14. If you have the ability to have your team work on more than one section at once, and would like some prioritization, let us know.

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: Saturday, April 23, 2016 2:43 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA on House "Draft in progress" section 5 (4-23)

Michal,
The attached TA responds to the request for big picture review of House section 5 (4-23). Please let me know next steps on 5; we are also reviewing section 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 additional questions. Thanks,

Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460

202-566-2753

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Saturday, April 23, 2016 12:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Fw: Draft in progress

Sven

See attached.

Please start your review with section 5, which we believe may have been rewritten again. Specifically, we'd like you to pull together your "big picture" comments on section 5 in the way you did the last time. We can decide from there whether it makes sense for you to focus on more granular review of 5 or not.

From there, pls go next to specific edits on 14. When I get in I can send you the line edits on the last HLC 14 that were sent to the House if you feel they would help your review - let me know.

Once we have a chance to look at this we may have different direction, but for now, we think that order makes the most sense.

thanks

M

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

From: McCarthy, David <David.McCarthy@mail.house.gov>

Sent: Saturday, April 23, 2016 12:37 PM

To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)

Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick; Fruci, Jean

Subject: Draft in progress

Attached is the most current draft. We have not yet finished reading it and have not begun discussing it on our side, as several of us are not available to work on it this weekend. Also, it still has some bracketed words and a few questions about provision interactions. Language to amend section 18 is, as the draft says, "to be determined."

<Section 14 (HLC 4-20).docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/1/2016 10:54:26 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal – got it. Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 01, 2016 4:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 6 - quick unreasonable risk q

Here is a construct being discussed:

1) epa promulgates a rule for how risk evaluations are supposed to be conducted - study a chemical to decide whether it poses an unreasonable risk, and don't consider costs/non-risk factors - the unreasonable risk "fix" is made in the rule itself.

2) later in the section, we tell people to conduct a risk evaluation in accordance with the rule above, in order to figure out whether the substance poses an unreasonable risk, but I do NOT remove cost consideration in this place because of the reference to the RULE, which does require the fix.

Any concerns with this description re "unreasonable risk"?

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: 3/15/2016 8:35:14 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA Request - CBI - 14(c)(4) and 14(d)(1)(D)

Michal – this TA responds to your request on CBI – sections 14(c)(4) and 14(d)(1)(D). 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

Are senate 14(c)(B)(4)
Or 14(d)(1)(D)
Needed? Redundant? In conflict with other parts of the section?

Response:
14(c)(4): EPA does not believe this provision is redundant. It is a provision of current TSCA section 14(b)(2)) that we think helps bolster the argument that health and safety information (and a broader class of information under S 697) that is releasable under TSCA also cannot be protected under other authority in the event of a FOIA request.

14(d)(1)(D):The requirement in 14(a) (also referenced in 14(b)) that the information be exempt under FOIA Exemption 4, already includes an implied requirement that the information not already be publicly available.

However, the way 14(d)(1)(D) is worded, that "no person may assert a claim", suggests that EPA could treat such information as not subject to a confidentiality claim at all. It would make it easier to deny a claim, but EPA would need to have procedures in place to ensure that the information is not simply disclosed without at the very least an internal verification that it is subject to 14(d)(1)(D).

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 11:28 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: More senate 14 qs

Are senate 14(c)(B)(4)
Or 14(d)(1)(D)
Needed? Redundant? In conflict with other parts of the section?
Thx

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: 4/15/2016 1:48:55 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request - Quick on section 4

Got it - checking

On Apr 14, 2016, at 9:40 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

What about the addition of "hazard and exposure"?

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, April 14, 2016 5:00 PM
To: Freedhoff, Michal (Markey)
Subject: FW: Sen. Markey TSCA TA Request - Quick on section 4

Michal,
This TA responds to the request on section 4 adding "federal."

This seems to do what it tries to – limit the requests for developing new information in 4(b)(1)(A)(iv) to requests from federal authorities, whereas they could presumably come from states implementing under a federal law under the language without the insertion of "federal."

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: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 14, 2016 10:53 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick on section 4

This may be too late as I think it was signed off on (by others) but this is a proposed change to section 4. Highlights and brackets note the added text.

this?

‘‘(iv) at the request of the federal implementing authority under another Federal law, to meet the regulatory (hazard and exposure) testing needs of that authority;

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: 4/21/2016 12:27:44 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: Re: Sen Markey TSCA TA- Version control questions

Great- thanks

On Apr 20, 2016, at 8:27 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

See caps below

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

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

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 20, 2016 8:21 PM
To: Freedhoff, Michal (Markey)
Subject: Sen Markey TSCA TA- Version control questions

Michal,
Thanks for sending over the documents for TA review. Some questions have come up to make sure we've got the right info.

- In the notes from the House, there's a reference to additional Senate language:

> " In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable""

ODDLY, AND I AM COPYING DIMITRI ON THIS FOR FUN, THE LANGUAGE THAT IS BEING REFERRED TO IS IN THE 4/20 VERSION OF SECTION 6 BUT WAS SENT TO THE HOUSE AS A SENATE DEMOCRATIC PROPOSAL, ALONG WITH MOST OF THE REST OF THE SIGNIFICANT CHANGES THAT ARE IN THE 4/20 VERSION. IT IS THE COST-EFFECTIVE LANGUAGE WE WORKED ON WITH YOU.

Do we have already or can you provide the new language attributed to you and Dimitri. We think it's key to the analysis.

- Also can we get confirmation of what version these are changes to--they have an april 12 date for section 6, but don't specify for the others. YOU'RE RIGHT. THEY DON'T. BUT WITH THE EXCEPTION OF ANIMAL TESTING AND NOMENCLATURE, THESE ARE CONCEPTS AND NOT DRAFTED.

Are the others the HLC versions we just got the other day or the SLC versions that went over? The section 6 one is the April 12 one which obviously can't be the HLC one we just got. I ALSO SENT YOU A 4/20 SECTION 6 IN A SEPARATE EMAIL. THAT IS THE CURRENT VERSION OF SECTION 6 EVEN THOUGH THE COVER EMAIL REFERRED MOSTLY TO THE 4/12 SECTION 6.

- last, on section 8 the House says either the long or short version the Senate sent the House is OK. It also refers to two savings clauses that were drafted earlier that the Senate has. this looks like an agreement to either Senate version, but for the reference to the two savings clauses, we would benefit from the language they are talking about to be sure we are looking at the right stuff. I DON'T KNOW WHAT VERSION THEY MEAN – THE SENATE DEMOCRATIC PROPOSAL INCLUDED THE VERSION YOU AND I WORKED ON TOGETHER, IE THE ONE THAT YOU SAID DOES NOT REQUIRE A SAVINGS CLAUSE. I IMAGINE THE LONGER VERSION WAS THE ONE THAT WAS IN PLAY RIGHT BEFORE THOSE CHANGES WERE MADE, BUT I DON'T KNOW. PROBABLY BEST FOR YOU TO EVALUATE THE TEXT THAT WAS ATTACHED AS THOUGH IT IS THE "LONGER" VERSION AND TELL US WHAT YOU THINK.

Thanks again,
Sven

On Apr 20, 2016, at 6:33 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Pls review. Section 6 coming soon.

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

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.
"(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent

necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:
Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

"(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.";

<animal_02_xml.pdf>
<nomenclature with savings.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/22/2016 2:07:42 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA -another 6(a) alternative

I'm stuck in a meeting so haven't heard message yet.

On Mar 22, 2016, at 10:05 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Left you a vm on this – want to give me a quick call?

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
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 22, 2016 10:04 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA -another 6(a) alternative

Michal, Got it.

Also for the 10:30 call, how do you want things to proceed. Thanks,
Sven

On Mar 22, 2016, at 9:56 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

And here are a couple more alternatives. There appears to be an interest in explicit references to cost and I don't really care as long as it is clear that when you're calculating risk, you don't use them and when you are writing rules, you do.

OPTION 2

(a) <!--[if !supportLists]--><!--[endif]--><image001.png> <image002.png> <image001.png> <image003.png> <image004.png> <image005.png> <image001.png>SCOPE OF REGULATION.—If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18, apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome~~ requirements so that the chemical substance, taking into consideration costs and other non-risk factors in accordance with subsection (c)(2), does not present such unreasonable risk under the conditions of use.

Or

OPTION 2

(b) <!--[if !supportLists]--><!--[endif]--><image001.png> <image002.png> <image001.png> <image003.png> <image004.png> <image005.png> <image001.png>SCOPE OF REGULATION.—If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18, apply one or more of the following requirements to such substance or mixture to the extent necessary, taking into consideration costs and other non-risk factors in accordance with subsection (c)(2), ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance, does not present such unreasonable risk under the conditions of use.:

OPTION 2

(c) <!--[if !supportLists]--><!--[endif]--><image001.png> <image002.png> <image001.png> <image003.png> <image004.png> <image005.png> <image001.png>SCOPE OF REGULATION.—If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, taking into consideration costs and other non-risk factors in accordance with subsection (c)(2), and subject to section 18, apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such unreasonable risk under the conditions of use.:

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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Connect with Senator Markey
<image006.png><image007.png><image013.png><image014.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, March 21, 2016 12:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA -another 6(a) alternative

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, March 21, 2016 12:17 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: another 6(a) alternative

OPTION 2

(a) <image001.png> <image002.png> <image001.png> <image003.png> <image004.png> <image005.png> <image001.png>SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

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
<image006.png><image007.png><image013.png><image014.jpg>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/30/2016 2:00:59 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: Sen. Markey Inquiry on TSCA section 6 rules

Michal, this responds to your inquiry on the timing of section 6 rules.

We're looking at August for the first TCE rule on aerosol degreasing and dry cleaning. October for the paint removers (methylene chloride and NMP) and second TCE rule on vapor degreasing.

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 30, 2016 at 4:55:11 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on partial risk evaluations

What is the timeframe for proposed rules on TCE, MC and NMP?

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

From: Kaiser, Sven-Erik
Sent: Friday, March 25, 2016 8:51 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA on partial risk evaluations

Michal- The 5 referenced partial risk evaluations were TCE, NMP, MC, ATO and HHCB. EPA found no concern for ATO (Antimony Trioxide) and HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[γ]-2-benzopyran). 1-BP is a draft risk assessment, and was not included in the count. See EPA's website on TSCA Work Plan Assessments:

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.

Please let me know if any additional questions. Thanks,

Sven

On Mar 25, 2016, at 7:51 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sorry, one last thing on this - you originally listed these chemicals as the subjects of these RES. But I thought in other TA you said there were 5. What is the 5th?

TCE, NMP, MC, and 1-BP.

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

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 6:48 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,
The attached TA responds to the request on partial risk evaluations. 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)" <Michal_Freedhoff@markey.senate.gov>
Date: March 22, 2016 at 10:02:12 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on partial risk evaluations

Would this do it for you? I don't think a discussion about what you add below re cost considerations would be a constructive one. I am not sure that this works to address your concern re rules/deadlines though.

(3) (A) PRIOR-INITIATED EVALUATIONS[A1] .—

(i) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation or partial risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under this Act[A2] .

(ii) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As relevant policies and procedures under this Act are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing risk evaluations.

(B) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation or partial risk evaluation, determination or rule solely because the action was completed prior to the completion of a policy or procedure established under this Act.

Michal Ilana Freedhoff, Ph.D.
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Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image002.png><image003.png><image004.png><image005.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, March 21, 2016 6:25 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,
This TA responds to your request on partial risk evaluations. Please let me know if any questions. Thanks,
Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Response: EPA has completed risk assessments for 5 chemicals under the TSCA Workplan process. Those assessments only consider risk. There is no cost consideration. 3 of the

chemicals have high risk and are moving to the risk management phase. We are developing proposed rules. As required by TSCA we will balance costs and benefits (the value of risk reduction) and identify the least burdensome means to reduce the risk. We are scheduled to propose rules for these three chemicals later this year.

The risk assessments for all three of these chemicals had narrow scopes. We did not look at all uses of the chemicals as would be required under both House and Senate passed bills. We assume that if a bill passes before we finalize these rules we would need to finalize them using the new rulemaking standard in the law. But because the risk assessments were done without consideration of costs, we would not need to redo the work for the uses which have already been assessed.

The issue we are flagging is that meeting the scoping intent of either bill would require a significant amount of additional work on these three chemicals to assess the uses that were not included in our final assessments. That could delay regulation of the uses with known risks. Modification of the cost considerations would take a little time but much less as the cost considerations under the current law are more onerous than either the House or Senate bills. If the Senate or House bill passed as drafted we would likely call these three chemicals high priority and make an argument that we can go forward with the narrower scoped regulations using the new standard. There is some legal vulnerability that we'd be prevented from doing so. Because the rulemaking deadlines in 6(c)(1) begin to run once EPA deems a chemical unsafe, EPA would be on a tighter time clock (4 years, as opposed to 3 years + 4 years) to both complete the risk evaluations AND any associated rulemakings with respect to other uses not part of the original evaluation. It is not clear to us whether those additional uses have risk. In the alternative, we could identify these three chemicals as high priority and then assess the additional uses before moving to risk management. The down side is that we would know there was risk for certain uses of these chemicals but we would be waiting to assess the remaining uses before doing any risk management.

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, March 20, 2016 11:16 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Questions on partial risk evaluations

Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Thanks - just trying to figure out what to do with this and how to draft it etc. Not a weekend thing for you guys!

M

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

EPA TA – needs clarifying to ensure section 6 activities can proceed as intended
EPA TA here and below

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2016 2:14:22 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: RE: HEC Min TSCA TA Request on Nomenclature

Yep – that's what I thought – Thanks for confirming. Best,
Sven

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

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Wednesday, April 27, 2016 10:13 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC Min TSCA TA Request on Nomenclature

Both, thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 27, 2016 9:53 AM
To: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: RE: HEC Min TSCA TA Request on Nomenclature

Jacqueline – thanks for getting back to me. Sorry to be a pain, I'm checking to make sure we've got it right. Do you still want our TA on the House nomenclature provisions, or just the section 5 provisions? Please let me know if any questions. Best,
Sven

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

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Wednesday, April 27, 2016 8:27 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: HEC Min TSCA TA Request on Nomenclature

Yes, we would still like your assistence on the other provisions, thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 26, 2016 06:16 PM Eastern Standard Time
To: Cohen, Jacqueline
Subject: HEC Min TSCA TA Request on Nomenclature

Jacqueline,
Thanks for meeting with us today to go over the section 5 and 8 issues. Following up on the nomenclature discussion, we want to share that it appears to us that the Senate counter offer drops 8(b)(3)(B)(i) entirely (the provision requiring EPA to maintain chemical nomenclature conventions), and modifies substantially 8(b)(3)(B)(ii) so that it merely gives EPA discretionary authority to recognize multiple listings as a single chemical if a manufacturer or processor demonstrates that a chemical substance appears multiple times on the inventory (something EPA has authority to do anyway). In light of that, do you still want us to draft language to address the issues we identified in 8(b)(3)(B)(i), and also do you still want us to draft language addressing the issues with the savings clause for 8(b)(3)(B)(ii). We think that the concerns raised by these provisions are addressed by the dropping of the one and the significant modification of the other. We're also drafting the language we discussed on the statutory mixtures savings clause.

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: 12/30/2016 5:53:43 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TA request on TSCA section 5

Michal – thanks for the request on TSCA section 5. I'll get it to folks for technical assistance. Please let me know if any additional questions and best wishes on the new year,
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, December 22, 2016 5:06 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - section 5

Svem

I'm drafting a submittal to EPA's new chemicals docket and wanted to share this with you. No specific request other than please review for any inaccuracies/inconsistencies – feedback welcome. Early January is fine, in case your team is all off now, but I note that January is going to be busy up here, and I haven't shared this with my colleagues yet.

Thanks and happy holidays

Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 3:33:19 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Thanks

On Apr 10, 2016, at 11:32 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

The version you commented on yesterday. If we move the guidance in 6 on industry RES into 26, does that solve the problem and are you ok w the language in the prior initiated RE section if that move is made

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 11:29 AM
To: Freedhoff, Michal (Markey)
Subject: Fwd: Sen. Markey TSCA TA follow up on section 6/26

Michal - we have a version on this. See Brian's question below. Thanks,
Sven

From: "Grant, Brian" <Grant.Brian@epa.gov>
Date: April 10, 2016 at 11:21:15 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Hey Sven. I don't know what version of the House language she is referring to, with an HLC formulation. Can you please forward to me if you know or ask Michal to forward the version she would like us to look at? thx.
From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 10, 2016 at 9:29:57 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

And then I guess associated question is if you're ok w the language in House 26 in this section and the way HLC wrote what used to say "this section"

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 9:28 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Michal- got it- checking. Thanks,
Sven

On Apr 10, 2016, at 9:28 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

If we move the section 6 guidance for how manufacturers do their own RES to EPA into section 26, have we solved the problem?

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 9:24 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA follow up on section 6/26

Michal,
This TA responds to the request on section 6 and 26.

We'd need to see the full current draft of Section 6 and 26 to give definitive TA, but it seems that (3) is unproblematic. It is not referring to any procedures that EPA needs to develop. Similarly, (4) is unproblematic, assuming that neither (1) nor (2) is referring to policies, procedures, or guidance that EPA needs to develop.

If the language in section 26 is only preserving EPA's ability to proceed in advance of any policies/procedures/guidance developed pursuant to section 26, then the retention of a direction to develop a guidance document pursuant to section 6 (i.e., regarding how outside parties should develop draft risk assessments) is potentially problematic. By specifically not mentioning this guidance document generation obligation, Section 26 could be the basis of an argument that Congress believed that a failure to timely prepare this specific type of guidance document might indeed be grounds to defer work on safety evaluations.

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: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 7:06:01 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: follow up on section 6/26

This is the only guidance/policies/practices language that is left in section 6. Is your section 26 Act vs section concern resolved knowing this
GUIDANCE.—
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 develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator, The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

(3) PROCEDURES.—When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) promulgate a final rule based on the matter in the rulemaking record and (D) make and publish with the rule the determination described in subsection (a).

4) APPLICATION.—Paragraphs (1), (2) and (3) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/10/2016 11:26:18 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request - House fees

Michal,
Thanks for the heads up – I'll share with the team so we can get ready. 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, March 10, 2016 6:25 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request - House fees

Thank you. tomorrow we are working thru sections 14 and 26 and perhaps others. There are also plans to work through the weekend which will bring in sections 5, 6, 18, etc. we'll need you guys to be reachable, and I'm trying to figure out whether there is a preferred means by which we should be able to get to you. will keep you posted.

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, March 10, 2016 6:22 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: RE: Sen. Markey TSCA TA request - House fees

Michal, Jonathan and Adrian,
We're working on the other requests and expect to have as much as possible for you tomorrow. Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 10, 2016 6:19 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: Sen. Markey TSCA TA request - House fees

Thanks very much.

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, March 10, 2016 5:45 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - House fees

Michal,
This responds to your TA request on House fees language and section 4.

Under either the House bill or the House offer, section 26(b)(1) provides that fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected." In general, it will be difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.

Constraining the use of fees in this manner will likely lead to other sorts of implementation problems. For example, it appears that fees collected for data submitted under section 4 could only be used to cover the cost of collecting the information, not of using the information to perform risk evaluations. This is because the fee collection authority would be categorized under section 4, yet the use of the information in a risk evaluation would be under section 6(b). Furthermore, because CBI review obligations are undertaken under section 14, EPA could not use these fees to defray the cost of reviewing and otherwise processing CBI claims. Finally, a manufacturer's decision to request a risk evaluation may eventually result in EPA being subject to a legal obligation to undertake risk management rulemaking, but EPA could not use industry fees to defray the cost of that rulemaking.

The House offer partially addresses these implementation concerns regarding funding by adding fee collection authority for EPA initiated risk evaluations (the House bill only provides for fees to defray risk evaluation when industry requests the risk evaluation). However, the House offer still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims. This is especially problematic in combination with the House offer's introduction of a new and very resource intensive program for the review of older CBI claims.

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, March 10, 2016 3:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - House fees

Sven

House fees language basically says that a fee collected under section 4 can only be used for section 4 activities, and so forth. Does EPA have any workability or other concern associated with this provision?

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: 4/23/2016 6:54:36 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on House "Draft in progress" section 5 (4-23)

Michal, heads up for you that we were able to turn around House section 5 TA quickly because House Ds asked for TA on this document that we sent over at around 6:30 pm last night. There were only minor differences between the 4-22 and 4-23 versions. Please let me know if any questions. Thanks,
Sven

On Apr 23, 2016, at 2:47 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thank you

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: Saturday, April 23, 2016 2:43 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA on House "Draft in progress" section 5 (4-23)

Michal,
The attached TA responds to the request for big picture review of House section 5 (4-23). Please let me know next steps on 5; we are also reviewing section 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 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

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Saturday, April 23, 2016 12:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Fw: Draft in progress

Sven

See attached.

Please start your review with section 5, which we believe may have been rewritten again. Specifically, we'd like you to pull together your "big picture" comments on section 5 in the way you did the last time. We can decide from there whether it makes sense for you to focus on more granular review of 5 or not.

From there, pls go next to specific edits on 14. When I get in I can send you the line edits on the last HLC 14 that were sent to the House if you feel they would help your review - let me know.

Once we have a chance to look at this we may have different direction, but for now, we think that order makes the most sense.

thanks

M

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

From: McCarthy, David <David.McCarthy@mail.house.gov>

Sent: Saturday, April 23, 2016 12:37 PM

To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)

Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick; Fruci, Jean

Subject: Draft in progress

Attached is the most current draft. We have not yet finished reading it and have not begun discussing it on our side, as several of us are not available to work on it this weekend. Also, it still has some bracketed words and a few questions about provision interactions. Language to amend section 18 is, as the draft says, "to be determined."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 12:21:20 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen Markey TSCA TA- Version control questions

Michal,
Thanks for sending over the documents for TA review. Some questions have come up to make sure we've got the right info.

- In the notes from the House, there's a reference to additional Senate language:

> " In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable""

Do we have already or can you provide the new language attributed to you and Dimitri. We think it's key to the analysis.

- Also can we get confirmation of what version these are changes to--they have an april 12 date for section 6, but don't specify for the others. Are the others the HLC versions we just got the other day or the SLC versions that went over? The section 6 one is the April 12 one which obviously can't be the HLC one we just got.

- last, on section 8 the House says either the long or short version the Senate sent the House is OK. It also refers to two savings clauses that were drafted earlier that the Senate has. this looks like an agreement to either Senate version, but for the reference to the two savings clauses, we would benefit from the language they are talking about to be sure we are looking at the right stuff.

Thanks again,
Sven

On Apr 20, 2016, at 6:33 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Pls review. Section 6 coming soon.

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

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.

''(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:

Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

''(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.'';

<animal_02_xml.pdf>
<nomenclature with savings.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 7:04:43 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: FW: 04-12-16PBT (Conf Proposal)d.docx
Attachments: 04-12-16PBT (Conf Proposal)d.docx

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: Tuesday, April 12, 2016 3:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: 04-12-16PBT (Conf Proposal)d.docx

See if this works on pbts

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/30/2016 1:42:54 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: RE: Sen. Markey TSCA TA - slightly new Senate 14(c) construct

Sure – 10:15 okay – I lose people at 11. Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 30, 2016 9:42 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: Sen. Markey TSCA TA - slightly new Senate 14(c) construct

Can we push to 10:15? Couple folks are running late.

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: Wednesday, March 30, 2016 7:53 AM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Re: Sen. Markey TSCA TA - slightly new Senate 14(c) construct

We can do 10am. Please call 866-299-3188, code 202-566-2753#. Thanks,
Sven

On Mar 29, 2016, at 7:26 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Also – we may want to try to do a call on this w our usual group tomorrow sometime btw 10-12. Any times in here work better than others?

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
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 29, 2016 3:04 PM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA - slightly new Senate 14(c) construct

Michal - Got it, thanks. Please let me know if a call needed. Best,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 29, 2016 2:56 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA - slightly new Senate 14(c) construct

Sven

Could you please look at the following text? Basically, we are looking to address a House issue with the Senate 14 offer by going back to something that looks more like what the Senate reported out of EPW. We are particularly interested in EPA's take on whether there is conflict between the highlighted text portions. My own read of how this works is

- Health and safety studies get disclosed. No protecting them from disclosure until someone files a FOIA or makes another type of request. They go out.
- However, certain types of chem ID info (what currently gets statutory protection under TSCA) can be redacted from these studies.

PLs add your views, suggestions, etc as appropriate.

Thanks

michal

(c) Information Not Protected From Disclosure.—
(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:
(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
(i) IN GENERAL.—Subject to clause (ii), subsection (a) does not prohibit the disclosure of—

(I) any health and safety study that is submitted under this Act with respect to—

(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

(bb) any chemical substance or mixture for which—

(AA) testing is required under section 4; or (BB) a notification is required under section

5; or

(I) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

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: 10/24/2016 5:30:26 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Bogdanoff, Alec (Markey) [Alec_Bogdanoff@markey.senate.gov]
Subject: Sen. Markey PCB Bill TA
Attachments: Markey.PCB TA.10.24.16.docx

Michal,
The attached technical assistance responds to the request to review the draft bill on PCBs.

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.

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: Thursday, September 15, 2016 2:38 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: first bill

Sven

This is a document that is sort of a combined MASK Act as drafted as an amendment to title II of TSCA (it excludes the portions of MASK that are not TSCA amdts) with additional redlined text that adds in PCBs to some of the obligations in Title II. We tried to use your earlier TA to avoid giving EPA direction in Title II that it already provides for PCBs in Title I, but there may well be inconsistencies or redundancies that we have not already identified. We'd welcome any and all input.

Thanks
michal

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

NOTE: Section 2 of MASK is an amendment to Title I of TSCA and isn't in this document. Also not included in here is language in MASK that amends Title III or is not an amendment to TSCA. Those parts of MASK would not be expected to change as a result of adding PCB requirements. Additionally, there are some places below where we have NOT added PCBs – generally this is intentional, and stems from either OSHA already governing the PCB-related activity in question or TSCA Title I addressing it differently. You'll also see some places where we are still waiting for EPA feedback.

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TITLE II—ASBESTOS AND POLYCHLORINATED BIPHENYLS HAZARD EMERGENCY RESPONSE [1]

SEC. 201. CONGRESSIONAL FINDINGS AND PURPOSE.

(a) FINDINGS.—The Congress finds the following:

(1) The Environmental Protection Agency's rule on local educational agency inspection for, and notification of, the presence of friable asbestos-containing material in school buildings includes neither standards for the proper identification of asbestos-containing material and appropriate response actions with respect to friable asbestos-containing material, nor a requirement that response actions with respect to friable asbestos-containing material be carried out in a safe and complete manner once actions are found to be necessary. As a result of the lack of regulatory guidance from the Environmental Pro-

[1] Title II of the Toxic Substances Control Act was added by the Asbestos Hazard Emergency Response Act of 1986 (Public Law 99–519; Oct. 22, 1986; 100 Stat. 2970

Commented [A1]: EPA: We have a few overarching comments:

- Our understanding is that this bill is intended to supplement the PCB ban in TSCA 6(e). Specifically we understand that it intended to require inspections/testing for the presence of PCBs in building materials in schools, and if PCBs above 50 ppm are discovered, that removal of those materials will be required in accordance with TSCA 6(e). (TSCA 6(e) and EPA implementing regulations prohibit the use of PCBs in building materials at levels greater than or equal to 50 ppm, including the continued use of such materials that are already in place. PCB-containing materials for which use has ceased must be removed and disposed of in accordance with 40 CFR part 761.) We recommend stating, perhaps in Sec. 201 or Sec. 209(a), that this bill supplements TSCA Title I and does not supersede or override the PCB ban in TSCA 6(e).
- We understand that the intent may also to be to require EPA to consider whether PCBs building materials at <50 ppm should be removed, and to do so based on the standard contained in Title II, not the unreasonable risk standard in section 6(e).. We do not see that bill currently creates such an obligation. In general, the bill references "Polychlorinated biphenyl-containing material", which is defined as having a 50 ppm cut-off.
- There are numerous places in the bill that are keyed to the date of enactment. That date has long passed. If the intent is to create new deadlines for PCBs (but not for asbestos), that would need to be clarified

Commented [A2]: EPA: There are no findings about PCBs even though PCBs are added to the legislation

tection Agency, some schools have not undertaken response action while many others have undertaken expensive projects without knowing if their action is necessary, adequate, or safe. Thus, the danger of exposure to asbestos continues to exist in schools, and some exposure actually may have increased due to the lack of Federal standards and improper response action.

(2) There is no uniform program for accrediting persons involved in asbestos identification and abatement, nor are local educational agencies required to use accredited contractors for asbestos work.

(3) The guidance provided by the Environmental Protection Agency in its "Guidance for Controlling Asbestos-Containing Material in Buildings" is insufficient in detail to ensure adequate responses. Such guidance is intended to be used only until the regulations required by this title become effective.

(4) Because there are no Federal standards whatsoever regulating daily exposure to asbestos in other public and commercial buildings, persons in addition to those comprising the Nation's school population may be exposed daily to asbestos.

(b) PURPOSE.—The purpose of this title is—

(1) to provide for the establishment of Federal regulations which require inspection for asbestos-containing material and polychlorinated biphenyl- containing material and implementation of appropriate response actions with respect to asbestos-containing material and polychlorinated biphenyl-containing material in the Nation's schools in a safe and complete manner;

(2) to mandate safe and complete periodic reinspection of school buildings following response actions, where appropriate; and

(3) to require the Administrator to conduct a study to find out the extent of the danger to human health posed by asbestos and polychlorinated biphenyls in public and commercial buildings and the means to re-spond to any such danger.

[15 U.S.C. 2641]

SEC. 202. DEFINITIONS.

For purposes of this title—

(1) ACCREDITED ASBESTOS CONTRACTOR.—The term "accredited asbestos contractor" means a person accredited pursuant to the provisions of section 206.

(2) ADMINISTRATOR.—The term "Administrator" means the Administrator of the Environmental Protection Agency.

(3) ASBESTOS.—The term "asbestos" means asbestiform varieties of—

(A) chrysotile (serpentine),
(B) crocidolite (riebeckite),
(C) amosite (cummingtonite-grunerite),
(D) anthophyllite,
(E) tremolite, or
(F) actinolite.

(4) ASBESTOS-CONTAINING MATERIAL.—The term "asbestos-containing material" means any material which contains more than 1 percent asbestos by weight.

(5) POLYCHLORINATED BIPHENYL-CONTAINING MATERIAL.—The term "polychlorinated biphenyl-containing material" means electrical equipment filled with liquid PCBs at concentrations of 50 parts per million or greater, manufactured building materials containing non-liquid PCBs at concentrations of 50 parts per million or greater, or any material that has been contaminated by a spill or release of PCBs from a source that contained PCBs in concentrations

Commented [A3]: EPA: In certain places throughout, only PCBs are mentioned rather than PCB containing material. Check for accuracy and consistency. An approach could be to presumptively use PCBs wherever it previous referred to asbestos, and PCB-containing material wherever it previously referred to asbestos-containing material.

Commented [A4]: EPA: As written, this definition could potentially capture pre-1978 spills that by regulation are presumed not to present unreasonable risk. Is this the intent?

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.

of 50 parts per million or greater.

(65) EPA GUIDANCE DOCUMENT.—The term ''Guidance for Controlling Asbestos-Containing Material in Buildings'' means

the Environmental Protection Agency document with such title as in effect on March 31, 1986.

(76) FRIABLE ASBESTOS-CONTAINING MATERIAL.—The term ''friable asbestos-containing material'' means any asbestos-containing material applied on ceilings, walls, structural members, piping, duct work, or any other part of a building which when dry may be crumbled, pulverized, or reduced to powder by hand pressure. The term includes non-friable asbestos-containing material after such previously non-friable material becomes damaged to the extent that when dry it may be crumbled, pulverized, or reduced to powder by hand pressure.

(87) LOCAL EDUCATIONAL AGENCY.—The term ''local educational agency'' means—

(A) any local educational agency as defined in section 9101 of the Elementary and Secondary Education Act of 1965;, [1]

(B) the owner of any private, nonprofit elementary or secondary school building;, and

(C) the governing authority of any school operated under the defense dependents' educational system provided for under the Defense Dependents' Education Act of 1978 (20 U.S.C. 921 et seq.).

(89) MOST CURRENT GUIDANCE DOCUMENT.—The term ''most current guidance document'' means the Environmental Protection Agency's ''Guidance for Controlling Asbestos-Containing Material in Buildings'' as modified by the Environmental Protection Agency after March 31, 1986 or the guidance documents found on the Environmental Protection Agency's polychlorinated-biphenyls.''Policy and Guidance for PCBs'' and ''PCBs in Building Materials'' internet websites (or successor materials).

(910) NON-PROFIT ELEMENTARY OR SECONDARY SCHOOL.—The term ''non-profit elementary or secondary school'' means any elementary or secondary school (as defined in section 9101 of the Elementary and Secondary Education Act of 1965) owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(1011) PUBLIC AND COMMERCIAL BUILDING.—The term ''public and commercial building'' means any building which is not a school building, except that the term does not include any residential apartment building of fewer than 10 units.

(1112) RESIDENTIAL BUILDING - The term 'residential building' means any real property improvement of not less than 1 and not more than 4 residential dwelling units, units in residential cooperatives, or condominium units, including the limited common elements allocated to the exclusive use of the condominium unit.

(1213) RESPONSE ACTION.—The term ''response action'' means methods that protect human health and the environment from asbestos-containing material and polychlorinated biphenyl-containing material. Such methods include methods described in chapters 3 and 5 of the Environmental Protection Agency's ''Guidance for Controlling Asbestos-Containing Materials in Buildings. and the methods described on the Environmental Protection Agency's polychlorinated-biphenyls.''Policy and Guidance for PCBs'' and ''PCBs in Building Materials'' internet websites (or successor materials).

22

(1314) SCHOOL.—The term ''school'' means any elementary or secondary school as defined in section 9101 of the Elementary and Secondary Education Act of 1965.

(1415) SCHOOL BUILDING.—The term ''school building'' means—

(A) any structure suitable for use as a classroom, including a school facility such as a laboratory, library,

Commented [A5]: EPA: It could cause confusion to have the same definition apply to two different documents.

Commented [A6]: EPA: Including this part of the EPA PCB website would include more than PCBs in building materials. Also it is not clear what the impact would be if the website information was changed or removed in the future. So might reconsider referencing website information or ensure the wording allows future guidance or updates to be included under the act.

Commented [A7]: EPA: this does not include daycare facilities. We understand that the intent is to include daycares and pre-schools. One option to consider for defining "daycare" is as follows:

Daycare means any preschool, nursery school, child care facility, or portion thereof. This definition includes daycare space located within a non-daycare facility, including daycare services that are hosted in commercial, multi-family residential, and/or public buildings, except that such a place does not include a private home.

Commented [A8]: MASK

Commented [A9]: EPA: Should this say "or"?

Commented [A10]: EPA: Our understanding is that this bill is not intended to supersede the PCB ban in TSCA 6(e). Thus, if an inspection/testing reveals PCBs over 50 ppm in building materials, the use of such materials is unauthorized and the "response action" should be removal and disposal. The guidance documents on EPA's website discuss actions to reduce exposure, but those actions won't be appropriate if the intent is removal, so it would be misleading to refer to those documents. You may want to define "response action" separately for PCBs to mean removal and disposal upon discovery of PCBs over 50 ppm.

Commented [A11]: Confirm this is the most up-to-date definition of a school.

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] So in law. The period probably should be a comma.

school eating facility, or facility used for the preparation of food,

(B) any gymnasium or other facility which is specially designed for athletic or recreational activities for an academic course in physical education,

(C) any other facility used for the instruction of students or for the administration of educational or research programs, and

(D) any maintenance, storage, or utility facility, including any hallway, essential to the operation of any facility described in subparagraphs (A), (B), or (C).

(154) STATE.—The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Northern Marianas, the Trust Territory of the Pacific Islands, and the Virgin Islands.

[15 U.S.C. 2642]

SEC. 203. EPA REGULATIONS.

(a) IN GENERAL.—Within 360 days after the date of the enactment of this title, the Administrator shall promulgate regulations as described in subsections (b) through (i). With respect to regulations described in subsections (b), (c), (d), (e), (f), (g), and (i), the Administrator shall issue an advanced notice of proposed rulemaking within 60 days after the date of the enactment of this title, and shall propose regulations within 180 days after such date. Any regulation promulgated under this section must protect human health and the environment.

(b) INSPECTION.—

(A) The Administrator shall promulgate regula- tions which prescribe procedures, including the use of personnel ac- credited under section 206(b) or 206(c) and laboratories accredited under section 206(d), for determining whether asbestos-containing material is present in a school building under the authority of a local educational agency. The regulations shall provide for the exclusion of any school building, or portion of a school building, if (1) an inspection of such school building (or portion) was completed before the effective date of the regulations, and (2) the inspection meets the procedures and other requirements of the regulations under this title or of the "Guidance for Controlling Asbestos-Containing Materials in Buildings" (unless the Administrator determines that an inspection in accordance with the guidance document is inadequate). The regulations shall require inspection of any school building (or portion of a school building) that is not excluded by the preceding sentence.

(B) The Administrator shall promulgate regulations which prescribe procedures for determining whether polychlorinated biphenyl-containing material is present in a school building under the authority of a local educational agency.

(c) CIRCUMSTANCES REQUIRING RESPONSE ACTIONS.—(1) The Administrator shall promulgate regulations which define the appropriate response action in a school building under the authority of a local educational agency in at least the following circumstances:

(A) DAMAGE.—Circumstances in which friable asbestos-containing material or its covering is damaged, deteriorated, or delaminated.

(B) SIGNIFICANT DAMAGE.—Circumstances in which friable asbestos-containing material or its covering is significantly damaged, deteriorated, or delaminated.

Commented [A12]: EPA: While perhaps practical in the 1980s, this one year schedule will be difficult if not impossible to meet, given the current rulemaking process, especially if an ANPRM is stipulated in addition to the required NPRM.

Commented [A13R12]: EPA: Also, how does this deadline work for the new requirements? This deadline passed years ago. Seems like this needs a new section or subsection for the PCB regs.

Commented [A14]: EPA: Section 6(e) standard is 'no unreasonable risk'; this standard is 'protect health and environment'. How does the latter relate to the former?

Commented [A15]: EPA: Our understanding is that EPA is expected to require schools to inspect/test for PCBs, but it's unclear as drafted if the new regulations should require inspections/testing, or if that is being left to the discretion of the school authority.

Commented [A16]: EPA: This does not indicate which schools would have to comply: would EPA specify only schools built or renovated within certain dates?

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.

(C) POTENTIAL DAMAGE.—Circumstances in which—

(i) friable asbestos-containing material is in an area regularly used by building occupants, including maintenance personnel, in the course of their normal activities, and

(ii) there is a reasonable likelihood that the material or its covering will become damaged, deteriorated, or delam- inated.

(D) POTENTIAL SIGNIFICANT DAMAGE.—Circumstances in which—

(i) friable asbestos-containing material is in an area regularly used by building occupants, including maintenance personnel, in the course of their normal activities, and

(ii) there is a reasonable likelihood that the material or its covering will become significantly damaged, deteriorated, or delaminated.

(E) Circumstances in which the presence of Polychlorinated biphenyl-containing material in a school building is confirmed.

(2) In promulgating such regulations, the Administrator shall consider and assess the value of various technologies intended to improve the decisionmaking process regarding response actions and the quality of any work that is deemed necessary, including air monitoring and chemical encapsulants.

(d) RESPONSE ACTIONS.—

(1) IN GENERAL.—The Administrator shall promulgate regulations describing a response action in a school building under the authority of a local educational agency, ~~using the least burdensome methods which~~in order to protect human health and the envi- ronment. ~~In determining the least burdensome methods, the~~ The Administrator shall take into –account local circumstances, in- cluding occupancy and use patterns within the school building and short- and long-term costs.

(2) RESPONSE ACTION FOR DAMAGED ASBESTOS.—In the case of a response action for the circumstances described in subsection (c)(1)(A), methods for responding shall include methods identified in chapters 3 and 5 of the ''Guidance for Controlling Asbestos-Containing Material in Buildings.''

(3) RESPONSE ACTION FOR SIGNIFICANTLY DAMAGED ASBESTOS.—In the case of a response action for the circumstances described in subsection (c)(1)(B), methods for responding shall include methods identified in chapter 5 of the ''Guidance for Controlling Asbestos-Containing Material in Buildings.''

(4) RESPONSE ACTION FOR POTENTIALLY DAMAGED ASBESTOS.—In the case of a response action for the circumstances described in subsection (c)(1)(C), methods for responding shall include methods identified in chapters 3 and 5 of the ''Guidance for Controlling Asbestos-Containing Material in Buildings,'' unless preventive measures will eliminate the reasonable likelihood that the asbestos-containing material will become damaged, deteriorated, or delaminated.

(5) RESPONSE ACTION FOR POTENTIALLY SIGNIFICANTLY DAMAGED ASBESTOS.—In the case of a response action for the circumstances described in subsection (c)(1)(D), methods for responding shall include methods identified in chapter 5 of the ''Guidance for Controlling Asbestos-Containing Material in

Commented [A17]: EPA: Could 'confirm' include assuming the presence of PCBs?

Commented [A18]: EPA: This only makes sense for PCBs if immediate removal isn't required and short-term in-place management will be allowed, which we do not understand to be the intent.

Commented [A19]: EPA: Our understanding is that this bill is not intended to supersede the PCB ban in TSCA 6(e), so once PCBs over 50 ppm are discovered through inspection/testing, the use of such materials is unauthorized and those materials should be removed and disposed of in accordance with the PCB regulations in 40 CFR Part 761. This would make the instruction to promulgate regulations describing response actions for PCBs unnecessary (again, unless the intent is for EPA to describe and require response actions for PCBs < 50 ppm, which would require some textual revision). If EPA is being instructed to promulgate regulations that will "protect human health and the environment," though, this is a different standard than under TSCA 6(e), and could be read as an instruction for EPA to promulgate new disposal regulations. If this isn't the intent, you may want to limit this paragraph to asbestos only.

Buildings,'' unless preventive measures will eliminate the reasonable likelihood that the asbestos-containing material will become significantly damaged, deteriorated, or delaminated.

(6) PREVENTIVE MEASURES DEFINED.—For purposes of this section, the term ''preventive measures'' means actions which eliminate the reasonable likelihood of asbestos-containing material becoming damaged, deteriorated, or delaminated, or significantly damaged[1] deteriorated, or delaminated (as the case may be) or which protect human health and the environment.

(7) The Administrator shall, not later than 30 days after enactment of this paragraph, publish and distribute[1] to all local education agencies and State Governors information or an advisory to—

(A) facilitate public understanding of the comparative risks associated with in-place management of asbestos-containing building materials and removals;

(B) promote ~~the least burdensome~~ response actions for asbestos and Polychlorinated biphenyl-containing material that are necessary to protect human health, safety, and the envi- ronment; and

(C) describe the circumstances in which asbestos and Polychlorinated biphenyl-containing material re- moval is necessary to protect human health.

Such information or advisory shall be based on the best available scientific evidence and shall be revised, republished, and redistributed as appropriate, to reflect new scientific findings.

(e) IMPLEMENTATION.—The Administrator shall promulgate regulations requiring the implementation of response actions in school buildings under the authority of a local educational agency and, where appropriate, for the determination of when a response action is completed. Such regulations shall include standards for the education and protection of both workers and building occupants for the following phases of activity:

(1) Inspection.

(2) Response Action. [1]

(3) Post-response action, including any periodic reinspection of asbestos-containing material or Polychlorinated biphenyl-containing material and long-term surveillance activity.

(f) OPERATIONS AND MAINTENANCE.—The Administrator shall promulgate regulations to require implementation of an operations and maintenance and repair program as described in chapter 3 of the ''Guidance for Controlling Asbestos-Containing Materials in Buildings'' for all friable asbestos-containing material in a school building under the authority of a local educational agency.

(g) PERIODIC SURVEILLANCE.—The Administrator shall promulgate regulations to require the following:

(1) An identification of the location of friable and non-friable asbestos and Polychlorinated biphenyl-containing material in a school building under the authority of a local educational agency.

(2) Provisions for surveillance and periodic reinspection of such friable and non-friable asbestos and Polychlorinated biphenyl-containing material.

(3) Provisions for education of school employees, including school service and maintenance personnel, about the location of

[1] So in law. Probably should be followed by a comma.

Commented [A20]: EPA: This is a short timeframe that may not permit the development of any new materials. Existing guidance is available on EPA's website and publicly available. Also, this is an outdated model for information dissemination (i.e., from the 1980s). Much like our comment for 203(a), it is ambiguous how this timing works. Wasn't enactment of "this paragraph" [meaning paragraph (7)] back in 1986?

Commented [A21R20]: EPA: Again, when does the 30 days run from? If from these new changes, then EPA will have to do these things again for asbestos.

Commented [A22]: EPA: Again, this only makes sense for PCBs if immediate removal isn't required. .

Commented [A23]: EPA: Our understanding is that this bill is not intended to supersede the PCB ban in TSCA 6(e), and since the use of PCBs over 50 ppm in building materials is unauthorized under TSCA 6(e), those materials should be removed whenever PCBs over 50 ppm are discovered. Removal would not be discretionary. .

Commented [A24]: EPA: If the only response action intended for PCBs is removal, then EPA already has applicable cleanup and disposal regulations. .

If EPA is being directed to promulgate worker/occupant protection and education standards applicable to PCB actions, such standards don't seem to be strictly "response action" regulations. Perhaps this could say, "EPA shall also promulgate regulations including standards for the education and protection..."

Commented [A25]: EPA: It is unclear if EPA could defer to OSHA as it currently does, or must it write new worker protection regulations to supplement/duplicate OSCA regulations.

Commented [A26]: EPA: This implies that long-term in-place management of PCBs may be allowed. Our understanding is that this bill is not intended to supersede the PCB ban in TSCA 6(e) by providing a de facto use authorization for PCBs in building materials.

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] So in law. ''Action'' should probably not be capitalized.

and safety procedures with respect to such friable and nonfriable asbestos and Polychlorinated biphenyl-containing material.

(h) TRANSPORTATION AND DISPOSAL.—The Administrator shall promulgate regulations which prescribe standards for transportation and disposal of asbestos-containing waste material to protect human health and the environment. Such regulations shall include such provisions related to the manner in which transportation vehicles are loaded and unloaded as will assure the physical integrity of containers of asbestos-containing waste material.

(i) MANAGEMENT PLANS.—

(1) IN GENERAL.—The Administrator shall promulgate regulations which require each local educational agency to develop, and update no less frequently than every 10 years, an asbestos and polychlorinated biphenyl management plan for school buildings under its authority, to begin implementation of such plan within 990 days after the date of the enactment of this title, and to com- plete implementation of such plan in a timely fashion. The reg- ulations shall require that each plan include the following ele- ments, wherever relevant to the school building:

(A) An inspection statement describing inspection and response action activities carried out before the date of the enactment of this title.

(B) A description of the results of the inspection conducted pursuant to regulations under subsection (b), including a description of the specific areas inspected.

(C) A detailed description of measures to be taken to respond to any friable asbestos-containing material or polychlorinated biphenyl-containing material pursu- ant to the regulations promulgated under subsections (c), (d), and (e), including the location or locations at which a response action will be taken, the method or methods of response action to be used, and a schedule for beginning and completing response actions.

(D) A detailed description of any asbestos-containing material or polychlorinated biphenyl-containing material which remains in the school building once re- sponse actions are undertaken pursuant to the regulations promulgated under subsections (c), (d), and (e).

(E) A plan for periodic reinspection and long-term surveillance activities developed pursuant to regulations promulgated under subsection (g), and a plan for operations and maintenance activities developed pursuant to regulations promulgated under subsection (f).

(F) With respect to the person or persons who inspected for asbestos-containing material and who will design or carry out response actions with respect to the friable asbestos-containing material, one of the following statements:

(i) If the State has adopted a contractor accreditation plan under section 206(b), a statement that the person (or persons) is accredited under such plan.

(ii) A statement that the local educational agency used (or will use) persons who have been accredited by another State which has adopted a contractor accreditation plan under section 206(b) or is accredited pursuant to an Administrator-approved course under section 206(c).

Commented [A27]: Leave out PCBs – covered in title I

Commented [A28]: EPA: Is there consideration to exclude newer buildings that are unlikely to have PCBs or asbestos, or buildings that have been completely renovated?

Commented [A29]: EPA: Should this be for PCB-containing material only?

Commented [A30]: EPA: This appears to envision long-term management. Would the TSCA I ban on use of unauthorized materials be in force?

Commented [A31]: EPA: Our understanding is that this bill is not intended to supersede the PCB ban in TSCA 6(e) by providing a de facto use authorization (through a long-term management plan) for PCBs in building materials. This provision seems to provide for long-term management.

Commented [A32]: EPA: In line with overarching comment, is this enactment of the new legislation? As it reads, it is from the date of enactment many years ago so this date has already passed.

Commented [A33]: Per EPA, OSHA regs govern for PCBs. Going to leave them out.

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.

(G) A list of the laboratories that analyzed any bulk samples of asbestos-containing material or polychlorinated biphenyl-containing material found in the school building or air samples taken to detect asbestos or polychlorinated biphenyls in the school building and a statement that each laboratory has been accredited pursuant to the accreditation program under section 206(d).

(H) With respect to each consultant who contributed to the management plan, the name of the consultant and one of the following statements:

(i) If the State has adopted a contractor accreditation plan under section 206(b), a statement that the consultant is accredited under such plan.

(ii) A statement that the contractor is accredited by another State which has adopted a contractor accreditation plan under section 206(b) or is accredited pursuant to an Administrator-approved course under section 206(c).

(I) An evaluation of resources needed to successfully complete response actions and carry out reinspection, surveillance, and operation and maintenance activities.

(2) STATEMENT BY CONTRACTOR.—A local educational agency may require each management plan to contain a statement signed by an accredited asbestos contractor that such contractor has prepared or assisted in the preparation of such plan, or has reviewed such plan, and that such plan is in compliance with the applicable regulations and standards promulgated or adopted pursuant to this section and other applicable provisions of law. Such a statement may not be signed by a contractor who, in addition to preparing or assisting in preparing the management plan, also implements (or will implement) the management plan.

(3) WARNING LABELS.—(A) The regulations shall require that each local educational agency which has inspected for and discovered any asbestos-containing material with respect to a school building shall attach a warning label to any asbestos-containing material still in routine maintenance areas (such as boiler rooms) of the school building, including—

(i) friable asbestos-containing material which was responded to by a means other than removal, and

(ii) asbestos-containing material for which no response action was carried out.

(B) The warning label shall read, in print which is readily visible because of large size or bright color, as follows: **"CAUTION: ASBESTOS. HAZARDOUS. DO NOT DISTURB WITHOUT PROPER TRAINING AND EQUIPMENT."**

(4) PLAN MAY BE SUBMITTED IN STAGES.—A local educational agency may submit a management plan in stages, with each submission of the agency covering only a portion of the school buildings under the agency's authority, if the agency determines that such action would expedite the identification and abatement of hazardous asbestos-containing material or polychlorinated biphenyl-containing material in the school buildings under the authority of the agency.

(5) PUBLIC AVAILABILITY.—A copy of the management plan developed under the regulations shall be available in the ad-

Commented [A34]: EPA: this is not applicable to testing for PCBs.

Commented [A35]: EPA: this is not applicable to consultants who only contributed to the PCB portions of the plan.

Commented [A36]: EPA: this would not applicable to PCB-only plans (if such a situation exists)

Commented [A37]: Title I covers for PCBs, leaving them out here

Commented [A38]: EPA: PCB labeling requirements apply to PCB equipment, like transformers, capacitors, containers. We don't have requirements for warning labels on PCB-containing building materials, like caulk or windows. If over 50 ppm, these materials must be removed, but if on-going use is contemplated, you may want to include requirements for such PCB-containing materials. At the same time, it may be impractical to label individual building materials; some are not readily accessible nor visible (for example, PCBs have been found in moisture barriers in between walls or under exterior roofing material).

ministrative offices of the local educational agency for inspection by the public, including teachers, other school personnel, and parents. The local educational agency shall notify parent, teacher, and employee organizations of the availability of such plan.

(6) SUBMISSION TO STATE GOVERNOR.—Each plan developed under this subsection shall be submitted to the State Governor under section 205.

(j) CHANGES IN REGULATIONS.—Changes may be made in the regulations promulgated under this section only by rule in accordance with section 553 of title 5, United States Code. Any such change must protect human health and the environment.

(k) CHANGES IN GUIDANCE DOCUMENT.—Any change made in the "Guidance for Controlling Asbestos-Containing Material in Buildings" shall be made only by rule in accordance with section 553 of title 5, United States Code, unless a regulation described in this section dealing with the same subject matter is in effect. Any such change must protect human health and the environment.

(l) TREATMENT OF DEPARTMENT OF DEFENSE SCHOOLS.—

(1) SECRETARY TO ACT IN LIEU OF GOVERNOR.—In the administration of this title, any function, duty, or other responsibility imposed on a Governor of a State shall be carried out by the Secretary of Defense with respect to any school operated under the Defense Dependents' Education Act of 1978 (20 U.S.C. 921 et seq.).

(2) REGULATIONS.—The Secretary of Defense, in cooperation with the Administrator, shall, to the extent feasible and consistent with the national security, take such action as may be necessary to provide for the identification, inspection, and management (including abatement) of asbestos or polychlorinated biphenyl in any building used by the Department of Defense as an overseas school for dependents of members of the Armed Forces. Such identification, inspection, and management (including abatement) shall, subject to the preceding sentence, be carried out in a manner comparable to the manner in which a local educational agency is required to carry out such activities with respect to a school building under this title.

(m) Certification, Periodic Review, and Oversight.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015, and after an opportunity for public notice and comment, the Administrator shall—

"(A) revise regulations issued by the Administrator regarding waivers described in section 763.98 of title 40, Code of Federal Regulations, to ensure that the regulations are at least as stringent as the requirements under this section and section 204; and

"(B) review asbestos and polychlorinated biphenyl management in each State and any waiver that was issued to a State before the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015—

"(i) to ensure that the asbestos and polychlorinated biphenyl management program of each State is at least as stringent as the regulations contained in subpart E of part 763 of title 40, Code of Federal Regulations (as in effect on March 1, 2015); and

"(ii) to ensure that each State has made adequate efforts to comply with the requirements under this title.

"(2) CONTENTS OF REGULATIONS.—The revised regulations issued under paragraph (1) shall—

Commented [A39]: Alec – shd it also be online?

Commented [A40]: EPA: This only makes sense for PCBs if short-term in-place management will be allowed.

Commented [A41]: EPA: There is nothing here that limits the PCBs to > 50ppm.

Commented [A42R41]: EPA: All references to PCBs would include PCBs over and under 50 ppm. Was the intent to expand the scope of these provisions to encompass materials beyond those covered under the definition of PCB-containing materials?

Commented [A43]: EPA: This subsection seems like a confusing mixture of provisions relating to states with waiver programs, and provisions relating to general EPA oversight of states with and without waiver programs.

Commented [A44]: Flag potential for title change

Commented [A45]: EPA: This suggests that EPA can continue to grant waivers, but the express statutory authority to grant has been stricken, on top of p 14.

Commented [A46]: EPA: It is unclear what is meant here.

Commented [A47]: EPA: Our understanding is that this bill is not intended to supersede the PCB ban in TSCA 6(e), and long-term management would be inconsistent with the ban. .

Commented [A48]: EPA: The waiver provision in part 763 subpart E does not apply to PCBs. The intent of including PCBs is not clear.

Commented [A49]: Flag potential for title change

Commented [A50]: EPA: Recommend these terms be further described or defined so it is clear what is meant by "management program of each state."

Commented [A51]: EPA: Aside from part 763 not addressing PCBs, States are not delegated authority under TSCA I to regulate PCBs, so it is not clear how this standard could be satisfied.

Commented [A52]: Question for EPA – we have PCB regulations under title I AND title II of TSCA – do we need to reference the Title I here (and in similar provisions below) as well?

Commented [A53R52]: EPA: It is recommended that something is said about how PCBs fit here because, as part 763 doesn't cover them.

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"(A) require that each State, not later than 1 year after the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015 and every 10 years thereafter, shall submit to the Administrator—

"(i) a copy of the asbestos and polychlorinated biphenyl management program of the State that demonstrates that the management program implemented by the State is at least as stringent as the regulations contained in subpart E of part 763 of title 40, Code of Federal Regulations (as in effect on March 1, 2015); and

"(ii)(I) written notification that the State has not requested a waiver in accordance with the regulations revised under paragraph (1);

"(II) a copy of the asbestos accreditation plan of the State that—

"(aa) includes the date on which the program was adopted and implemented;

"(bb) demonstrates that the accreditation program implemented by the State is at least as stringent as the regulations contained in subpart E of part 763 of title 40, Code of Federal Regulations (as in effect on March 1, 2015); and

"(cc) if applicable, includes the date on which the State received formal approval from the Administrator, the Director of the National Institute of Standards and Technology, or other appropriate official for the contractor and laboratory accreditation plan under section 206; or

"(III) a verification that the State has adopted and implemented a model accreditation plan in accordance with the Asbestos Model Accreditation Plan issued by the Administrator and described in Appendix C of subpart E of part 763 of title 40, Code of Federal Regulations; and

"(B) reestablish Federal oversight of asbestos accreditation plans and management programs to ensure that each State addresses asbestos and polychlorinated biphenyl hazards with plans that are at least as stringent as the requirements under this section and section 204.

"(3) CERTIFICATION BY ADMINISTRATOR.—On receipt of the asbestos accreditation plan and the management program submitted in accordance with paragraph (2), the Administrator shall—

"(A) assess the asbestos and polychlorinated biphenyl inspection plan and management program of each State under this section;

"(B) make a determination regarding whether the programs referred to in subparagraph (A) meet the requirements under this section and section 204;

"(C) issue to the State the determination made under subparagraph (B); and

"(D) if the Administrator determines that the plans or programs referred to in subparagraph (A) do not meet the requirements under this section and section 204—

"(i) describe the aspects of the plans or programs that are inadequate;

"(ii) describe the facts upon which the Administrator relied to make the finding under this subparagraph; and

"(iii) describe the corrective action that is required and the timeframe in which the State must take the corrective action.

"(4) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015 and annually thereafter, the Administrator shall submit to Congress a report that describes—

"(A) the certifications of accreditation plans under paragraph (3), including—

"(i) a description of the States that adopted the model accreditation plan described in paragraph (2)(A)(ii)(III); and

"(ii) a description of the States that received a certification from the Administrator under paragraph (3) for the accreditation plan;

"(B) any applications for a waiver submitted by a State and reviewed and approved by the Administrator; and

Commented [A54]: Title change flag

Commented [A55]: EPA: A program for in-place management of PCBs would be inconsistent with the PCB ban in TSCA 6(e).

Commented [A56]: EPA: It is unclear what is meant by "management program of the State." Is this in the context of waiver states? If so, this doesn't seem applicable to PCBs being an undelegated program.

Commented [A57]: EPA: It is unclear how this would be implemented in regards to PCBs.

Commented [A58]: EPA: Since II and III do not apply to PCBs, it appears that this is the only option re PCBs. Is the intent that the PCB requirements cannot be waived?

Commented [A59]: EPA: How can re-establishment of fed oversight re asbestos plans and programs ensure stringency of PCB plans?

Commented [A60]: EPA: No reference to PCBs here, although PCBs are included in (2).

Commented [A61]: EPA: It is unclear what is meant by the state's management plan, which (m)(2)(B) clearly distinguishes from accreditation.

Commented [A62]: Possible change

Commented [A63]: EPA: *Identification* of the states?

Commented [A64]: EPA: It looks like the authority to grant waivers has been stricken, on the next page. Is this referring to applications submitted pre-MASK?

"(C) any actions that the Administrator has taken to ensure compliance with this title in each State that—

"(i) submitted a written notification in accordance with paragraph (2)(A)(ii)(I); or

"(ii) did not receive a certification under paragraph (3).";

~~WAIVER.—The Administrator, upon request by a Governor and after notice and comment and opportunity for a public hearing in the affected State, may waive some or all of the requirements of this section and section 204 with respect to such State if it has established and is implementing a program of asbestos inspection and management that contains requirements that are at least as stringent as the requirements of this section and section 204.~~

~~[15 U.S.C. 2643]~~

Commented [A65]: EPA: Is the intent behind striking this that states cannot get PCB waivers, and that additional states cannot get asbestos waivers?

SEC. 204. REQUIREMENTS IF EPA FAILS TO PROMULGATE REGULATIONS.

(a) IN GENERAL.—

(1) FAILURE TO PROMULGATE.—If the Administrator fails to promulgate within the prescribed period—

(A) regulations described in section 203(b) (relating to inspection);

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(B) regulations described in section 203 (c), (d), (e), (f), (g), and (i) (relating to responding to asbestos or polychlorinated biphenyl); or

(C) regulations described in section 203(h) (relating to transportation and disposal);

each local educational agency shall carry out the requirements described in this section in subsection (b); subsections (c), (d), and (e); or subsection (f); respectively, in accordance with the Environmental Protection Agency's most current guidance document.

(2) STAY BY COURT.—If the Administrator has promulgated regulations described in paragraph (1)(A), (B), or (C) within the prescribed period, but the effective date of such regulations has been stayed by a court for a period of more than 30 days, a local educational agency shall carry out the pertinent requirements described in this subsection in accordance with the Environmental Protection Agency's most current guidance document.

(3) EFFECTIVE PERIOD.—The requirements of this section shall be in effect until such time as the Administrator promulgates the pertinent regulations or until the stay is lifted (as the case may be).

(b) INSPECTION.—(1) Except as provided in paragraph (2), the local educational agency, within 540 days after the date of the enactment of this title, shall conduct an inspection for asbestos-containing material using personnel accredited under section 206(b) or 206(c) and laboratories accredited under section 206(d), in each school building under its authority, and shall conduct an inspection for polychlorinated-biphenyl containing material in each school building under its authority.

(2) The local educational agency may exclude from the inspection requirement in paragraph (1) any school building, or portion of a school building, if (A) an inspection of such school building, or portion was completed before the date on which this section goes into effect, and (B) the inspection meets the inspection requirements of this section.

(c) OPERATION AND MAINTENANCE.—The local educational agency shall, within 720 days after the date of the enactment of this title, develop and begin implementation of an operation and maintenance plan with respect to friable asbestos-containing material and polychlorinated biphenyl-containing material in a school building under its authority. Such plan shall provide for the education of school service and maintenance personnel about safety procedures with respect to asbestos-containing material and polychlorinated biphenyl-containing material, including friable asbestos-containing material.

(d) MANAGEMENT PLAN.—

(1) In General.—The local educational agency shall—

(A) develop a management plan for responding to asbestos-containing material and polychlorinated biphenyl-containing material in each school building under its authority and submit such plan to the Governor under section 205 within 810 days after the date of the enactment of this title,

(B) begin implementation of such plan within 990 days after the date of the enactment of this title, and

(C) complete implementation of such plan in a timely fashion.

(2) PLAN REQUIREMENTS.—The management plan shall—

Commented [A66]: Question for leg counsel on how to draft this to make them do pcb regs but not redo asbestos

Commented [A67R66]: EPA: Presumably the section needs to be rewritten to remove all references to asbestos and apply to PCBs only.

Commented [A68]: EPA: In line with overarching comment, this date has already passed

Commented [A69]: EPA: Would inspection be expected to involve testing? It is not clear how feasible it is to test all types of building materials for PCBs.

Commented [A70]: EPA: Our understanding is that this bill is not intended to supersede the PCB ban in TSCA 6(e), and long-term management would be inconsistent with the ban.

Commented [A71]: EPA: Same comment as above re: management in-place being inconsistent with TSCA 6(e).

Commented [A72]: EPA: In line with the overarching comment, the dates in this paragraph have already passed

(A) include the elements listed in section 203(i)(1), including an inspection statement as described in paragraph (3) of this section, [1]

(B) provide for the attachment of warning labels as described in section 203(i)(3),

(C) be prepared in accordance with the most current guidance document,

(D) meet the standard described in paragraph (4) for actions described in that paragraph, and

(E) be submitted to the State Governor under section 205.

(3) INSPECTION STATEMENT.—The local educational agency shall complete an inspection statement, covering activities carried out before the date of the enactment of this title, which meets the following requirements:

(A) The statement shall include the following information:

(i) The dates of inspection.

(ii) The name, address, and qualifications of each inspector.

(iii) A description of the specific areas inspected.

(iv) A list of the laboratories that analyzed any bulk samples of asbestos-containing material or polychlorinated biphenyl-containing material or air samples of asbestos or polychlorinated biphenyls found in any school building and a statement describing the qualifications of each lab- oratory.

(v) The results of the inspection.

(B) The statement shall state whether any actions were taken with respect to any asbestos-containing material or polychlorinated biphenyl-containing material found to be present, including a specific reference to whether any actions were taken in the boiler room of the building. If any such action was taken, the following items of information shall be included in the statement:

(i) The location or locations at which the action was taken.

(ii) A description of the method of action.

(iii) The qualifications of the persons who conducted the action.

(4) STANDARD.—The ambient interior concentration of asbestos or polychlorinated biphenyl after the completion of actions described in the most current guidance document, other than the type of action de- scribed in sections 203(f) and subsection (c) of this section, shall not exceed the ambient exterior concentration, dis- counting any contribution from any local stationary source. Ei- ther a scanning electron microscope or a transmission electron microscope shall be used to determine the ambient interior concentration. In the absence of reliable measurements, the ambient exterior concentration shall be deemed to be—

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

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

[1] So in law. Probably should be ''subsection''.

Commented [A73]: EPA: As currently written, this would not apply to PCB-containing building materials.

Commented [A74]: EPA: this date refers to time before AHERA was enacted

Commented [A75]: EPA: it is unclear on what would trigger testing here.

Commented [A76]: EPA: EPA does not have any standards for PCBs in indoor air, nor outdoor air and determining "background" in outdoor air for PCBs would be problematic. The EPA air exposure levels for evaluation of indoor air are meant to be guidance, they are not regulatory values and have not been peer reviewed.

Commented [A77]: EPA: This equipment cannot measure PCBs. PCBs are typically measured using gas chromatography.

Commented [A78]: EPA: This includes PCBs in the text but the standards are not relevant to PCBs.

Commented [A79]: EPA: Note, this is not a PCB measurement.

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.

(5) PUBLIC AVAILABILITY.—A copy of the management plan shall be available in the administrative offices of the local educational agency for inspection by the public, including teachers, other school personnel, and parents. The local educational agency shall notify parent, teacher, and employee organizations of the availability of such plan.

(e) BUILDING OCCUPANT PROTECTION.—The local educational agency shall provide for the protection of building occupants during each phase of activity described in this section.

(f) TRANSPORTATION AND DISPOSAL.—The local educational agency shall provide for the transportation and disposal of asbestos in accordance with the most recent version of the Environmental Protection Agency's ''Asbestos Waste Management Guidance'' (or any successor to such document).

[15 U.S.C. 2644]

SEC. 205. SUBMISSION TO STATE GOVERNOR.

(a) SUBMISSION.—Within 720 days after the date of the enactment of this title (or within 810 days if there are no regulations under section 203(i)), a local educational agency shall submit a management plan developed pursuant to regulations promulgated under section 203(i) (or under section 204(d) if there are no regulations) to the Governor of the State in which the local educational agency is located.

(b) GOVERNOR REQUIREMENTS.—Within 360 days after the date of the enactment of this title, the Governor of each State—

(1) shall notify local educational agencies in the State of where to submit their management plans under this section, and

(2) may establish administrative procedures for reviewing management plans submitted under this section.

If the Governor establishes procedures under paragraph (2), the Governor shall designate to carry out the reviews those State officials who are responsible for implementing environmental protection or other public health programs, or with authority over asbestos or polychlorinated biphenyl programs, in the State.

(c) MANAGEMENT PLAN REVIEW.—

(1) REVIEW OF PLAN.—The Governor may disapprove a management plan within 90 days after the date of receipt of the plan if the plan—

(A) does not conform with the regulations under section 203(i) (or with section 204(d) if there are no regulations),

(B) does not assure that contractors who are accredited pursuant to this title will be used to carry out the plan, or

(C) does not contain a response action schedule which is reasonable and timely, taking into account circumstances relevant to the speed at which the friable asbestos-containing material or polychlorinated biphenyl-containing material in the school buildings under the local educational agency's authority should be re- sponded to, including human exposure to the asbestos or polychlorinated biphenyls while the friable asbestos-containing material or polychlorinated biphenyl-containing material remains in the school building, and the ability of the local educational

Commented [A80]: Alec – online also?

Commented [A81]: Transportation/disposal for PCBs is in title I, leaving them out here.

Commented [A82]: EPA: The dates in this paragraph have already passed. Also, states are not delegated authority under TSCA I to regulate PCBs, so it is not clear that state review of management plans or consideration of deferral requests would be appropriate for PCBs (if management plans are intended for PCBs).

agency to continue to provide educational services to the community.

(2) REVISION OF PLAN.—If the State Governor disapproves a plan, the State Governor shall explain in writing to the local educational agency the reasons why the plan was disapproved and the changes that need to be made in the plan. Within 30 days after the date on which notice is received of disapproval of its plan, the local educational agency shall revise the plan to conform with the State Governor's suggested changes. The Governor may extend the 30-day period for not more than 90 days.

(d) DEFERRAL OF SUBMISSION—

(1) REQUEST FOR DEFERRAL.—A local educational agency may request a deferral, to May 9, 1989, of the deadline under subsection (a). Upon approval of such a request, the deadline under subsection (a) is deferred until May 9, 1989, for the local educational agency which submitted the request. Such a request may cover one or more schools under the authority of the agency and shall include a list of all the schools covered by the request. A local educational agency shall file any such request with the State Governor by October 12, 1988, and shall include with the request either of the following statements:

(A) A statement—

(i) that the State in which the agency is located has requested from the Administrator, before June 1, 1988, a waiver under section 203(m); and

(ii) that gives assurance that the local educational agency has carried out the notification and, in the case of a public school, public meeting required by paragraph (2).

(B) A statement, the accuracy of which is sworn to by a responsible offical of the agency (by notarization or other means of certification), that includes the following with respect to each school for which a deferral is sought in the request:

(i) A statement that, in spite of the fact that the local educational agency has made a good faith effort to meet the deadline for submission of a management plan under subsection (a), the agency will not be able to meet the deadline. The statement shall include a brief explanation of the reasons why the deadline cannot be met.

(ii) A statement giving assurance that the local educational agency has made available for inspection by the public, at each school for which a deferral is sought in the request, at least one of the following documents:

(I) A solicitation by the local educational agency to contract with an accredited asbestos contractor for inspection or management plan development.

(II) A letter attesting to the enrollment of school district personnel in an Environmental Pro-

Commented [A83]: EPA: it is not clear how this works for PCBs. PCBs are only now being covered under 205(a) but the dates here are from original AHERA.

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.

tection Agency-accredited training course for inspection and management plan development.

(III) documentation showing that an analysis of suspected asbestos-containing material from the school is pending at an accredited laboratory.

(IV) Documentation showing that an inspection or management plan has been completed in at least one other school under the local educational agency's authority.

(iii) A statement giving assurance that the local educational agency has carried out the notification and, in the case of a public school, public meeting required by paragraph (2).

(iv) A proposed schedule outlining all significant activities leading up to submission of a management plan by May 9, 1989, including inspection of the school (if not completed at the time of the request) with a deadline of no later than December 22, 1988, for entering into a signed contract with an accredited asbestos contractor for inspection (unless such inspections are to be performed by school personnel), laboratory analysis of material from the school suspected of containing asbestos, and development of the management plan.

(2) NOTIFICATION AND PUBLIC MEETING.—Before filing a deferral request under paragraph (1), a local educational agency shall notify affected parent, teacher, and employee organizations of its intent to file such a request. In the case of a deferral request for a public school, the local educational agency shall discuss the request at a public meeting of the school board with jurisdiction over the school, and affected parent, teacher, and employee organizations shall be notified in advance of the time and place of such meeting.

(3) RESPONSE BY GOVERNOR.—(A) Not later than 30 days after the date on which a Governor receives a deferral request under paragraph (1) from a local educational agency, the Governor shall respond to the local educational agency in writing by acknowledging whether the request is complete or incomplete. If the request is incomplete, the Governor shall identify in the response the items that are missing from the request.

(B) A local educational agency may correct any deficiencies in an incomplete deferral request and refile the request with the Governor. In any case in which the local educational agency decides to refile the request, the agency shall refile the request, and the Governor shall respond to such refiled request in the manner described in subparagraph (A), no later than 15 days after the local educational agency has received a response from the Governor under subparagraph (A).

(C) Approval of a deferral request under this subsection occurs only upon the receipt by a local educational agency of a written acknowledgment from the Governor that the agency's deferral request is complete.

(4) SUBMISSION AND REVIEW OF PLAN.—A local educational agency whose deferral request is approved shall submit a man-

Commented [A84]: EPA: If accreditation isn't required for PCB-related activities, this should be limited to asbestos. Also, Sec. 206(b)(1)(A) refers to EPA's development of a model contractor accreditation plan for states. This is an issue for PCBs as such analogous programs do not exist for PCBs and it is not clear what it would take for EPA to develop programs for PCBs

agement plan to the Governor not later than May 9, 1989. Such management plan shall include a copy of the deferral request and the statement accompanying such request. Such management plan shall be reviewed in accordance with subsection (c), except that the Governor may extend the 30-day period for revision of the plan under subsection (c)(2) for only an additional 30 days (for a total of 60 days.)

(5) IMPLEMENTATION OF PLAN.—The approval of a deferral request from a local educational agency shall not be considered to be a waiver or exemption from the requirement under section 203(i) for the local educational agency to begin implementation of its management plan by July 9, 1989.

(6) EPA NOTICE.—(A) Not later than 15 days after the date of the enactment of this subsection, the Administrator shall publish in the Federal Register the following:

(i) A notice describing the opportunity to file a request for deferral under this subsection.

(ii) A list of the State offices (including officials (if available) in each State as designated under subsection (b)) with which deferral requests should be filed.

(B) As soon as practicable, but in no event later than 30 days, after the date of the enactment of this subsection, the Administrator shall mail a notice describing the opportunity to file a request for deferral under this subsection to each local educational agency and to each State office in the list published under subparagraph (A).

(e) STATUS REPORTS.—(1) Not later than December 31, 1988, the Governor of each State shall submit to the Administrator a written statement on the status of management plan submissions and deferral requests by local educational agencies in the State. The statement shall be made available to local educational agencies in the State and shall contain the following:

(A) A list containing each local educational agency that submitted a management plan by October 12, 1988.

(B) A list containing each local educational agency whose deferral request was approved.

(C) A list containing each local educational agency that failed to submit a management plan by October 12, 1988, and whose deferral request was disapproved.

(D) A list containing each local educational agency that failed to submit a management plan by October 12, 1988, and did not submit a deferral request.

(2) Not later than December 31, 1989, the Governor of each State shall submit to the Administrator an updated version of the written statement submitted under paragraph (1). The statement shall be made available to local educational agencies in the State and shall contain the following:

(A) A list containing each local educational agency whose management plan was submitted and not disapproved as of October 9, 1989.

(B) A list containing each local educational agency whose management plan was submitted and disapproved, and which remains disapproved, as of October 9, 1989.

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.

(C) A list containing each local educational agency that submitted a management plan after May 9, 1989, and before October 10, 1989.

(D) A list containing each local educational agency that failed to submit a management plan as of October 9, 1989.

(3) WRITTEN STATUS REPORT.—Not less frequently than once every 10 years, the Governor of each State shall submit to the Administrator a report on the status of management plan submissions and deferral requests by local educational agencies in the State, which shall—

"(A) be made available to local educational agencies in the State; and

"(B) contain a list that includes, with respect to the period covered by the report—

"(i) each local educational agency within the jurisdiction of the State;

"(ii) each local educational agency the management plan of which was submitted and not disapproved;

"(iii) each local educational agency the management plan of which—

"(I) was submitted and disapproved; and

"(II) remains disapproved;

"(iv) each local educational agency that failed to submit a management plan; and

"(v) any emergency actions taken by the State pursuant to emergency authority under section 208 to protect human health or the environment from asbestos hazards, and the outcomes of those emergency actions.";

[15 U.S.C. 2645]

SEC. 206. CONTRACTOR AND LABORATORY ACCREDITATION.

(a) CONTRACTOR ACCREDITATION.—A person may not—

(1) inspect for asbestos-containing material in a school building under the authority of a local educational agency or in a public, ~~or~~ commercial or residential building,

(2) prepare a management plan for such a school, or

(3) design or conduct response actions, other than the type of action described in sections 203(f) and 204(c), with respect to friable asbestos-containing material in such a school or in a public, ~~or~~ commercial or residential building,

unless such person is accredited by a State under subsection (b) or is accredited pursuant to an Administrator-approved course under subsection (c).

(b) ACCREDITATION BY STATE.—

(1) MODEL PLAN.—

(A) PERSONS TO BE ACCREDITED.—Within 180 days after the date of the enactment of this title, the Administrator, in consultation with affected organizations, shall develop a model contractor accreditation plan for States to give accreditation to persons in the following categories:

(i) Persons who inspect for asbestos-containing material in school buildings under the authority of a local educational agency or in public or commercial buildings.

(ii) Persons who prepare management plans for such schools.

(iii) Persons who design or carry out response actions, other than the type of action described in sections 203(f) and 204(c), with respect to friable asbestos-containing material in such schools or in public or commercial buildings. [1]

Commented [A85]: EPA: EPA's understanding is contractor accreditation is not being extended to PCB work.

Commented [A86]: EPA: Likely need to specify "asbestos management plan" unless prescriptive training requirements are envisioned for preparing PCB management plans.

[1] Subsection (a)(3) of section 15 of the Asbestos School Hazard Abatement Reauthorization Act of 1990 (P.L. 101–637; 104 Stat. 4596) provides:

(3) Not later than one year after the date of the enactment of this Act [Nov. 28, 1990], the Administrator of the Environmental Protection Agency shall revise the model contractor accreditation plan promulgated under section 206(b)(1) of the Toxic Substances Control Act (15 U.S.C. 2646(b)(1)) to increase the minimum number of hours of training, including additional hours of hands-on health and safety training, required for asbestos abatement workers and to make such other changes as may be necessary to implement the amendments made by paragraphs (1) and (2). [The amendments made by paragraphs (1) and (2) added references to public and commercial buildings in subsections (a)(1), (a)(3), (b)(1)(A)(i), and (b)(1)(A)(iii) of section 206 of the Toxic Substances Control Act.]

Subsections (b) and (c) of section 15 of such Act provide:

(b) DISCLAIMER.—In exercising any authority under the Toxic Substances Control Act in connection with the amendment made by subsection (a) of this section [amendment added references to public and commercial buildings, as described in bracketed material above], the Administrator of the Environmental Protection Agency shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653(b)(1)), be considered to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(c) EFFECTIVE DATE.—This section shall take effect upon the expiration of the 12-month period following the date of the enactment of this Act [Nov. 28, 1990]. The Administrator may extend

Continued

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.

(B) PLAN REQUIREMENTS.—The plan shall include a requirement that any person in a category listed in paragraph (1)[2] achieve a passing grade on an examination and participate in continuing education to stay informed about current asbestos inspection and response action technology. The examination shall demonstrate the knowledge of the person in areas that the Administrator prescribes as necessary and appropriate in each of the categories. Such examinations may include requirements for knowledge in the following areas:

(i) Recognition of asbestos-containing material and its physical characteristics.

(ii) Health hazards of asbestos and the relationship between asbestos exposure and disease.

(iii) Assessing the risk of asbestos exposure through a knowledge of percentage weight of asbestos-containing material, friability, age, deterioration, location and accessibility of materials, and advantages and disadvantages of dry and wet response action methods.

(iv) Respirators and their use, care, selection, degree of protection afforded, fitting, testing, and maintenance and cleaning procedures.

(v) Appropriate work practices and control methods, including the use of high efficiency particle absolute vacuums, the use of amended water, and principles of negative air pressure equipment use and procedures.

(vi) Preparing a work area for response action work, including isolating work areas to prevent bystander or public exposure to asbestos, decontamination procedures, and procedures for dismantling work areas after completion of work.

(vii) Establishing emergency procedures to respond to sudden releases.

(viii) Air monitoring requirements and procedures.

(ix) Medical surveillance program requirements.

(x) Proper asbestos waste transportation and disposal procedures.

(xi) Housekeeping and personal hygiene practices, including the necessity of showers, and procedures to prevent asbestos exposure to an employee's family.

(2) STATE ADOPTION OF PLAN.—Each State shall adopt a contractor accreditation plan at least as stringent as the model plan developed by the Administrator under paragraph (1), within 180 days after the commencement of the first regular session of the legislature of such State which is convened following the date on which the Administrator completes develop-

the effective date for a period not to exceed one year if the Administrator determines that accredited asbestos contractors are needed to perform school-site abatement required under the Asbestos Hazard Emergency Response Act [should be: title II of the Toxic Substances Control Act] (15 U.S.C. 2641) and such an extension is necessary to ensure effective implementation of section 203 of the Toxic Substances Control Act.

[2] So in law. Probably should be "subparagraph (A)".

ment of the model plan. In the case of a school operated under the defense dependents' education system provided for under the Defense Dependents' Education Act of 1978 (20 U.S.C. 921 et seq.), the Secretary of Defense shall adopt a contractor accreditation plan at least as stringent as that model.

(c) ACCREDITATION BY ADMINISTRATOR-APPROVED COURSE.—

(1) COURSE APPROVAL.—Within 180 days after the date of the enactment of this title, the Administrator shall ensure that any Environmental Protection Agency-approved asbestos training course is consistent with the model plan (including testing requirements) developed under subsection (b). A contractor may be accredited by taking and passing such a course.

(2) TREATMENT OF PERSONS WITH PREVIOUS EPA ASBESTOS TRAINING.—A person who—

(A) completed an Environmental Protection Agency-approved asbestos training course before the date of the enactment of this title, and

(B) passed (or passes) an asbestos test either before or after the date of the enactment of this title,

may be accredited under paragraph (1) if the Administrator determines that the course and test are equivalent to the requirements of the model plan developed under subsection (b). If the Administrator so determines, the person shall be considered accredited for the purposes of this title until a date that is one year after the date on which the State in which such person is employed establishes an accreditation program pursuant to subsection (b).

(3) LISTS OF COURSES.—The Administrator, in consultation with affected organizations, shall publish (and revise as necessary)—

(A) a list of asbestos courses and tests in effect before the date of the enactment of this title which qualify for equivalency treatment under paragraph (2), and

(B) a list of asbestos courses and tests which the Administrator determines under paragraph (1) are consistent with the model plan and which will qualify a contractor for accreditation under such paragraph.

(d) LABORATORY ACCREDITATION.—(1) The Administrator shall provide for the development of an accreditation program for laboratories by the National Bureau of Standards in accordance with paragraph (2). The Administrator shall transfer such funds as are necessary to the National Bureau of Standards to carry out such program.

(2) The National Bureau of Standards, upon request by the Administrator, shall, in consultation with affected organizations—

(A) within 360 days after the date of the enactment of this title, develop an accreditation program for laboratories which conduct qualitative and semi-quantitative analyses of bulk samples of asbestos-containing material, and

(B) within 720 days after the date of the enactment of this title, develop an accreditation program for laboratories which conduct analyses of air samples of asbestos from school buildings under the authority of a local educational agency.

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.

(3) A laboratory which plans to carry out any such analysis shall comply with the requirements of the accreditation program.

(e) FINANCIAL ASSISTANCE CONTINGENT ON USE OF ACCREDITED PERSONS.—(1) A school which is an applicant for financial assistance under section 505 of the Asbestos School Hazard Abatement Act of 1984 (Public Law 98–377; 20 U.S.C. 4011 et seq.) is not eligible for such assistance unless the school, in carrying out the requirements of this title—

(A) uses a person (or persons)—

(i) who is accredited by a State which has adopted an accreditation plan based on the model plan developed under subsection (b), or

(ii) who is accredited pursuant to an Administrator-approved course under subsection (c), and

(B) uses a laboratory (or laboratories) which is accredited under the program developed under subsection (d).

(2) This subsection shall apply to any financial assistance provided under the Asbestos School Hazard Abatement Act of 1984 for activities performed after the following dates:

(A) In the case of activities performed by persons, after the date which is one year after the date of the enactment of this title.

(B) In the case of activities performed by laboratories, after the date which is 180 days after the date on which a laboratory accreditation program is completed under subsection (d).

(f) LIST OF EPA-APPROVED COURSES.—Not later than August 31, 1988, and every three months thereafter until August 31, 1991, the Administrator shall publish in the Federal Register a list of all Environmental Protection Agency-approved asbestos training courses for persons to achieve accreditation in each category described in subsection (b)(1)(A) and for laboratories to achieve accreditation. The Administrator may continue publishing such a list after August 31, 1991, at such times as the Administrator considers it useful. The list shall include the name and address of each approved trainer and, to the extent available, a list of all the geographic sites where training courses will take place. The Administrator shall provide a copy of the list to each State official on the list published by the Administrator under section 205(d)(6) and to each regional office of the Environmental Protection Agency.

[15 U.S.C. 2646]

SEC. 207. ENFORCEMENT.

(a) PENALTIES.—Any local educational agency—

(1) which fails to conduct an inspection pursuant to regulations under section 203(b) or under section 204(b),

(2) which knowingly submits false information to the Governor regarding any inspection pursuant to regulations under section 203(i) or knowingly includes false information in any inspection statement under section 204(d)(3),

(3) which fails to develop a management plan pursuant to regulations under section 203(i) or under section 204(d),

(4) which carries out any activity prohibited by section 215, or

(5) which knowingly submits false information to the Governor regarding a deferral request under section 205(d),[1]

is liable for a civil penalty of not more than $5,000 for each day during which the violation continues. Any civil penalty under this subsection shall be assessed and collected in the same manner, and subject to the same provisions, as in the case of civil penalties assessed and collected under section 16. For purposes of this subsection, a ''violation'' means a failure to comply with respect to a single school building. The court shall order that any civil penalty collected under this subsection be used by the local educational agency for purposes of complying with this title. Any portion of a civil penalty remaining unspent after compliance by a local educational agency is completed shall be deposited into the Asbestos Trust Fund established by section 5 of the Asbestos Hazard Emergency Response Act of 1986.

(b) RELATIONSHIP TO TITLE I.—A local educational agency is not liable for any civil penalty under title I of this Act for failing or refusing to comply with any rule promulgated or order issued under this title.

(c) ENFORCEMENT CONSIDERATIONS.—

(1) In determining the amount of a civil penalty to be assessed under subsection (a) against a local educational agency, the Administrator shall consider—

(A) the significance of the violation;

(B) the culpability of the violator, including any history of previous violations under this Act;

(C) the ability of the violator to pay the penalty; and

(D) the ability of the violator to continue to provide educational services to the community.

(2) Any action ordered by a court in fashioning relief under section 20 shall be consistent with regulations promulgated under section 203 (or with the requirements of section 204 if there are no regulations).

(d) CITIZEN COMPLAINTS.—Any person may file a complaint with the Administrator or with the Governor of the State in which the school building is located with respect to asbestos-containing material or polychlorinated biphenyl-containing material in a school building. If the Administrator or Governor re- ceives a complaint under this subsection containing allegations which provide a reasonable basis to believe that a violation of this Act has occurred, the Administrator or Governor shall investigate and respond (including taking enforcement action where appro- priate) to the complaint within a reasonable period of time.

(e) CITIZEN PETITIONS.—(1) Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a regulation or order under this title.

(2) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a regulation or order under this title.

(3) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems

[1] In Public Law 99–519, a period appears after ''section 205(d)''. The comma is shown in this print to reflect the probable intent of Congress.

Commented [A87]: EPA: Note that this is where the penalty money will be deposited even if the state failure pertains to PCBs, not asbestos.

Commented [A88]: Question for EPA: should this be limited to asbestos?

Commented [A89R88]: EPA: Our understanding is that this bill is intended to supplement Title I. There wouldn't necessarily be overlap between Title I and Title II with respect to PCBs. However, if "response action" for PCBs is defined in this bill in terms of what a regulated party is required to do under Title I (e.g., remove and dispose of unauthorized PCB-containing materials), then this subsection should not preclude enforcement under Title I for failure to comply with PCB-related rules or orders and this subsection should be limited to asbestos.

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.

appropriate in order to determine whether or not such petition should be granted.

(4) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance w ith this title. If the Administrator denies such petition, the Adminis- trator shall publish in the Federal Register the Administrator's reasons for such denial. The granting or denial of a petition under this subsection shall not affect any deadline or other requirement of this title.

(f) CITIZEN CIVIL ACTIONS WITH RESPECT TO EPA REGULATIONS.—(1) Any person may commence a civil action without prior notice against the Administrator to compel the Administrator to meet the deadlines in section 203 for issuing advanced notices of proposed rulemaking, proposing regulations, and promulgating regulations. Any such action shall be brought in the district court of the United States for the District of Columbia.

(2) In any action brought under paragraph (1) in which the court finds the Administrator to be in violation of any deadline in section 203, the court shall set forth a schedule for promulgating the regulations required by section 203 and shall order the Administrator to comply with such schedule. The court may extend any deadline (which has not already occurred) in section 204(b), 204(c), or 204(d) for a period of not more than 6 months, if the court-ordered schedule will result in final promulgation of the pertinent regulation within the extended period. Such deadline extensions may not be granted by the court beginning 720 days after the date of enactment of this title.

(3) Section 20 of this Act shall apply to civil actions described in this subsection, except to the extent inconsistent with this subsection.

(g) Any contractor who—

(1) inspects for asbestos-containing material in a school, public, ~~or~~ commercial or residential building;

(2) designs or conducts response actions with respect to friable asbestos-containing material in a school, public, ~~or~~ commercial or residential building; or

(3) employs individuals to conduct response actions with respect to friable asbestos-containing material in a school, public, ~~or~~ commercial or residential building;

and who fails to obtain the accreditation under section 206 of this Act, or in the case of employees to require or provide for the accreditation required, is liable for a civil penalty of not more than $5,000 for each day during which the violation continues, unless such contractor is a direct employee of the Federal Government.

(h) Authorization of Appropriations.—There are authorized to be appropriated to carry out enforcement activities under this title not less than $240,000,000 for each fiscal year.

(i) Compliance by States.—In order to receive funds to carry out activities under this title, a State shall be in compliance with the requirements of this title, as determined by the Administrator.

[15 U.S.C. 2647]

SEC. 208. EMERGENCY AUTHORITY.

(a) EMERGENCY ACTION.—

(1) AUTHORITY.—Whenever—

(A) the presence of airborne asbestos or the condition of friable asbestos-containing material or polychlorinated biphenyl-containing material in a school building governed by a local educational agency poses an imminent

Commented [A90]: EPA: This date has already passed.

Commented [A91]: Flag for potential changes

Commented [A92]: EPA: States are not delegated authority under TSCA I to regulate PCBs, so it's unclear how states would be in compliance and receive funding under this provision with respect to PCBs. Is funding limited to states and unavailable to schools or school districts that would inspect/test?

and substantial endangerment to human health or the environment, and

(B) the local educational agency is not taking sufficient action (as determined by the Administrator or the Governor) to respond to the airborne asbestos or polychlorinated biphenyls or friable as- bestos-containing material or polychlorinated biphenyl-containing material,

the Administrator or the Governor of a State is authorized to act to protect human health or the environment.

(2) LIMITATIONS ON GOVERNOR ACTION.—The Governor of a State shall notify the Administrator within a reasonable period of time before the Governor plans to take an emergency action under this subsection. After such notification, if the Administrator takes an emergency action with respect to the same hazard, the Governor may not carry out (or continue to carry out, if the action has been started) the emergency action.

(3) NOTIFICATION.—The following notification shall be provided before an emergency action is taken under this subsection:

(A) In the case of a Governor taking the action, the Governor shall notify the local educational agency concerned.

(B) In the case of the Administrator taking the action, the Administrator shall notify both the local educational agency concerned and the Governor of the State in which such agency is located.

(4) COST RECOVERY.—The Administrator or the Governor of a State may seek reimbursement for all costs of an emergency action taken under this subsection in the United States District Court for the District of Columbia or for the district in which the emergency action occurred. In any action seeking reimbursement from a local educational agency, the action shall be brought in the United States District Court for the district in which the local educational agency is located.

(b) INJUNCTIVE RELIEF.—Upon receipt of evidence that the presence of airborne asbestos or polychlorinated biphenyls or the condition of friable asbestos- containing material or polychlorinated biphenyl-containing material in a school building governed by a local edu- cational agency poses an imminent and substantial endangerment to human health or the environment—

(1) the Administrator may request the Attorney General to bring suit, or

(2) the Governor of a State may bring suit,

to secure such relief as may be necessary to respond to the hazard. The district court of the United States in the district in which the response will be carried out shall have jurisdiction to grant such relief, including injunctive relief.

[15 U.S.C. 2648]

SEC. 209. STATE AND FEDERAL LAW.

(a) NO PREEMPTION.—Nothing in this title shall be construed, interpreted, or applied to preempt, displace, or supplant any other State or Federal law, whether statutory or common.

(b) COST AND DAMAGE AWARDS.—Nothing in this title or any standard, regulation, or requirement promulgated pursuant to this title shall be construed or interpreted to preclude any court from

Commented [A93]: EPA: Again, states are not delegated authority under TSCA I to regulate PCBs, so it's unclear how governors would act to protect health or the environment with respect to PCBs.

Commented [A94]: EPA: With PCBs added to Title II, how do the preemption of PCB provisions under title I interact with this?

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awarding costs and damages associated with the abatement, including the removal, of asbestos-containing material or polychlorinated biphenyl-containing material, or a portion of such costs, at any time prior to the actual date on which such material is removed.

(c) STATE MAY ESTABLISH MORE REQUIREMENTS.—Nothing in this title shall be construed or interpreted as preempting a State from establishing any additional liability or more stringent requirements with respect to asbestos or polychlorinated biphenyls in school buildings within such State.

(d) NO FEDERAL CAUSE OF ACTION.—Nothing in this title creates a cause of action or in any other way increases or diminishes the liability of any person under any other law.

(e) INTENT OF CONGRESS.—It is not the intent of Congress that this title or rules, regulations, or orders issued pursuant to this title be interpreted as influencing, in either the plaintiff's or defendant's favor, the disposition of any civil action for damages relating to asbestos or polychlorinated biphenyls. This subsection does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State law with respect to the admission into evi- dence or any other use of this title or rules, regulations, or orders issued pursuant to this title.

[15 U.S.C. 2649]

SEC. 210. ASBESTOS CONTRACTORS AND LOCAL EDUCATIONAL AGENCIES.

(a) STUDY.—

(1) GENERAL REQUIREMENT.—The Administrator shall conduct a study on the availability of liability insurance and other forms of assurance against financial loss which are available to local educational agencies and asbestos contractors with respect to actions required under this title. Such study shall examine the following:

(A) The extent to which liability insurance and other forms of assurance against financial loss are available to local educational agencies and asbestos contractors.

(B) The extent to which the cost of insurance or other forms of assurance against financial loss has increased and the extent to which coverage has become less complete.

(C) The extent to which any limitation in the availability of insurance or other forms of assurance against financial loss is the result of factors other than standards of liability in applicable law.

(D) The extent to which the existence of the regulations required by subsections (c) and (d) of section 203 and the accreditation of contractors under section 206 has affected the availability or cost of insurance or other forms of assurance against financial loss.

(E) The extent to which any limitation on the availability of insurance or other forms of assurance against financial loss is inhibiting inspections for asbestos-containing material or the development or implementation of management plans under this title.

Commented [A95]: EPA: Is this intended to delegate authority to states to regulate PCBs? States are not delegated authority to regulate PCBs under Title I.

Commented [A96]: Alec – I'm not seeing a need to alter this but let me know

Commented [A97]: EPA: Should this include PCBs/PCB-containing materials?

(F) Identification of any other impediments to the timely completion of inspections or the development and implementation of management plans under this title.

(2) INTERIM REPORT.—Not later than April 1, 1988, the Administrator shall submit to the Congress an interim report on the progress of the study required by this subsection, along with preliminary findings based on information collected to that date.

(3) FINAL REPORT.—Not later than October 1, 1990, the Administrator shall submit to the Congress a final report on the study required by this subsection, including final findings based on the information collected.

(b) STATE ACTION.—On the basis of the interim report or the final report of the study required by subsection (a), a State may enact or amend State law to establish or modify a standard of liability for local educational agencies or asbestos contractors with respect to actions required under this title.

[15 U.S.C. 2650]

SEC. 211. PUBLIC PROTECTION.

(a) PUBLIC PROTECTION.—No State or local educational agency may discriminate against a person in any way, including firing a person who is an employee, because the person provided information relating to a potential violation of this title to any other person, including a State or the Federal Government.

(b) LABOR DEPARTMENT REVIEW.—Any public or private employee or representative of employees who believes he or she has been fired or otherwise discriminated against in violation of subsection (a) may within 90 days after the alleged violation occurs apply to the Secretary of Labor for a review of the firing or alleged discrimination. The review shall be conducted in accordance with section 11(c) of the Occupational Safety and Health Act.

[15 U.S.C. 2651]

SEC. 212. ASBESTOS OMBUDSMAN.

(a) APPOINTMENT.—The Administrator shall appoint an Asbestos Ombudsman, who shall carry out the duties described in subsection (b).

(b) DUTIES.—The duties of the Asbestos Ombudsman are—

(1) to receive complaints, grievances, and requests for information submitted by any person with respect to any aspect of this title,

(2) to render assistance with respect to the complaints, grievances, and requests received, and

(3) to make such recommendations to the Administrator as the Ombudsman considers appropriate.

[15 U.S.C. 2652]

SEC. 213. EPA STUDY OF ASBESTOS-CONTAINING MATERIAL IN PUBLIC BUILDINGS.

~~Within 360 days after the date of the enactment of this title,~~ Not later than 2 years after the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015 and every 10 years thereafter, the Administrator shall conduct and submit to the Congress the re- sults of a study which shall—

(1) assess the extent to which asbestos-containing materials and polychlorinated biphenyl-containing material are present in public, ~~and~~ commercial or residential buildings;

Commented [A98]: EPA: The dates for interim and final reports have passed.

Commented [A99]: There is a TSCA hotline that could cover PCB calls... not seeing a need to change here

Commented [A100]: EPA: Recommend updating this title to include PCB-Containing Material as well as Commercial Buildings. Is the intent to also include residential buildings for PCB-containing equipment, as listed under #1 below?

Commented [A101]: EPA: Where is EPA supposed to get the information that forms the basis of its study? Is EPA supposed to conduct inspections, and if so, is EPA supposed to use its TSCA Section 11 inspection authority to do this assessment?

Commented [A102]: EPA: Seems like "or" should be "and" – wouldn't you want to know the extent in all these building types?

Commented [A103]: EPA: Is it intentional that "residential" was not added in 2-5 below?

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(2) assess the condition of asbestos-containing material and polychlorinated biphenyl-containing material in public or commercial buildings and the likelihood that persons occupying such buildings, including service and maintenance personnel, are, or may be, exposed to asbestos fibers;

(3) consider and report on whether public ~~and/or~~ commercial buildings should be subject to the same inspection and response action requirements that apply to school buildings;

(4) assess whether existing Federal regulations adequately protect the general public, particularly abatement personnel, from exposure to asbestos and polychlorinated biphenyls during renovation and demolition of such buildings; and

(5) include recommendations that explicitly address whether there is a need to establish standards for, and regulate asbestos exposure in, public ~~and/or~~ commercial buildings.

[15 U.S.C. 2653]

SEC. 214. TRANSITION RULES.

Any regulation of the Environmental Protection Agency under title I which is inconsistent with this title shall not be in effect after the date of the enactment of this title. Any advanced notice of proposed rulemaking, any proposed rule, and any regulation of the Environmental Protection Agency in effect before the date of the enactment of this title which is consistent with the regulations required under section 203 shall remain in effect and may be used to meet the requirements of section 203, except that any such regulation shall be enforced under this Act.

[15 U.S.C. 2654]

SEC. 215. WORKER PROTECTION.

(a) PROHIBITION ON CERTAIN ACTIVITIES.—Until the local educational agency with authority over a school has submitted a management plan (for the school) which the State Governor has not disapproved as of the end of the period for review and revision of the plan under section 205, the local educational agency may not do either of the following in the school:

(1) Perform, or direct an employee to perform, renovations or removal of building materials, except emergency repairs, in the school, unless—

(A) the school is carrying out work under a grant awarded under section 505 of the Asbestos School Hazard Abatement Act of 1984; or

(B) an inspection that complies with the requirements of regulations promulgated under section 203 has been carried out in the school and the agency complies with the following sections of title 40 of the Code of Federal Regulations:

(i) Paragraphs (g), (h), and (i) of section 763.90 (response actions).

(ii) Appendix D to subpart E of part 763 (transport and disposal of asbestos waste).

(2) Perform, or direct an employee to perform, operations and maintenance activities in the school, unless the agency complies with the following sections of title 40 of the Code of Federal Regulations:

Commented [A104]: EPA: Please see earlier comment. Additionally, the defined term is for public AND commercial buildings.

Commented [A105]: EPA: But not PCBs?

Commented [A106]: EPA: See earlier comment.

Commented [A107]: EPA: To the extent this applies to PCBs, what do the drafters intend that EPA consider in making this determination? Use of non liquid PCBs is already banned in these buildings. Should EPA consider whether a ban is too strict, and whether a procedure under which LEAs can approve the continued presence of PCBs is therefore more appropriate?

Commented [A108]: EPA: But not PCBs?

Commented [A109]: EPA: As we understand the intent, no existing PCB regulations should be construed as inconsistent with this title (at least until EPA issues any rules under this title requiring removal of PCBs < 50 ppm that are allowed under existing regs). To avoid confusion, it might make sense to limit this section to asbestos.

Commented [A110]: EPA: To the extent title II permits use of PCBs that title I otherwise banned, existing EPA regulations would be inconsistent with Title II and this would leave a gap between enactment (assumed to mean enactment of amended legislation) and issuance of final rules under Title II.

Commented [A111]: Alec – do we need more here for PCBs?

Commented [A112]: EPA: This subsection will prevent LEAs from conducting renovation, removal, operations and maintenance with respect to PCBs unless the asbestos-related requirements identified below are met. In other words, it will prevent them from complying with the currently applicable Title I requirement to remove PCBs from school buildings. Is that the intent?

(A) Section 763.91 (operations and maintenance), including appendix B to subpart E of part 763.

(B) Paragraph (a)(2) of section 763.92 (training and periodic surveillance).

(b) EMPLOYEE TRAINING AND EQUIPMENT.—Any school employee who is directed to conduct emergency repairs involving any building material containing asbestos or suspected of containing asbestos, or to conduct operations and maintenance activities, in a school—

(1) shall be provided the proper training to safely conduct such work in order to prevent potential exposure to asbestos; and

(2) shall be provided the proper equipment and allowed to follow work practices that are necessary to safely conduct such work in order to prevent potential exposure to asbestos.

(c) DEFINITION OF EMERGENCY REPAIR.—For purposes of this section, the term ''emergency repair'' means a repair in a school building that was not planned and was in response to a sudden, unexpected event that threatens either—

(1) the health or safety of building occupants; or

(2) the structural integrity of the building.

[15 U.S.C. 2655]

SEC. 216. TRAINING GRANTS.

Commented [A113]: Flag for potential changes

(a) GRANTS.—The Administrator is authorized to award grants under this section to nonprofit organizations that demonstrate experience in implementing and operating health and safety asbestos training and education programs for workers who are or will be engaged in asbestos-related activities (including State and local governments, colleges and universities, joint labor-management trust funds, and nonprofit government employee organizations) to establish and, or, operate asbestos training programs on a not-for-profit basis. Applications for grants under this subsection shall be submitted in such form and manner, and contain such information, as the Administrator prescribes.

(b) AUTHORIZATION.—Of such sums as are authorized to be appropriated pursuant to section 512(a) of the Asbestos School Hazard Abatement Act of 1984 (20 U.S.C. 4011 et seq.) for the fiscal years 1991, 1992, 1993, 1994, and 1995, not more than $5,000,000 are authorized to be appropriated to carry out this section in each such fiscal year.

[15 U.S.C. 2656]

SEC. 217. DISCLOSURE OF ASBESTOS INFORMATION ON TRANSFER OF REAL PROPERTY.

"(a) In General.—Not later than 1 year after the date of enactment of this section, the Administrator, in consultation with the Secretary of Housing and Urban Development and the Secretary of Health and Human Services, shall issue regulations under this section requiring the disclosure by the seller or lessor of the existence of any known asbestos or asbestos-containing material in a residential or commercial property that is offered for sale or lease.

Commented [A114]: EPA: These are not defined terms. Section 202, as amended in this draft, would define "residential building" and carryover the "public and commercial building" definition.

"(b) Requirements.—The regulations issued under subsection (a) shall require that, before the purchaser or lessee is obligated under any contract to purchase or lease a residential or commercial property, the seller or lessor shall—

"(1) disclose to the purchaser or lessee the presence of any known asbestos or asbestos-containing material in or on the property;

"(2) provide to the purchaser or lessee—

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"(A) an asbestos information pamphlet required under subsection (c); and

"(B) any asbestos inspection available to the seller or lessor; and

"(3) permit the purchaser a 10-day period (or a period of time mutually agreed upon by all parties) to conduct an inspection for the presence of asbestos or asbestos-containing material.

"(c) Asbestos Information Pamphlet.—The Administrator shall develop, publish, make available on the website of the Environmental Protection Agency, and periodically revise an asbestos information pamphlet, which shall—

"(1) contain information regarding the health risks associated with exposure to asbestos;

"(2) contain information regarding the presence of asbestos and asbestos-containing materials, including asbestos-containing building material, in residential and commercial properties in the United States;

"(3) describe the risks of asbestos exposure to occupants of buildings, including the risks of renovation or remodeling in buildings that may have asbestos or asbestos-containing material;

"(4) explain that an inspection for asbestos is recommended prior to purchase, lease, renovation, or demolition of residential or commercial property;

"(5) disclose that certain State and local laws may impose additional requirements related to asbestos or asbestos-containing material, and provide contact information for appropriate Federal, State, and local agencies within each State that can provide information about applicable laws and available resources, including those on websites maintained by the Administrator; and

"(6) provide such other information about environmental hazards associated with residential or commercial property as the Administrator determines is appropriate.

"(d) Asbestos Warning Statement in Contracts for Purchase or Sale.—

"(1) IN GENERAL.—The regulations issued under subsection (a) shall require that each contract for the purchase or sale of residential or commercial property shall contain—

"(A) an asbestos warning statement; and

"(B) a statement signed by the purchaser that the purchaser—

"(i) has read and understands the asbestos warning statement;

"(ii) has received the asbestos information pamphlet under subsection (c); and

"(iii) has received a 10-day opportunity (or a period of time mutually agreed upon by all parties) to conduct an inspection for the presence of asbestos hazards before becoming obligated under the contract to purchase the property.

"(2) CONTENTS.—The asbestos warning statement required under paragraph (1)(A) shall contain the following text printed in bold-face type, no smaller than 12-point font, on a separate page attached to the contract:

"'Each purchaser of any interest in real property on which a residential or commercial building is located is notified that the property may contain asbestos or asbestos-containing materials. Asbestos was used extensively in construction in the United States ~~between 1900 and 1980~~. Asbestos is a hazardous air pollutant associated with several serious health problems for anyone exposed to it. Asbestos that is in good condition and left undisturbed is unlikely to present a health risk; however, if asbestos is damaged or disturbed (which may happen as the building ages and during construction, renovation, and demolition), the asbestos fibers can become airborne, be inhaled, and cause serious health risks (including asbestosis, lung cancer, and mesothelioma). Accordingly, an ~~risk assessment or~~ inspection for possible asbestos hazards is recommended prior to purchase of any building, and buildings known to have asbestos or asbestos-containing materials should be inspected periodically for signs of asbestos damage or deterioration and repaired as necessary by professional inspectors and contractors who are accredited by the Environmental Protection Agency.'.

Commented [A115]: EPA: The 1989 EPA Asbestos Ban and Phaseout rule was overturned and remanded to EPA in 1991 as a result of the Corrosion Proof Fittings case. As such, asbestos use in buildings may have continued beyond 1980. There is no alternative date to offer with no existing ban for most uses of asbestos.

Commented [A116]: EPA: "Risk assessment" is not commonly used in this context, like it is with lead-based paint.

"(3) COMPLIANCE ASSURANCE.—In the case of an agent entering into a contract on behalf of a seller or lessor for the purpose of selling or leasing a residential or commercial property, the regulations issued under subsection (a) shall require the agent to ensure compliance with the requirements of this section.

"(e) Enforcement.—

"(1) PROHIBITED ACT.—It shall be unlawful for any person to fail or refuse to comply with any rule or order issued under this section.

"(2) CIVIL PENALTY.—Any person who violates paragraph (1) shall be subject to a civil penalty in an amount not to exceed $10,000 for each violation.

"(3) ACTION BY ADMINISTRATOR.—The Administrator may take action as necessary to enjoin a violation of a regulation issued under subsection (a).

"(4) PURCHASER AND LESSEE REMEDIES.—A person who knowingly violates a regulation issued under subsection (a) shall be jointly and severally liable to the purchaser or lessee in an amount equal to 3 times the amount of damages incurred by the purchaser or lessee as a result of the violation.

"(5) COSTS.—In a civil action for damages under paragraph (4), the court may award to the party commencing the action court costs, reasonable attorney fees, and expert witness fees, if that party prevails in the action.

"(f) No Effect on Contracts and Liens.—Nothing in this section—

"(1) affects the validity of any sale or contract for the purchase and sale of residential or commercial real property or any loan, loan agreement, mortgage, or lien made or arising in connection with a mortgage loan; or

"(2) creates a defect in title.

SEC. 218. DISCLOSURE OF ASBESTOS INFORMATION ON APPLICATION FOR BUILDING PERMITS.

"(a) In General.—Not later than 1 year after the date of enactment of this section, the Administrator, in consultation with the Secretary of Housing and Urban Development, shall issue regulations under this section for the disclosure of asbestos or asbestos-containing material in any residential or commercial property on any application for a building permit to make any addition, alteration, repair, replacement, or demolition to or of the residential or commercial property.

"(b) Requirements.—The regulations issued under subsection (a) shall require that, before a building permit described in subsection (a) is issued, the State or unit of local government authorized to issue the permit shall provide to the applicant an asbestos information pamphlet required under section 217(c).

"(c) Applications for Building Permits.—The regulations issued under subsection (a) shall require that each application for a building permit to make any addition, alteration, repair, replacement, or demolition to or of any residential or commercial property shall contain—

"(1) an asbestos warning statement under subsection (d); and

"(2) a statement signed by the applicant that the applicant—

"(A) has read and understands the asbestos warning statement;

"(B) has received an asbestos information pamphlet under section 217(c); and

"(C) certifies that, if asbestos or asbestos-containing material is known to be or is discovered in or on the property during the performance of work under the building permit, all work shall cease until the work can be continued by a professional contractor accredited by the appropriate authority in the jurisdiction to handle asbestos safely.

"(d) Asbestos Warning Statement.—The asbestos warning statement required under subsection (c)(1) shall contain the following text printed in bold-face type, no smaller than 12-point font, on a separate page attached to the building permit application:

"'Every applicant for a building permit for a major improvement to or demolition of real property on which a residential or commercial building is located is notified that such property may contain asbestos or asbestos-containing materials. Asbestos was used extensively in construction in the United States ~~between 1900 and 1980~~. Asbestos is a hazardous air pollutant associated with several serious health problems for anyone exposed to it. Asbestos that is in good condition and left undisturbed is unlikely to present a health

Commented [A117]: EPA: Same reason as above

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risk; however, if asbestos is damaged or disturbed (which may happen as the building ages and during construction, renovation, and demolition), the asbestos fibers can become airborne, be inhaled, and cause serious health risks (including asbestosis, lung cancer, and mesothelioma). Accordingly, an ~~risk assessment or~~ inspection for possible asbestos hazards is recommended prior to undertaking major improvements to or demolition of any building. Major improvements to or demolition of any building known to have asbestos or asbestos-containing materials should be performed by professional inspectors and contractors who are accredited by the Environmental Protection Agency.' ".

Commented [A118]: EPA: Same reason as above

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 6:42:51 PM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Sen. Markey TSCA TA on House "Draft in progress" section 5 (4-23)
Attachments: Markey.TSCA TA.House Section 5 (4-23).docx; ATT00001.htm

Michal,
The attached TA responds to the request for big picture review of House section 5 (4-23). Please let me know next steps on 5; we are also reviewing section 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 additional questions. Thanks,

Sven

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

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Saturday, April 23, 2016 12:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Fw: Draft in progress

Sven

See attached.

Please start your review with section 5, which we believe may have been rewritten again. Specifically, we'd like you to pull together your "big picture" comments on section 5 in the way you did the last time. We can decide from there whether it makes sense for you to focus on more granular review of 5 or not.

From there, pls go next to specific edits on 14. When I get in I can send you the line edits on the last HLC 14 that were sent to the House if you feel they would help your review - let me know.

Once we have a chance to look at this we may have different direction, but for now, we think that order makes the most sense.

thanks

M

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

From: McCarthy, David <David.McCarthy@mail.house.gov>

Sent: Saturday, April 23, 2016 12:37 PM

To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)

Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick; Fruci, Jean

Subject: Draft in progress

Attached is the most current draft. We have not yet finished reading it and have not begun discussing it on our side, as several of us are not available to work on it this weekend. Also, it still has some bracketed words and a few questions about provision interactions. Language to amend section 18 is, as the draft says, "to be determined."

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There are significant drafting problems with this amendment to Section 5. In large part, they arise from a drafting strategy that appears intended to preserve 5(e) and 5(f). In addition, significant issues arise from the multiplicity of overlapping categories of risk findings that this draft introduces.

We read 5(a)(1)(B) as establishing a series of alternative conditions for the commencement of manufacture. 5(a)(1)(A) establishes a general bar on manufacturing new chemicals. 5(a)(1)(B) lifts the bar if EPA makes a risk finding and "takes the actions required in association with that determination under such subparagraph." The actions in question are all subject to the proviso under 5(a)(3) that they must occur "[n]ot later than 90 days after receipt of a notice." The review period is itself subject to the proviso of 5(c) that the review period may be extended an additional 90 days.

Conditions for the Commencement of Manufacture

If EPA makes the following risk finding prior to the lapse of the review period (90 to 180 days).	**Manufacture may not commence unless EPA does the following before the review period lapses …**
A. Presents or Will Present	Issues a rule under 5(f)(2) or an order under 5(f)(3)
B. Likely to Present	Issues an order under 5(a)(3)(B)(i) + f(4-8) to ensure not likely to present an UR
C. May Present	Issues an order under (e) (assuming that information is inadequate) If information is adequate, a 5(e) order is not "action[] required" and manufacture may commence automatically.
D. Likely Not to Present	Issues a notice of the finding
E. Low Hazard	Issues a notice of the finding
F. No risk finding	Manufacture simply cannot commence. EPA needs to review a re-submitted PMN

As an initial matter, Findings B and D are opposites of each other, so they seem to occupy the entire field of possibilities. The other findings (especially "May Present") appear to be overlapping in coverage. For these reasons, it will often be unclear which of the risk levels corresponds to the appropriate finding. Moreover, the overlaps that appear to exist introduce significant flexibility for different policy objectives to play a substantial role in determining which levels of risk receive which risk findings. For example, the same chemical substance could receive either a may present or a likely not to present, which would lead to different outcomes in terms of the existence of any restrictions.

Under current TSCA, sections 5(e) and 5(f) describe actions to *block* manufacture, which EPA would undertake before the 90-180 day review period expires. Retaining the basic structure of 5(e) and 5(f) from current TSCA is likely to present difficulties if they are being repurposed into *pre-requisites* for manufacture. Here are some examples of the sorts of structural problems that arise:

- 5(e) orders are premised on EPA making a finding that "the information available [to EPA] is insufficient to permit a reasoned evaluation." If EPA makes a may present finding based on adequate information, EPA cannot and need not issue an order under (e), since inadequate information is one of the prerequisites for a 5(e) order. Therefore, manufacture can commence without any restriction. Paradoxically, if EPA makes a may present finding based on inadequate information, then manufacture is blocked until EPA issues a 5(e) order.
- The complex order and injunction procedures of (e) and (f) (i.e., for the issuance of administrative orders and the subsequent referral to federal court if the administrative orders are challenged) doesn't fit with the new framework of 5(a)(1)(B) (i.e., the restriction is what allows manufacture to proceed). For example, if a manufacturer objects to EPA's 5(e) order, the order wouldn't take effect, because of 5(e)(1)(C). Wouldn't that mean that EPA has not taken "applicable action under subsection (e)" and that manufacture is now wholly blocked? Would the manufacturer then need to then apply to district court to have a judge issue a 5(e) order so that manufacture could proceed?
- It is difficult to see how EPA could ever issue a timely 5(f)(2) rule, under 6(a), given that EPA would need to take action within 180 days of receiving the notice and would not have completed a safety evaluation.
- If EPA makes a determination that a chemical substance presents or is likely to present an unreasonable risk, then 5(f)(6) imposes certain analytical requirements to consider cost and limit the forms of risk management that are available (i.e., to just those described in 6(a)). Paradoxically, neither of these restrictions apply if EPA finds makes the lesser risk finding of "may present." This could produce a disincentive to make the higher-level risk findings.

The operation of the "Prohibition" paragraph at 5(f)(4) is also extremely unclear in the context of 5(a)(1)(B). It seems to specifically prohibit commencement except in compliance with the restrictions established by rule under 5(f)(2). Is the implication that if EPA issues a 5(f)(3) <u>order</u> then no manufacture may commence? Or that manufacture may commence but not necessarily in compliance with the 5(f)(3) order? Along similar lines, it is unclear how 5(f)(4) operates when it is being applied to a risk management order under 5(a)(3)(B)(i) [recall that these orders need to be issued along with action under 5(f)(4). As a general matter, it seems unnecessary to specify that manufacture cannot proceed except in compliance with certain orders or rules that are already binding by their own terms, and that are already pre-requisites for the commencement of manufacture under 5(a)(1)(B). Also, because this provision makes no reference to 5(e), it suggests that perhaps manufacture can generally proceed if EPA makes a "may present" finding but takes no follow-on risk management action.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 6:17:38 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Chem ID
Attachments: Markey.TSCA TA.ChemID CBI claims.4-12.docx

Michal,
This TA responds to the request on CBI and Chem ID.

As a general note, the ideas you are exploring on this issue would likely result in less transparency of chemical information as compared to current law. This is something that the Administration has flagged in its 2009 Principles: TSCA reform should include "stricter requirements" for a manufacturer's claim of CBI and "data relevant to health and safety should not be claimed or otherwise treated as CBI." Outside of the limited circumstances mentioned, EPA does not typically consider chemical identity in a health and safety study to be entitled to confidential treatment. Any expansion of these circumstances could be viewed as contradictory to the Principles.

That being said, we have attached some information on the statistics you requested, as well as an additional drafting suggestion that would improve (but not eliminate) the transparency issues.

> (2) (A) Subject to (2)(B), the specific identity of a chemical substance that is the subject of a health and safety study that satisfies the conditions of (1)(A) shall not be disclosed, if such chemical identity is otherwise eligible for protection under this section, unless the Administrator initiates a risk evaluation on the substance under Section 6(b), the Administrator determines under section 6 that a chemical substance presents or will present an unreasonable risk of injury to health or the environment, or the Administrator initiates an action with respect to the chemical substance under section 7(a).
>
> (B)(i) The duration of protection for the specific identity of a chemical substance described in (2)(A) and the renewal of such protection shall be governed by section 14(e), except that the duration of protection shall be 5 years.
>
> (ii) The Administrator may, in limited circumstances, review a claim for protection of the identity of a chemical described in (2)(A) if the Administrator determines that disclosure of such specific chemical identity would assist with the identification or remediation of an environmental hazard or exposure, or the diagnosis or treatment of an adverse health effect, that might be caused by the chemical substance.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

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

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 11, 2016 at 9:23:03 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Chem ID

Sven

Getting back to this question from a different direction – your TA below says that there is a 3rd basis for withholding chemID from HS: "where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study."

We have the pre-NOC exclusion in current senate 14

> (i) The specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5.

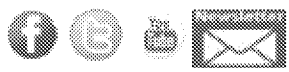
I am wondering if "if the specific identity is not necessary to interpret the HS study" is something that I should be exploring in addition to the other ideas for inclusion alongside process and concentration/proportion. To that end, is there an easy way that you could provide me with some statistics/#s along the following lines (approximate #s ok)

1- How many chemID CBI claims are there generally? Per year?
2- How many chem IDs are withheld (both generally and per year) from HS studies because releasing would reveal
    a. Process
    b. Concentration/proportion
    c. Pre-NOC AND info not necessary

If this is impossible to figure out in a quick timeframe let me know and maybe we can figure out some other way to answer my question, which is, generally, "what is the actual impact of adding the specific identity is not necessary to interpret the health and safety study" under this EPA's practice.

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: Saturday, April 09, 2016 12:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Chem ID

Michal,
This TA responds to the request on chem ID.

Your two emails seem to be asking questions in different directions: the first seems to be asking whether another basis could be added for allowing the withholding of chem id *in health and safety studies* (presumably something industry would want), and the second seems to be asking the very different question of whether there should be more stringent expiration or voiding conditions for chem id *outside the context of health and safety studies* than for other CBI (presumably something the NGOs would want).

Re your first question: although the statute allows for withholding of chem ID (or other info) in health and safety studies only on two bases (reveals process information of proportions of a mixture), EPA regulations allow withholding of specific chem ID on a third basis: where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study. That kind of provision could be codified in the bill.

Re your second question: The idea sounds like a beefing up of sec 14(c)(3) of the Senate offer, which presumptively voids CBI claims for chem ID and other information elements following a ban of a chemical. The triggering event for that provision could be moved up to the finding of unreasonable risk.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 11:20:40 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on ChemID

As part of your thought process here, and perhaps as an alternative option, let's think about a way where if chemID is kept CBI it goes public if a) epa makes a section 6 or 7 unreasonable risk finding about it and b) it has to be re-substantiated every 5/10 years with reasonable potential of an unreasonable risk being one of the things EPA has to consider.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations
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255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

On Apr 9, 2016, at 5:40 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:
Good morning

We increasingly hear that "molecular structure" is a huge threshold issue for the House. It is for us too. I'm trying to learn more about the history here and also see if there exists middle ground - something akin to a 3rd condition for when chemID is withheld, like "keep molecular structures secret if X or Y, or unless X or Y". I'm not sure if a space like this exists for either side, but thought perhaps looking towards the recent decisions by EPA on why it did or did not release molecular structure could be useful.

Can you put together background materials or suggestions if you have any? Doesn't have to be before 1, but would be helpful if it was before 5 or 6 pm so I can review tonight as part of some of the other prep work I'm planning.

Thanks
Michal

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

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.

TA on Chem ID CBI Claims

1- How many chemID CBI claims are there generally? Per year?

We looked at 2012, where figures are available for a broad range of submission types. Overall, we received 1117 documents with CBI claims for chemical identity out of a total of 1879 documents, so about 59% of these documents had chemical ID claimed as confidential.

Certain other figures:

- For 2012 CDR reporting, 550 chemical IDs were claimed as CBI out of a total of 7666 unique chemical IDs reported (about 7%).

- In 2007, when we required reporting on certain chemicals under TSCA section 8a and 8d, for 8a, 3/169 submissions (about 4%) had chem ID claimed as confidential, and for 8d, 5/49 submissions (about 10%) had chem ID claimed as confidential.

2- How many chem IDs are withheld (both generally and per year) from HS studies because releasing would reveal

a. Process

b. Concentration/proportion

c. Pre-NOC AND info not necessary

This information is not available.

If this is impossible to figure out in a quick timeframe let me know and maybe we can figure out some other way to answer my question, which is, generally, "what is the actual impact of adding the specific identity is not necessary to interpret the health and safety study" under this EPA's practice.

It's very difficult to estimate the impact of this in the existing chemicals world. In the new chemicals program, where this provision exists in regulation, we had for other reasons looked at the question for PMNs submitted from 2006 to 2010. Of the approximately 3600 PMNs received, about 500 included health and safety studies (14%). Chemical ID was claimed and protected in 380 (76%) of those 500. We would guess that the percentage for health and safety studies on existing chemicals would be significantly lower than for chemicals which have not yet been commercialized, but I couldn't say how much lower. Also, industry may make more CBI claims in the future for existing chemical health and safety studies if they know they are likely to be upheld.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/30/2016 12:25:39 PM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Sen. Markey TSCA Inquiry on Section 14(f)(2)(A)(iv)

Michal,

This TA responds to the request on section 14(f)(2)(A)(iv).

Question: If [Section 14(f)(2)(A)(iv)] was deleted, would EPA still retain its discretionary authority to review CBI claims in the manner it currently does (ie, the example given in past TA was when disclosure of CBI might be useful to get better public comments on proposed rules etc)? Would EPA be able to, for example, review a. CBI claim of a company making a chemical substitute for a chemical EPA was planning to ban, in order to get more information about that substitute during the rulemaking process?

Response: EPA believes the deletion of Section 14(f)(2)(A)(iv) has the potential to impair EPA's authority to disclose information claimed as CBI as part of development of a rule. This potential impairment would arise largely from the decision to delete the provision from the Senate bill as passed, since it would likely be argued that that decision was intended to have some effect.

Had the provision never been in the Senate bill, we do not think its absence would significantly impair EPA's authority to disclose information claimed as CBI as part of development of a rule, for two reasons:

<!--[if !supportLists]-->1. <!--[endif]-->Although section 14(f)(2)(A) identifies situations in which EPA "may" *review* CBI claims, section 14(i) limits EPA's authority only with respect to imposing *substantiation or re-substantiation* requirements. Thus, EPA would likely take the position that the list of bases for review in section 14(a)(2)(A) is not exclusive, and that EPA has inherent authority to conduct internal reviews of CBI claims. (Again, such an argument would be undercut if (iv) were dropped from section 14(a)(2)(A), unless the deletion were accompanied by a very clear explanatory statement in the conference report that acknowledges that EPA already has general authority to review CBI claims, even without 14(f)(2)(A)(iv), and that Congress simply removed redundant verbiage.)

<!--[if !supportLists]-->2. <!--[endif]-->Even if Section 14(f)(2)(A)(iv) limits EPA's authority to review claims, section 14(e)(7) of the bill authorizes EPA to disclose CBI where "relevant in a proceeding under the Act". Although EPA would be required to preserve confidentiality to the maximum extent practicable without impairing the proceeding, EPA would have discretion to determine how much disclosure is needed to avoid impairing the proceeding.

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 24, 2016 12:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 14(f)(2)(A)(iv)

Sven

If this was deleted, would EPA still retain its discretionary authority to review CBI claims in the manner it currently does (ie, the example given in past TA was when disclosure of CBI might be useful to get better public comments on proposed rules etc)? Would EPA be able to, for example, review a. CBI claim of a company making a chemical substitute for a chemical EPA was planning to ban, in order to get more information about that substitute during the rulemaking process?

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: 4/14/2016 9:48:20 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on PBTs

Michal – whoops – obviously we got the TA and I'm circulating. 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: Thursday, April 14, 2016 5:47 PM
To: 'Freedhoff, Michal (Markey)' <Michal_Freedhoff@markey.senate.gov>
Subject: Sen. Markey TSCA TA Request on PBTs

TSCA team – please see Michal's request on PBTs. Thoughts? Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 14, 2016 5:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Pbts again

Dimitri doesn't like the para 4 and 5 stuff on fixing the unreasonable risk piece. He says can't do a UR finding w"o an RE. Proposes that the text in 6(a) that used to just say "identified under the PBT section" could instead say "or, in the case of a PBT identified in the PBT section, the risk posed by the PBT " or something like that? I am in w them now and can't talk by phone but figured you can start people thinking.

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: 4/27/2016 1:45:24 PM
To: McCarthy, David [David.McCarthy@mail.house.gov]
Subject: HEC TSCA TA Request on section 5 and 8

Dave,
We are working on the TA requests on section 5 and 8 now and will have something for you later this afternoon. Please let me know if any updates or 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: 4/23/2016 4:46:19 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA request on Draft in progress (4-23)

Michal,
Got it, along with the priorities. Thanks,
Sven

On Apr 23, 2016, at 12:43 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

See attached.

Please start your review with section 5, which we believe may have been rewritten again. Specifically, we'd like you to pull together your "big picture" comments on section 5 in the way you did the last time. We can decide from there whether it makes sense for you to focus on more granular review of 5 or not.

From there, pls go next to specific edits on 14. When I get in I can send you the line edits on the last HLC 14 that were sent to the House if you feel they would help your review - let me know.

Once we have a chance to look at this we may have different direction, but for now, we think that order makes the most sense.

thanks
M

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

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Saturday, April 23, 2016 12:37 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick; Fruci, Jean
Subject: Draft in progress

Attached is the most current draft. We have not yet finished reading it and have not begun discussing it on our side, as several of us are not available to work on it this weekend. Also, it still has some bracketed words and a few questions about provision interactions. Language to amend section 18 is, as the draft says, "to be determined."
<2016_02_xml.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/29/2016 11:00:51 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA - section 5 restrictions and inclusions
Attachments: Markey.TSCA TA.Section 5 Restrictions and Inclusions.docx

Michal,
The attached technical assistance responds to your request on section 5 restrictions and inclusions.

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 23, 2016 5:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA - redrafted section 5

For starters:

On the question of restrictions under section 5 – there is a desire by some to maintain the existing 697 list of restrictions rather than cross-referencing the 6(a) list, which as you point out is itself also more narrow than current authority. Can you point to times EPA has taken action related to a new chemical that it would not be able to take under S 697 as reported? What about under the 6(a)list?

michal

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

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.

TA Request:
On the question of restrictions under section 5 – there is a desire by some to maintain the existing 697 list of restrictions rather than cross-referencing the 6(a) list, which as you point out is itself also more narrow than current authority. Can you point to times EPA has taken action related to a new chemical that it would not be able to take under S 697 as reported? What about under the 6(a) list?

EPA Response:

The existing list of "inclusions" for new chemicals risk management (found in Senate 5(d)(4)(C)) is unnecessary in light of EPA's general authority under 5(d)(4)(A) to "prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal" of the chemical substance.

EPA would take the position that the sorts of actions it had previously taken under current TSCA 5(e) would also be authorized under the 5(d)(4)(C) list from the Senate bill. However, Courts might be disinclined to accept an interpretation that the addition of 5(d)(4)(C) was inoperative. Furthermore, there are drafting quirks in Senate 5(d)(4)(C) that some might argue deprive EPA of authority to:

- Require labeling of articles manufactured with new chemicals. (Current TSCA refers to labeling of articles containing a chemical substance, § 6(a)(3), yet Senate § 5(d)(4)(C)(i) drops the article reference.)
- Impose restrictions on the disposal of articles containing new chemicals. (Current TSCA refers to disposal of articles containing a chemical substance, § 6(a)(6)(A)), yet Senate § 5(d)(4)(C)(iv) drops the article reference.)
- Regulate the "manner," as opposed to a "method" of commercial use or disposal. (Current TSCA refers to "manner or method" in § 6(a)(5) and § 6(a)(6)(A), yet 5(d)(4)(C)(iv) refers only to "method.")

EPA is not aware of situations in which it has taken one of these actions with respect to a new chemical.

A cross reference to the text of TSCA 6(a) under current law would avoid the particular problems noted above, but introduce other ambiguities about the scope of EPA's authority. Section 5(d)(4)(A) would give EPA broad authority to restrict the manufacture, processing, or distribution in commerce of a new chemical substance. But some might argue that a cross reference to current section 6(a) limits 5(d)(4)(A) to the scope of section 6(a). And if so, it is unclear whether the authority under 6(a)(1) and (2) to "prohibit" manufacturing, processing, or distribution includes the authority to *regulate* manufacturing, processing, or distribution, if the requirement is something short of an outright ban.

EPA has issued a number of section 5(e) orders with provisions that a litigant might argue are impermissible under the section 6(a) list. For example, a number of section 5(e) orders have barred or regulated discharges to water incidental to manufacturing, or required that workers employed in manufacturing use personal protective equipment.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/4/2016 1:58:00 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Sen. Udall TSCA TA Request on section 4

Okay – thanks. Also, I meant section 14, not 19

Sven-Erik Kaiser
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202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 04, 2016 9:49 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Udall TSCA TA Request on section 4

Given that this is planned for sending over to the House, I think it makes sense to have folks review. My understanding is that you were reviewing this version of 4 and nomenclature. Things may have been cleaned up for sharing with the House, which could explain the size and fonts.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 04, 2016 9:47 AM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Sen. Udall TSCA TA Request on section 4

Jonathan – that is not exactly the same section 4 that we are looking at. It has a different title and file size is different. I'm not sure what the substantive differences are, if any. I will send this version to EPA reviewers. Also, do you want TA feedback on the section 19 changes? Thanks,
Sven

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

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 04, 2016 9:34 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Responses to HLC

FYI...

I believe you are reviewing this version of Sec. 4.

Saw the Sec. 14 TA and hope that what was done here addresses the concerns.

From: Karakitsos, Dimitri (EPW)
Sent: Sunday, April 03, 2016 5:59 PM
To: Jackson, Ryan (Inhofe) <Ryan_Jackson@inhofe.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Albritton, Jason (EPW) <Jason_Albritton@epw.senate.gov>
Subject: Responses to HLC

All,

Attached are some responses to the documents the House provided us on Friday that are designed to fix some issues flagged in those drafts that moved away from Senate concepts. This incorporates the comments Michal sent around as well as updated EPA TA. We plan to send the House these documents which are not only comments to the current drafts they sent us, but also revised 4, 14, and sections of 8.

Happy to discuss anytime or answer questions.

Dimitri

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 5:01:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Quick q section 5

Michal – got it - 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: Tuesday, April 12, 2016 12:59 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick q section 5

There is a concern that 3(A) lead in does not account for the extension review.

Would this work?

(3) Within 90 days of receipt of a notice under paragraph (1), or of receipt of information submitted pursuant to subsection (b) or (e) that the Administrator finds sufficient to support the determination under subsection (a)(3)A), and subject to any extensions of such review period pursuant to subsection (c) or (e), ~~Before the end of the applicable period for review under paragraph (1),~~ and subject to section 18, the Administrator shall review a notice received under paragraph (1) and— …
?

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: 3/30/2016 12:21:11 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on partial risk evaluations

Got it - thanks

On Mar 30, 2016, at 4:55 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

What is the timeframe for proposed rules on TCE, MC and NMP?

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

From: Kaiser, Sven-Erik
Sent: Friday, March 25, 2016 8:51 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA on partial risk evaluations

Michal- The 5 referenced partial risk evaluations were TCE, NMP, MC, ATO and HHCB. EPA found no concern for ATO (Antimony Trioxide) and HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[γ]-2-benzopyran). 1-BP is a draft risk assessment, and was not included in the count. See EPA's website on TSCA Work Plan Assessments:

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.

Please let me know if any additional questions. Thanks,

Sven

On Mar 25, 2016, at 7:51 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sorry, one last thing on this - you originally listed these chemicals as the subjects of these RES. But I thought in other TA you said there were 5. What is the 5th?

TCE, NMP, MC, and 1-BP.

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

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 6:48 PM

To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,
The attached TA responds to the request on partial risk evaluations. 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)" <Michal_Freedhoff@markey.senate.gov>
Date: March 22, 2016 at 10:02:12 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on partial risk evaluations

Would this do it for you? I don't think a discussion about what you add below re cost considerations would be a constructive one. I am not sure that this works to address your concern re rules/deadlines though.

(3) (A) PRIOR-INITIATED EVALUATIONS[A1] .—

(i) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation or partial risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under this Act[A2] .

(ii) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As relevant policies and procedures under this Act are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing risk evaluations.

(B) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation or partial risk evaluation, determination or rule solely because the action was completed prior to the completion of a policy or procedure established under this Act.

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
<image002.png><image003.png><image004.png><image005.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, March 21, 2016 6:25 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,
This TA responds to your request on partial risk evaluations. Please let me know if any questions. Thanks, Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Response: EPA has completed risk assessments for 5 chemicals under the TSCA Workplan process. Those assessments only consider risk. There is no cost consideration. 3 of the chemicals have high risk and are moving to the risk management phase. We are developing proposed rules. As required by TSCA we will balance costs and benefits (the value of risk reduction) and identify the least burdensome means to reduce the risk. We are scheduled to propose rules for these three chemicals later this year.

The risk assessments for all three of these chemicals had narrow scopes. We did not look at all uses of the chemicals as would be required under both House and Senate passed bills. We assume that if a bill passes

before we finalize these rules we would need to finalize them using the new rulemaking standard in the law. But because the risk assessments were done without consideration of costs, we would not need to redo the work for the uses which have already been assessed.

The issue we are flagging is that meeting the scoping intent of either bill would require a significant amount of additional work on these three chemicals to assess the uses that were not included in our final assessments. That could delay regulation of the uses with known risks. Modification of the cost considerations would take a little time but much less as the cost considerations under the current law are more onerous than either the House or Senate bills. If the Senate or House bill passed as drafted we would likely call these three chemicals high priority and make an argument that we can go forward with the narrower scoped regulations using the new standard. There is some legal vulnerability that we'd be prevented from doing so. Because the rulemaking deadlines in 6(c)(1) begin to run once EPA deems a chemical unsafe, EPA would be on a tighter time clock (4 years, as opposed to 3 years + 4 years) to both complete the risk evaluations AND any associated rulemakings with respect to other uses not part of the original evaluation. It is not clear to us whether those additional uses have risk. In the alternative, we could identify these three chemicals as high priority and then assess the additional uses before moving to risk management. The down side is that we would know there was risk for certain uses of these chemicals but we would be waiting to assess the remaining uses before doing any risk management.

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, March 20, 2016 11:16 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Questions on partial risk evaluations

Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Thanks - just trying to figure out what to do with this and how to draft it etc. Not a weekend thing for you guys!

M

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

EPA TA – needs clarifying to ensure section 6 activities can proceed as intended

EPA TA here and below

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/17/2016 10:15:32 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Udall TSCA TA request on Byproducts Reporting

Thanks

On Apr 17, 2016, at 6:14 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Section 8(a) is amended by adding the following new paragraph:

(A) The Administrator shall enter into a negotiated rulemaking [pursuant to 5 U.S.C. §§ 561-570] to develop and publish, not later than 180 days after enactment, a proposed rule providing for :the limiting of reporting for any inorganic byproducts which are subsequently recycled, reused or reprocessed, including by any other person;

(B) No later than three years from the date of enactment, the Administrator shall publish a final rule resulting from such negotiated rulemaking.

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 17, 2016 6:12 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA request on Byproducts Reporting

Jonathan, the first letters if each line are cut off. If possible, please adjust margins and resend. Thanks,
Sven

On Apr 17, 2016, at 5:55 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Concerns from epa?

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

From: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>
Sent: Sunday, April 17, 2016 5:50 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: FW: Byproducts Reporting

<Conference Amendment.docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/26/2016 10:56:31 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on Low-Priority Designations

Michal – perhaps we should have a call to discuss our thinking on possible TA on this. Any time available tomorrow – perhaps not first thing as we're still pondering it ourselves. 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, April 26, 2016 6:31 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on Low-Priority Designations

Excellent. ☺ so you're ok with "not likely" but not with "likely not"? if that is the case can you pls put it in the TA discussed? I think they may have been working on a redline to the word document we sent the House, right?

Is your TA on 5 likely to change materially?

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, April 26, 2016 6:29 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on Low-Priority Designations

Michal,
Upon a closer examination of the bill text (and in reviewing our TA on House's Section 5 language), we noticed a potential issue in Section 6 related to low priority designations. As currently written, "likely not to present an unreasonable risk of injury" could be read to mean that any chemical with less than a 50% chance of presenting an unreasonable risk would be a low priority. We understand that the intent was for the low priority category to be something with a much lower chance of risk. If so, it may be useful for us to reconnect on this issue.

Also, heads up that we are working on the section 6 cost language TA that we discussed today and expect to have it for you tomorrow.

Please let me know if any questions. Thanks,
Sven

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 1:34:21 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Got it- thanks

On Apr 10, 2016, at 9:30 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

And then I guess associated question is if you're ok w the language in House 26 in this section and the way HLC wrote what used to say "this section"

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 9:28 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Michal- got it- checking. Thanks,
Sven

On Apr 10, 2016, at 9:28 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

If we move the section 6 guidance for how manufacturers do their own RES to EPA into section 26, have we solved the problem?

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

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 9:24 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA follow up on section 6/26

Michal,
This TA responds to the request on section 6 and 26.

We'd need to see the full current draft of Section 6 and 26 to give definitive TA, but it seems that (3) is unproblematic. It is not referring to any procedures that EPA needs to develop. Similarly, (4) is unproblematic, assuming that neither (1) nor (2) is referring to policies, procedures, or guidance that EPA needs to develop.

If the language in section 26 is only preserving EPA's ability to proceed in advance of any policies/procedures/guidance developed pursuant to section 26, then the retention of a direction to develop a guidance document pursuant to section 6 (i.e., regarding how outside parties should develop draft risk assessments) is potentially problematic. By specifically not mentioning this guidance document generation

obligation, Section 26 could be the basis of an argument that Congress believed that a failure to timely prepare this specific type of guidance document might indeed be grounds to defer work on safety evaluations.

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: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 7:06:01 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: follow up on section 6/26

This is the only guidance/policies/practices language that is left in section 6. Is your section 26 Act vs section concern resolved knowing this
GUIDANCE.—
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 develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator, The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

(3) PROCEDURES.—When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) promulgate a final rule based on the matter in the rulemaking record and (D) make and publish with the rule the determination described in subsection (a).

4) APPLICATION.—Paragraphs (1), (2) and (3) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/10/2016 9:08:49 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Prioritization

Michal,
Didn't see a smiley face there so I think you mean it. Will alert the team. 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, March 10, 2016 4:01 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: TA request - House fees

And I need all my stuff accelerated as well. Thx.

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

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 4:00 PM
To: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Deveny, Adrian (Merkley)
Subject: RE: TA request - House fees

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: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 10, 2016 3:56 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Re: TA request - House fees

Would also like to elevate the house ta request from earlier. Possible to get response for tomorrow?

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

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 3:53 PM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: RE: TA request - House fees

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: Thursday, March 10, 2016 3:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - House fees

Sven

House fees language basically says that a fee collected under section 4 can only be used for section 4 activities, and so forth. Does EPA have any workability or other concern associated with this provision?

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: 4/23/2016 4:21:22 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on section 6 TA - House R language- followup

Michal,
This responds to the followup question on section 6- House R language.

You're right. We had not taken account of the conforming changes at the end.

That still leaves unresolved the issue we described, though, which is that section 4 as revised per HLC would contain no direction as to whom EPA can require to test when it acts under the new (a)(2) authority, and the solutions we suggested would work to address that issue.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753
From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 23, 2016 at 11:57:32 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on section 6 TA - House R language- followup

Are you assuming that 4(b) and 4(c) apply only to rules for a reason? Is it possible you're not looking at the conforming edits (which HLC puts at the end of the bill)? I believe there's only one part of 4 that isn't for rules orders and CAS, and I believe it is that section (maybe 4b3) that you pointed out would require epa to notify every single manufacturer or processor every time you did a test rule if we applied that section to rules and orders.

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

From: Kaiser, Sven-Erik
Sent: Saturday, April 23, 2016 11:54 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 6 TA - House R language- followup

Michal,
This TA responds to the followup request on section 6 TA- House R language.

The solution to the section 6 issue, as you suggest, is straightforward: simply delete the reference to section 4 added in HLC to section 6(a)(1)(G). That would conform the text to current TSCA. With this reference gone, EPA would most likely interpret the new authority in section 4 -- allowing EPA to require testing as necessary to ensure compliance with a section 6(a) rule -- as providing *additional* authority to require testing beyond what is required in a section 6 rule -- for example, to address unforeseen circumstances that arise during implementation.

The section 4 issues could be addressed in various ways, depending on the desired outcome. Under the latest HLC, the requirements of 4(b) and 4(c) apply only to rules, not to orders or consent agreements. These would apply regardless of whether the rule was issued under the "old" may present/substantial production bases, or under one of the "new" bases (eg, to implement section 6 rules, for prioritization). Thus, the specification of standards and protocols, the requirement to reduce use of vertebrates, the specification of who must test, and the provisions regarding the reimbursement period and testing exemptions would apply only to rules, not orders. This does not necessarily present an issue or concern, with the exception of the "who is required to test" provisions (4(b)(3)).

Per earlier TA, these provisions prescribe who must test based on the finding made by EPA in imposing testing under existing TSCA 4(a). Because EPA will not make those findings for a test rule under the new authority -- and because orders and consent agreements under the new authority will not be subject to these provisions at all -- the law would provide no guidance as to whom EPA can impose testing obligations on under the new authority. This could create implementation issues for rule and orders, since it could be argued that Congress should specify whom EPA can impose obligations on. (It should not create an issue for consent agreements, since they are consensual.)

Here are two possible solutions:

1. Strike 4(b)(3) and insert: "A rule or order under subsection (a) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would be the simplest approach from an implementation perspective, in that it gives EPA authority in any test rule or order to impose test requirements on the manufacturers and/or processors that are most suited to conduct the testing.

2. Another approach involving less textual change would be to retain the existing 4(b)(3) but add a (C) as follows: "(C) A rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would require several minor conforming changes to (b)(3), which we could provide if you are interested in this approach. This approach would maintain the existing allocation of testing responsibilities under TSCA for rules under the "old" authority but add direction for rules and order under the "new" authority. Under either of these approaches, "rule" should be stricken from the title of (b).

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: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 23, 2016 at 5:15:41 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on section 6 TA - House R language

Thanks - is there a way to address?
In 6a I assume it would be to remove the language
In 4, I believe you've said in the past that the language in question doesn't work for orders/consent agreements.

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

From: Kaiser, Sven-Erik
Sent: Friday, April 22, 2016 4:47 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 6 TA - House R language

Michal,
This TA responds to the request on section 6 TA followup on House R language.

Section 4 requires a statement of need for testing, requires a tiered approach, and requires identification of protocols and methodologies. Those are certainly manageable in the context of a section 6 rule, but they impose some requirements that otherwise would not be imposed in section 6. There also may be some difficulty in applying the provisions in 4(b)(4) regarding expiration of the reimbursement period, since the section 6 rule may not have a fixed testing requirement or period for testing but rather may have a more open ended obligation to conduct testing under circumstances specified in the rule. But these issues should be manageable.

The potentially more substantive issue is that the latest HLC version of section 4 we have seen does not provide any guidance on who can be made to test in a test rule or order under the new 4(a)(2) authority. But this is an issue with section 4 itself, and not unique to the incorporation of section 4 into section 6. TSCA 4(b)(3) requires that each test rule impose testing obligations on all manufacturers of the chemical substance, or all processors, or both, depending on which 4(a)(1) finding EPA makes to support the rule (may present, or substantial production/release/exposure). Specifically, it provides that "the following persons [all manufacturers and/or all processors] shall be required to conduct tests and submit data on a chemical substances or mixture subject to a rule under 4(a). . . .", and then lays out whether the entities required to test are the manufacturers or processors or both, depending on which 4(a)(1) finding was made. Because EPA will

not be making one of these findings under 4(a)(2), the current 4(b)(3) is not a great fit, since it assumes that one of those findings will have been made to support each test rule.

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

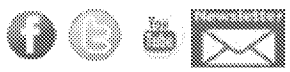
From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 22, 2016 1:50 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: question on your 6 TA from last night

1 (G) by striking "and monitor or conduct
2 tests" and inserting "or monitor or conduct
3 tests pursuant to section 4" [A1] in paragraph (4);
4 and

This was a House R request. What additional requirements will those be? btw, Senate agreed to add test orders to 4(a)(1) yesterday.

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



EPA TA: This will suggest that EPA must follow any applicable section 4 requirements, as well as section 6 requirements, in imposing test requirements.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/7/2016 4:05:27 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on section 6 - replacement parts

Michal – no attachment. Our response was at the bottom – repasted here. We are confused about why Senate offer 6(c)(2)(C doesn't work. Thanks,
Sven

Response: We would have thought an approach along the lines of Senate offer 6(c)(2)(C) would solve the problem:

> (C) The Administrator shall exempt replacement parts [designed] prior to the effective date of the rule for articles that are first manufactured prior to the effective date of publication in the Federal Register of the rule unless
>
> (i) the Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to potentially exposed or susceptible populations; or
> (ii) the replacement part is a component of an article that is reasonably expected to be used by children aged 12 years of age and younger.

We are unclear why this doesn't work – whether a lack of reception or something else. Can you give more insight into the problem?
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, April 07, 2016 12:01 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA request on section 6 - replacement parts

Not seeing anything on my phone here - was there a word attachment?

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

From: Kaiser, Sven-Erik
Sent: Thursday, April 7, 2016 11:57 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 6 - replacement parts

Michal – this TA responds to the request on replacement parts.

Request: A proposal is being floated as a potential solution to the replacement parts/designed by provision that would limit the provision's application to parts that are components of "durable goods" which is "Durable goods," is a widely used term - adapted from 16 C.F.R. 802.1(d)* A good is "durable" if it is designed to be used repeatedly and has a useful life greater than one year.

I don't think this works as is – it may address a sub-set of the kid/infant products I've expressed concerns about, but doesn't address the couch seat cushion covers for obvious reasons.

But I am wondering whether there exists anything in regulation or SNUR/article precedent that your team can think up? we did work through some language months ago that related to the difficulty of re-designing articles of which the parts were a component, but that language was not accepted. I may tinker with it more as well, but in the meantime, can your team think of anything they've done before, even if not in the TSCA context, that would define a universe of articles/parts it applied to in a manner that limits/excludes some and keeps others?

Response: We would have thought an approach along the lines of Senate offer 6(c)(2)(C) would solve the problem:

> (C) The Administrator shall exempt replacement parts [designed] prior to the effective date of the rule for articles that are first manufactured prior to the effective date of publication in the Federal Register of the rule unless
>
> (i) the Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to potentially exposed or susceptible populations; or

(ii) the replacement part is a component of an article that is reasonably expected to be used by children aged 12 years of age and younger.

We are unclear why this doesn't work – whether a lack of reception or something else. Can you give more insight into the problem? Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 06, 2016 2:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - replacement parts

Sven

A proposal is being floated as a potential solution to the replacement parts/designed by provision that would limit the provision's application to parts that are components of "durable goods" which is
"Durable goods," is a widely used term - adapted from 16 C.F.R. 802.1(d)* A good is "durable" if it is designed to be used repeatedly and has a useful life greater than one year.

I don't think this works as is – it may address a sub-set of the kid/infant products I've expressed concerns about, but doesn't address the couch seat cushion covers for obvious reasons.

But I am wondering whether there exists anything in regulation or SNUR/article precedent that your team can think up? we did work through some language months ago that related to the difficulty of re-designing articles of which the parts were a component, but that language was not accepted. I may tinker with it more as well, but in the meantime, can your team think of anything they've done before, even if not in the TSCA context, that would define a universe of articles/parts it applied to in a manner that limits/excludes some and keeps others?

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

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 8:08:58 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Merkley, Markey and Udall TSCA TA request - combined CBI on exemptions and partial bans

Adrian, Michal and Jonathan,
This TA responds to your questions about CBI and exemption and partial bans. 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

If EPA imposes a single-use ban, but allows the continuation of a separate, critical use under Senate 6(g), would it be sufficient to protect the CBI for that critical use by simply adding at the end of 14(c)(3) ", except for chemical substances for which EPA has provided a critical use exemption under section 6(g)"?

Also, for Senate Sec.14(c)(3), how would this language on disclosure in the event of a "ban or phase out" apply for chemicals that are manufactured for export only? If EPA banned a chemical under Sec 6, would that also include a ban on the domestic manufacture for export purposes only? And if not, would CBI be disclosed or protected in that case?

Follow on similar to Adrian's first q - what if EPA established a ban or phase out on a use of a chemical but not on all uses. Would disclosure of CBI related to the one use have the potential to adversely impact the competitive posture of the manufacturer?

Response: As we understand your questions, you are referring to the following provision of the Senate offer:

> *(3) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.*

We do not think the language you suggest would accomplish what we understand to be your objective.

We note that there is some uncertainty as to the scope of section 14(c)(3) and how it would operate in the case of a ban or phaseout for particular uses. The provision is triggered by a ban or phaseout of the manufacture, processing, or distribution in commerce of a chemical substance. It is not clear if only a complete ban or phaseout of one of these activities triggers the provision, or if it would also be triggered by a ban or phaseout for certain uses. Since section 6(d)(3) contemplates bans and phaseouts for particular uses, the better reading is probably that the provision would be triggered by such partial bans or phaseouts. However, the provision appears to void CBI protection for the chemical as a whole (subject to 14(g)), not just for particular uses. So the issue we understand you to be raising – preserving claims associated with uses that are not banned or phased-out – appears to arise for any partial ban or phaseout, irrespective of whether an exemption is granted.

With respect to your suggested language: it also speaks in terms of the chemical substance, not the use. So, if any critical use exemption is granted, your language would apparently void operation of 14(c)(3) for the chemical as a whole, not just as applied to the use.

With respect to exports: chemical substances that are manufactured, processed or distributed solely for export are exempt from TSCA requirements unless EPA finds the chemical will present an unreasonable risk in the United States (TSCA section 12(a)). While EPA has not addressed this question under current TSCA, arguably section 14, including the release provisions in 14(c)(3), would not apply to chemical substances manufactured solely for export.

From: "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>
Date: March 14, 2016 at 6:43:04 PM EDT
To: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>, "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Subject: TSCA TA request - CBI

Sven
I have two additional Sec 14 TA requests—

If EPA imposes a single-use ban, but allows the continuation of a separate, critical use under Senate 6(g), would it be sufficient to protect the CBI for that critical use by simply adding at the end of 14(c)(3) ", except for chemical substances for which EPA has provided a critical use exemption under section 6(g)"?

Also, for Senate Sec.14(c)(3), how would this language on disclosure in the event of a "ban or phase out" apply for chemicals that are manufactured for export only? If EPA banned a chemical under Sec 6, would that also include a ban on the domestic manufacture for export purposes only? And if not, would CBI be disclosed or protected in that case?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/29/2016 10:10:10 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: TA on 5/6 - can these all be accelerated pls? Thx

Michal – here's our current request list. Let me know if we missed anything. Thanks,
Sven

- Section 5 follow-up Q,5(d) restrictions, S.697 list v. 6(a) cross reference
- Senate Section 5, withdrawn PMNs
- Section 5, PBTs
- Section 5 costs and other non-risk factors
- House Section 6(b), "may present" finding
- Section 6 Cost Considerations
- Section 8 (entire section); review and comment
- Section 14(f), CBI

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, February 29, 2016 4:38 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA on 5/6 - can these all be accelerated pls? Thx

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: 4/20/2016 10:40:24 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on HLC Section 6 revised (4-20)

Michal – thanks – circulating for review. Best,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 20, 2016 6:36 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: Section 6 revised

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: 3/10/2016 7:18:12 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on Senate Discussion Draft
Attachments: Markey.TSCA TA on Discussion Draft.docx

Michal, This responds to your request for TA on the Discussion Draft 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: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Friday, March 04, 2016 10:57 AM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: FW: discussion draft and and outline of some changes toward House

Nichole

First of all, I wanted to extend my thanks to your team for all of the TA they provided over the past weeks (well, ok, months). It was all much appreciated, considered and hopefully well -integrated into this document.

Second of all, I'd like to request that EPA take a look at the Discussion Draft document and provide any feedback or suggestions for clarifying changes that are appropriate. I'd be particularly interested to learn whether EPA believes that the changes made to Senate sections 3A and 4A (both have been deleted, but elements of 3A have been shifted to section 26 and a more streamlined prioritization section has been shifted into section 6(b)) address some or all of the issues with those sections that EPA raised in its 1/20/16 letter to Congress.

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>

<TSCA - Discussion Draft - (3-3-16).pdf>
<MercuryTrevor.pdf>
<FRL Chemical Safety for the 21st Century Act.pdf>

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.

March 4 Request for TA:

Second of all, I'd like to request that EPA take a look at the Discussion Draft document and provide any feedback or suggestions for clarifying changes that are appropriate. I'd be particularly interested to learn whether EPA believes that the changes made to Senate sections 3A and 4A (both have been deleted, but elements of 3A have been shifted to section 26 and a more streamlined prioritization section has been shifted into section 6(b)) address some or all of the issues with those sections that EPA raised in its 1/20/16 letter to Congress.

Response:
EPA flags the following as particularly significant issues that have arisen as a result of the latest revisions to sections 6 and 26 (primarily relating to the removal of sections 3A and 4A). Throughout, "Senate Bill" refers to TSCA as it would be amended by the bill that passed in December 2016, and "Senate Offer" refers to TSCA as amended in the recently circulated offer text.

1. Clear duty to initiate risk management proceedings without regard to cost or other non-risk factors

The prior Senate bill was very clear that a negative safety determination necessarily triggered a duty to promulgate a risk management rule. Senate Bill § 6(d)(1). There is no decision-making step between the decision that a chemical substance does not meet the safety standard and the initiation of rulemaking to ensure that the chemical substance does meet the safety standard. But the Senate offer could be construed to introduce such a decision-making step, unconstrained by the key proviso to evaluate unreasonable risk "without consideration of costs or other non-risk factors."
See Senate Offer § 6(c)(1), which indicates that the deciding factor in whether rulemaking proceeds is whether EPA determines that that the chemical substance presents an unreasonable risk, "based on" a risk evaluation conducted in accordance with subsection (b)(4)(A). But that risk evaluation presumably already contains the unreasonable risk decision, since the purpose of the risk evaluation was to make such a decision, "without consideration of costs or other non-risk factors." Some might read 6(c)(1) as directing EPA to do a second unreasonable risk determination (i.e., building on the first but this time introducing cost and other non-risk factors) to decide whether risk management rulemaking is warranted.

There is a simple fix: § 6(c)(1): "If, ~~based on~~ in a risk evaluation conducted in accordance with subsection (b)(4)(A), the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment. . ."

2. Non-comprehensive menu of regulatory options.

EPA identified some possible limitations created by TSCA section 6(a) menu of requirements that EPA can impose in section 6 rulemaking. Although the Senate bill as passed expanded this menu to make it more comprehensive, those improvements have been eliminated in the draft. For example, under the

draft, EPA would lack express authority to regulate manufacture, processing or distribution in a way that does not involve a complete or partial prohibition or volume or concentration limitation.
Some might argue that "catch-all" regulatory authority over existing chemical substances was thereby withheld, especially since it was elsewhere supplied with respect to new chemical substances. Senate Offer § 5(d)(3)(C)(v). Beyond this specific issue, we do not see an obvious logic for having different menus of options under sections 5 and 6, and some might try to use the differences to argue for differing authorities or approaches under these two sections.

In operation, the lack of comprehensive menu of requirements could drive EPA to impose regulation that is more burdensome than necessary.

3. Clear and Enforceable Deadlines

Senate Offer § 6(b)(4)(G) provides that EPA "shall conduct and publish a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the dae on which the Administrator initiates a risk evaluation." We imagine the intent, consistent with Senate Bill § 6(a)(4), was to specify that EPA "shall ~~conduct~~ **complete** and publish a risk evaluation . . ." This is correction is important to ensure that the deadlines for completing risk evaluations are enforceable.

4. Impact of Developing Policies and Procedures on Other Aspects of Program Implementation

Senate Bill § 6(b) ensures risk evaluations and risk management actions can proceed even in the absence of completed policies and procedures, and thereby prevents general disputes about methodological issues from impeding the actual implementation of TSCA Reform during the early years after enactment. In the Senate Bill, the point of reference was to policies and procedures under §§ 3A and 4A. These included the prioritization procedures (Senate Bill § 4A(a)(1)) and the risk evaluation procedures (Senate Bill §3A(h)(2)). Senate Bill § 6(b) has since been relocated to Senate Offer § 26(j)(4), and instead of referring to policies and procedures under §§ 3A and 4A, it refers to policies and procedures that are established § 26. Some may therefore argue that it is therefore inoperative with respect to the key policies and procedures established under § 6 (for conducting prioritization and risk evaluations). These were clearly encompassed by Senate Bill § 6(b), but they are no longer clearly encompassed by Senate Offer § 26(j)(4). A simple drafting fix would be to revise §26(j)(4) as follows:

(4) Prior Actions and Notice of Existing Information.—

(A) PRIOR-INITIATED EVALUATIONS.—

(i) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under this ~~section~~ **Act**.

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.

(ii) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As **relevant** policies and procedures under this ~~**section**~~ **Act** are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing risk evaluations.

(B) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation, determination or rule solely because the action was completed prior to the completion of a policy or procedure established under this ~~**section**~~ **Act**.

ED_002117_00008558-00003

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/14/2016 5:32:58 PM
To: Larkin, Brendan [Brendan.Larkin@mail.house.gov]
CC: Davis, CatherineM [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9977d3119e394dcf9cf819e79b52992b-Davis, Catherine]
Subject: Re: Cong. Tonko Inquiry on TSCA PBT Expedited Action

Will do, thanks.

On Oct 14, 2016, at 12:47 PM, Larkin, Brendan <Brendan.Larkin@mail.house.gov> wrote:

Thanks, Sven. I have signed up for future updates through the site, but can you also please add me to any distribution lists you maintain for the Hill on TSCA implementation?

Brendan

Brendan W. Larkin
Office of Congressman Paul D. Tonko (NY-20)
2463 Rayburn House Office Building
Washington, DC 20515
brendan.larkin@mail.house.gov
(202) 225-5076

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, October 14, 2016 11:33 AM
To: Davis, CatherineM; Larkin, Brendan
Subject: Cong. Tonko Inquiry on TSCA PBT Expedited Action

Brendan,
Thanks for the request on the TSCA PBT expedited action.

EPA is taking steps to carry out requirements under TSCA reform to reduce exposure to certain persistent, bioaccumulative, and toxic (PBT) chemicals.

The five chemicals to receive expedited action under TSCA section 6(h) are:

- Decabromodiphenyl ethers (DecaBDE), used as a flame retardant in textiles, plastics and polyurethane foam;
- Hexachlorobutadiene (HCBD), used in the manufacture of rubber compounds and lubricants and as a solvent;
- Pentachlorothio-phenol (PCTP), used as an agent to make rubber more pliable in industrial uses;
- Tris (4-isopropylphenyl) phosphate, used as a flame retardant in consumer products and other industrial uses; and

- 2,4,6-Tris(tert-butyl)phenol, used as a fuel, oil, gasoline or lubricant additive.

The new law gave manufacturers an opportunity to request by September 19, 2016, that EPA conduct risk evaluations for the PBT chemicals on EPA's 2014 Work Plan, as an alternative to expedited action. Requests for risk evaluations were made for two chemicals that can be used in fragrance mixtures.

For the remaining PBT chemicals, EPA must move ahead to take expedited action to reduce exposure to those chemicals to the extent practicable. After EPA finishes identifying where these chemicals are used and how people are exposed to them, the Agency will move directly to propose limitations on their use. The statutory deadline for EPA to propose action is June 22, 2019.

PBT chemicals are of particular concern because they remain in the environment for significant periods of time and concentrate in the organisms exposed to them. These pollutants can transfer among air, water, and land, and span boundaries of geography and generations.

For more about TSCA reform and EPA's implementation activities, and to sign up for updates, visit: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.

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: Larkin, Brendan [mailto:Brendan.Larkin@mail.house.gov]
Sent: Friday, October 14, 2016 11:18 AM

To: Davis, CatherineM <Davis.CatherineM@epa.gov>
Subject: TSCA PBT Expedited Action

Hi Cathy,

Do you have any information you can send along regarding EPA's recent PBT decision?

Thank you,

Brendan

Brendan W. Larkin

Office of Congressman Paul D. Tonko (NY-20)

2463 Rayburn House Office Building

Washington, DC 20515

brendan.larkin@mail.house.gov

(202) 225-5076

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 4:03:42 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on section 6 TA - House R language- followup

Okay- I'll advise folks to be be ready. Thanks

On Apr 23, 2016, at 12:02 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Ok. Thx. I'm still expecting more language soon.

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

From: Kaiser, Sven-Erik
Sent: Saturday, April 23, 2016 12:01 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA on section 6 TA - House R language- followup

Michal- got it checking. By the way we're having a IT issues. The TA doesn't show up as sent so I sent it again. Can disregard resend- there is no change. Thanks,
Sven

On Apr 23, 2016, at 11:57 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Are you assuming that 4(b) and 4(c) apply only to rules for a reason? Is it possible you're not looking at the conforming edits (which HLC puts at the end of the bill)? I believe there's only one part of 4 that isn't for rules orders and CAS, and I believe it is that section (maybe 4b3) that you pointed out would require epa to notify every single manufacturer or processor every time you did a test rule if we applied that section to rules and orders.

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

From: Kaiser, Sven-Erik
Sent: Saturday, April 23, 2016 11:54 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 6 TA - House R language- followup

Michal,
This TA responds to the followup request on section 6 TA- House R language.

The solution to the section 6 issue, as you suggest, is straightforward: simply delete the reference to section 4 added in HLC to section 6(a)(1)(G). That would conform the text to current TSCA. With this reference gone, EPA would most likely interpret the new authority in section 4 -- allowing EPA to require testing as necessary to ensure compliance with a section 6(a) rule -- as providing *additional* authority to require testing beyond

what is required in a section 6 rule -- for example, to address unforeseen circumstances that arise during implementation.

The section 4 issues could be addressed in various ways, depending on the desired outcome. Under the latest HLC, the requirements of 4(b) and 4(c) apply only to rules, not to orders or consent agreements. These would apply regardless of whether the rule was issued under the "old" may present/substantial production bases, or under one of the "new" bases (eg, to implement section 6 rules, for prioritization). Thus, the specification of standards and protocols, the requirement to reduce use of vertebrates, the specification of who must test, and the provisions regarding the reimbursement period and testing exemptions would apply only to rules, not orders. This does not necessarily present an issue or concern, with the exception of the "who is required to test" provisions (4(b)(3)).

Per earlier TA, these provisions prescribe who must test based on the finding made by EPA in imposing testing under existing TSCA 4(a). Because EPA will not make those findings for a test rule under the new authority -- and because orders and consent agreements under the new authority will not be subject to these provisions at all -- the law would provide no guidance as to whom EPA can impose testing obligations on under the new authority. This could create implementation issues for rule and orders, since it could be argued that Congress should specify whom EPA can impose obligations on. (It should not create an issue for consent agreements, since they are consensual.)

Here are two possible solutions:

1. Strike 4(b)(3) and insert: "A rule or order under subsection (a) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would be the simplest approach from an implementation perspective, in that it gives EPA authority in any test rule or order to impose test requirements on the manufacturers and/or processors that are most suited to conduct the testing.

2. Another approach involving less textual change would be to retain the existing 4(b)(3) but add a (C) as follows: "(C) A rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would require several minor conforming changes to (b)(3), which we could provide if you are interested in this approach. This approach would maintain the existing allocation of testing responsibilities under TSCA for rules under the "old" authority but add direction for rules and order under the "new" authority. Under either of these approaches, "rule" should be stricken from the title of (b).

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: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 23, 2016 at 5:15:41 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on section 6 TA - House R language

Thanks - is there a way to address?
In 6a I assume it would be to remove the language
In 4, I believe you've said in the past that the language in question doesn't work for orders/consent agreements.

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

From: Kaiser, Sven-Erik
Sent: Friday, April 22, 2016 4:47 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 6 TA - House R language

Michal,
This TA responds to the request on section 6 TA followup on House R language.

Section 4 requires a statement of need for testing, requires a tiered approach, and requires identification of protocols and methodologies. Those are certainly manageable in the context of a section 6 rule, but they impose some requirements that otherwise would not be imposed in section 6. There also may be some difficulty in applying the provisions in 4(b)(4) regarding expiration of the reimbursement period, since the section 6 rule may not have a fixed testing requirement or period for testing but rather may have a more open ended obligation to conduct testing under circumstances specified in the rule. But these issues should be manageable.

The potentially more substantive issue is that the latest HLC version of section 4 we have seen does not provide any guidance on who can be made to test in a test rule or order under the new 4(a)(2) authority. But this is an issue with section 4 itself, and not unique to the incorporation of section 4 into section 6. TSCA 4(b)(3) requires that each test rule impose testing obligations on all manufacturers of the chemical substance, or all processors, or both, depending on which 4(a)(1) finding EPA makes to support the rule (may present, or substantial production/release/exposure). Specifically, it provides that "the following persons [all manufacturers and/or all processors] shall be required to conduct tests and submit data on a chemical substances or mixture subject to a rule under 4(a). . . .", and then lays out whether the entities required to test are the manufacturers or processors or both, depending on which 4(a)(1) finding was made. Because EPA will not be making one of these findings under 4(a)(2), the current 4(b)(3) is not a great fit, since it assumes that one of those findings will have been made to support each test rule.

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: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 22, 2016 1:50 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: question on your 6 TA from last night

1 (G) by striking "and monitor or conduct
2 tests" and inserting "or monitor or conduct
3 tests pursuant to section 4" [A1] in paragraph (4);
4 and

This was a House R request. What additional requirements will those be? btw, Senate agreed to add test orders to 4(a)(1) yesterday.

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
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EPA TA: This will suggest that EPA must follow any applicable section 4 requirements, as well as section 6 requirements, in imposing test requirements.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 7:20:44 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA request on section 12

Got it - checking

On Mar 15, 2016, at 3:01 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Previously you noted that the conforming changes to 12(b) were useful.

What about the changes to 12(a)(2) or 12(a)(3)? These have been argued to place limitations on existing epa practice/authority.

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: 4/20/2016 10:37:36 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on animal testing and nomenclature

Ok - thanks – will let folks know.

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, April 20, 2016 6:37 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on animal testing and nomenclature

It isn't just nomenclature and animal testing. See the cover email too.

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

From: Kaiser, Sven-Erik
Sent: Wednesday, April 20, 2016 6:34 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on animal testing and nomenclature

Michal – got it. Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 20, 2016 6:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: confidential draft

Pls review. Section 6 coming soon.

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

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.
"(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:
Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

"(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing

of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.’’;

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/21/2016 11:10:00 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 section 8

Michal,
Got it. Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 21, 2016 7:09 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Time-sensitive on section 8

Sven

Can you pls rush the review of this redlined text to portions of section 8?

Here are the basic questions:

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the tsca inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include biproducts that do not appear on the tsca inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

I think there is a desire to get this to the House asap.

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: 2/11/2016 11:07:48 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Section 4(f)

Michal - got it – urgency? We've got several on section 5 and 6 in process so let me know if this trumps. Also, I think Nichole talked to you about this – do we need to be on call over the weekend? 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 11, 2016 6:04 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 4 question

Sven

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?

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?

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) that 1) 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.

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 in 4(f)(2) after "5,6 or 7" and then go to "For good cause"?

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

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: 4/4/2016 1:40:00 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on section 19 Judicial Review

Michal - Thanks for the information. Please let me know if any questions come up. 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, April 04, 2016 9:34 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on section 19 Judicial Review

Thanks -- this is v helpful. We've flagged section 19 for hOuse as one that will require more review once section 6 is settled.

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: Sunday, April 03, 2016 4:33 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 19 Judicial Review

Michal,
This responds to the request for general TA on section 19. Note that there are RLSO changes and comments that might not show up on a phone. Please let me know if any questions. Thanks,
Sven

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/30/2016 12:18:07 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Sen. Markey TSCA TA - slightly new Senate 14(c) construct

Checking on times

On Mar 29, 2016, at 7:26 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Also – we may want to try to do a call on this w our usual group tomorrow sometime btw 10-12. Any times in here work better than others?

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
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 29, 2016 3:04 PM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA - slightly new Senate 14(c) construct

Michal - Got it, thanks. Please let me know if a call needed. Best,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 29, 2016 2:56 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA - slightly new Senate 14(c) construct

Sven

Could you please look at the following text? Basically, we are looking to address a House issue with the Senate 14 offer by going back to something that looks more like what the Senate reported out of EPW. We are particularly interested in EPA's take on whether there is conflict between the highlighted text portions. My own read of how this works is

- Health and safety studies get disclosed. No protecting them from disclosure until someone files a FOIA or makes another type of request. They go out.
- However, certain types of chem ID info (what currently gets statutory protection under TSCA) can be redacted from these studies.

PLs add your views, suggestions, etc as appropriate.

Thanks

michal

(c) Information Not Protected From Disclosure.—

(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

(i) IN GENERAL.—Subject to clause (ii), subsection (a) does not prohibit the disclosure of—

(I) any health and safety study that is submitted under this Act with respect to—

(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

(bb) any chemical substance or mixture for which—

(AA) testing is required under section 4; or (BB) a notification is required under section 5; or

(I) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

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
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 4:22:21 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on PBTs
Attachments: Markey.TSCA TA.PBT.4-12.docx

Michal – corrected TA that responds to the request on the revised PBT language. Please use this version of the PBT TA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 11, 2016 5:20 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: PBTS

I had made all of these changes before sending last time but must not have saved before sending. Pls use this version, and note that I changed many of the 6(c) references to 6(a) which should mean that both standards (necessary to reduce, and extent practicable) should be met, right? also got rid of "likely", if you think I should restore pls note.

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.

( ) Chemicals That Are Persistent, Bioaccumulative, and Toxic.--

(1) Expedited Action.--Not later than ~~2~~ 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose a rule ~~under~~ in accordance with subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments —

(A) that the Administrator has a reasonable basis to conclude are toxic and with respect to persistence and bioaccumulation, scores high for one 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), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation ~~under section 6~~, initiated a ~~risk assessment~~review under section 5, or entered into a consent agreement under section 4 prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and

(B) exposure to which under the conditions of use is likely to the general population ~~or, to~~ a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) Final Rule.--Notwithstanding subsections (__), subject to ~~the availability of appropriations and~~ subsections __ and __ , not later than ~~2 years~~18 months after proposing a rule under paragraph (1), the Administrator shall promulgate a rule in accordance with subsection (c).

(3) In selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a) the Administrator shall, for each chemical substance for which a rule is proposed under paragraph (1), reduce exposure to the substance to the extent practicable.

(4) Relationship to subsection (b).--If, at any time prior to the date that is 90 days after the date on which the Administrator proposes the rule under paragraph (1), the Administrator makes a finding under subsection (__), or a manufacturer requests a risk evaluation under subsection (__), with respect to a chemical substance, such chemical substance shall not be subject to this subsection, except that any proposed ~~and~~or final rule promulgated in accordance with section 6(a) for such chemical substance shall reduce ~~likely~~ exposure to the extent practicable.

(~~5~~4) OTHER CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC OR CARCINOGENS.—

(A) In designating high priority substances pursuant to subsection (b), the Administrator shall give preference to—

(i) chemical substances that, with respect to persistence and bioaccumulation, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals

Commented [A1]: To EPA: added in 12 months for the exposure assessment. Better?

Commented [A2R1]: **EPA TA:** See response below. Whether or not EPA has to do a risk evaluation for each chemical substance as part of doing the 6(a) rule affects the answer.

Commented [A3]: To EPA: this should answer your q on whether it has to comply w goal of restrictions?

Commented [A4R3]: **EPA TA:** This helps to clarify that EPA is intended to both protect against and UR and reduce exposure to the maximum extent practicable. But does EPA need to do a risk evaluation? 6(a) pre-supposes that EPA knows what uses of the chemical present an unreasonable risk, and the only way to know what UR is is to do a risk evaluation.

There is a general awkwardness with this provision because you are re-purposing the framework of section 6(a) rulemaking to handle special risk management for PBTs. It is unclear what aspects of 6(a) rulemaking (if any) are superseded by the requirements of this subsection.

This is an issue that will be left to EPA interpretive discretion (and potentially litigation) if not explained in the statutory text.

Commented [A5]: ~~EPA TA: Shouldn't this be (a)? Should be consistent with (1).~~

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Methods Document published by the Administrator in February 2012 (or a successor scoring system) ;and

(ii) chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(B) In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

(C) For a chemical substance subject to subsection (a) ~~and~~ that 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 promulgated in a rule pursuant to subsection (a~~c~~), reduce exposure to the substance to the extent practicable.

Retain expedited action provision in 6(c)

(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 paragraph and subsection (b)(4)(G) does not exceed two years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, 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), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/17/2016 7:12:34 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Requests

Michal- thanks for the info. Best,
Sven

On Apr 17, 2016, at 3:02 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

We didn't send any new sections to the House. What I was referring to was a list of changes to section 6 – implementation dates, costs, replacement parts etc. we are waiting on the House/

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

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 17, 2016 3:01 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Requests

Michal,
Just curious on how things are going. Didn't see section 6 - did it go to House? Thanks,
Sven

On Apr 16, 2016, at 6:21 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Tomorrow likely heavy activity and hoping for more from HLC – today, Senate side is getting ready and organized. I think we aim to send our list of section 6 changes tonight (earlier discussions you're no doubt aware of sort of delayed things).

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

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 16, 2016 6:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Requests

Michal – how is it going? Hopefully making great progress. We should have something for you shortly on nomenclature and on the section 9, 20, and 21 followups. Any sense of activity tonight and tomorrow? Thanks, Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Saturday, April 16, 2016 5:12 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Nomenclature

Try this version.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/16/2016 9:25:36 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey Inquiry on TSCA Preemption and the MA bill on children's jewelry

Are you in Monday – I can give you a call at a convenient time. Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, December 16, 2016 4:24 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Preemption and the MA bill on children's jewelry

I do have a question about section 5. Better to frame verbally, doesn't have to be today if you're out, but let's talk when you camn

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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, December 16, 2016 4:20 PM
To: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Preemption and the MA bill on children's jewelry

No worries – feel free to pester away. Let me know if you want to pursue this (or any other) questions. All part of working out the new TSCA. Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, December 16, 2016 4:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Preemption and the MA bill on children's jewelry

I know it is a long shot but the language does refer to a law in effect in 2003. Does not say anything about whether amdts to that same law would count as being part of the 2003 or 2016 law. No need to pester people though. Thank you.

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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, December 16, 2016 3:18 PM
To: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Preemption and the MA bill on children's jewelry

Michal – an initial reaction is that it seems like an amendment to TURA would be a 2016/2017 state law. In that case, the imposition of chemical specifications in children's jewelry would be an "action taken pursuant to" the 2016/2017 amendment, not the underlying pre-2003 TURA. That's an unofficial preliminary response and if desired I can run it by folks and get something more official on the amending and grandfathering question.
Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, December 16, 2016 11:18 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Preemption and the MA bill on children's jewelry

What is your view on what I have pasted below:

18(e) PRESERVATION OF CERTAIN LAWS.—

(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

(A) 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

(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

(2) EFFECT OF SUBSECTION.—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.

The plain reading of the highlighted text gives an argument that an action taken pursuant to TURA (or an amendment to TURA), which was in effect on August 31, 2003, should be free from any and all preemption.

If MA wrote a toxics law that was itself an amendment to TURA, I believe they could argue that it should be grandfathered.

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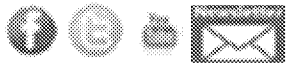

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, December 16, 2016 11:15 AM
To: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Sen. Markey Inquiry on TSCA Preemption and the MA bill on children's jewelry

Michal – this responds to your question about TSCA preemption and the MA bill on children's jewelry - https://malegislature.gov/Bills/189/H253. Please take a look at EPA's response and let me know if any questions. Thanks,
Sven

As a preliminary matter, this response conveys EPA's general and preliminary interpretation of TSCA section 18 and is not intended to establish the preemption status of a particular state law.

Prior to the recent amendments to TSCA, EPA had issued 3 significant new use rules (SNURs) covering cadmium-containing chemicals - see 40 CFR 721.10888, 10889, 10890. The MA bill appears to codify an ASTM standard with specifications for cadmium and cadmium compounds in children's jewelry, which could include the chemicals regulated in EPA's SNURs. However, because EPA's existing 3 SNURs are not "designed to protect against" a risk from those chemicals (the preemption standard for pre-amendment federal regulations), the portions of the MA bill pertaining to cadmium specifications would not be subject to preemption under TSCA § 18(d)(2). Further, because EPA has not otherwise regulated cadmium under new TSCA, the MA bill would not be subject to general preemption under TSCA § 18(a) or "pause" preemption under TSCA § 18(b). See below for a more detailed analysis:

- **Under TSCA § 18(d)(2), the preemptive effect of federal regulations promulgated prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Act") remains the same as the preemptive effect of those regulations prior to the enactment of the Act. Under the prior TSCA preemption scheme, TSCA § 18(a)(2) provided that a state requirement designed to protect against risk of injury to health or the environment from a chemical substance was preempted by a TSCA § 5 or 6 rule or order (other than a TSCA § 6(a)(6) rule) prescribed to protect against such risk, unless the state requirement was identical to the federal requirement, was adopted under the authority of another federal law, or prohibited the use of the substance in the state. It is the Agency's position that SNURs are not actions "designed to protect against a risk" within the meaning of TSCA § 18. As such, state laws or actions addressing cadmium-containing chemicals are not subject to preemption under this provision.**

- **A state law or action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce, or use of a chemical substance for which EPA has made a "no unreasonable risk" determination under TSCA § 6(i)(1) or for which EPA has promulgated a final TSCA 6(a) rule is subject to preemption under TSCA § 18(a)(1)(B), consistent with the scope of the risk evaluation for that substance. However, a state law or action of this type will not be preempted if it falls within an exception in TSCA § 18(d); if it falls within the "grandfather" provisions in TSCA § 18(e); or if EPA grants a waiver under TSCA § 18(f)(1). So long as EPA has not taken action under TSCA § 6(a) or 6(i)(1) with respect to cadmium, states are not prohibited or limited from regulating the manufacture, processing, distribution in commerce, or use of such chemical under TSCA § 18(a)(1)(B).**

- **A state law or action requiring the notification of a use of a chemical substance that EPA has specified as a significant new use and for which EPA has required notification pursuant to a TSCA § 5 rule is subject to preemption under TSCA § 18(a)(1)(C). If EPA issues a SNUR addressing cadmium, a state law or action requiring the notification of a use of that chemical will be subject to preemption under TSCA § 18(a)(1)(C). Again, a state law or action of this type will not be preempted if it falls within an exception in TSCA § 18(d); if it falls within the "grandfather" provisions in TSCA § 18(e); or if EPA grants a waiver under TSCA § 18(f)(1).**

- **A state law, criminal penalty, or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce, or use of "a high-priority substance designated under [TSCA §] 6(b)(1)(B)(i)" is subject to "pause" preemption under TSCA § 18(b). The exemptions and exceptions from preemption under TSCA § 18(d), (e), and (f)(2) would be applicable if a state law, penalty or action is subject to TSCA § 18(b) "pause" preemption. Cadmium has not been designated as a high-priority substance, so states are not prohibited or restricted from regulating the manufacture, processing, distribution in commerce, or use of cadmium under TSCA § 18(b).**

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/14/2016 3:33:08 PM
To: Davis, CatherineM [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9977d3119e394dcf9cf819e79b52992b-Davis, Catherine]; brendan.larkin@mail.house.gov
Subject: Cong. Tonko Inquiry on TSCA PBT Expedited Action

Brendan,
Thanks for the request on the TSCA PBT expedited action.

EPA is taking steps to carry out requirements under TSCA reform to reduce exposure to certain persistent, bioaccumulative, and toxic (PBT) chemicals.

The five chemicals to receive expedited action under TSCA section 6(h) are:

- Decabromodiphenyl ethers (DecaBDE), used as a flame retardant in textiles, plastics and polyurethane foam;
- Hexachlorobutadiene (HCBD), used in the manufacture of rubber compounds and lubricants and as a solvent;
- Pentachlorothio-phenol (PCTP), used as an agent to make rubber more pliable in industrial uses;
- Tris (4-isopropylphenyl) phosphate, used as a flame retardant in consumer products and other industrial uses; and
- 2,4,6-Tris(tert-butyl)phenol, used as a fuel, oil, gasoline or lubricant additive.

The new law gave manufacturers an opportunity to request by September 19, 2016, that EPA conduct risk evaluations for the PBT chemicals on EPA's 2014 Work Plan, as an alternative to expedited action. Requests for risk evaluations were made for two chemicals that can be used in fragrance mixtures.

For the remaining PBT chemicals, EPA must move ahead to take expedited action to reduce exposure to those chemicals to the extent practicable. After EPA finishes identifying where these chemicals are used and how people are exposed to them, the Agency will move directly to propose limitations on their use. The statutory deadline for EPA to propose action is June 22, 2019.

PBT chemicals are of particular concern because they remain in the environment for significant periods of time and concentrate in the organisms exposed to them. These pollutants can transfer among air, water, and land, and span boundaries of geography and generations.

For more about TSCA reform and EPA's implementation activities, and to sign up for updates, visit: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.

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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From: Larkin, Brendan [mailto:Brendan.Larkin@mail.house.gov]
Sent: Friday, October 14, 2016 11:18 AM
To: Davis, CatherineM <Davis.CatherineM@epa.gov>
Subject: TSCA PBT Expedited Action

Hi Cathy,

Do you have any information you can send along regarding EPA's recent PBT decision?

Thank you,

Brendan

Brendan W. Larkin

Office of Congressman Paul D. Tonko (NY-20)

2463 Rayburn House Office Building

Washington, DC 20515

brendan.larkin@mail.house.gov

(202) 225-5076

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 6:16:27 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA Request on Section 14(i)

Michal - Got it - checking. Thanks,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 2:14 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 14(i)

Does this section prevent epa from continuing the CBI reviews (I believe of health and safety mostly) that EPA is currently undertaking? Or just does so after the rules are in effect?

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: 4/7/2016 2:00:48 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: SEPW TSCA TA RE: section 4 - Senate Counter

Michal – this responds to the followup question on section 4.

Regarding 4(b)(2)(A), we suggest adding a third sentence (immediately before the new language on animal testing) that reads as follows:

"The exposure testing for which protocols and methodologies may be prescribed includes biomonitoring for the presence of a chemical substance or mixture, and monitoring for the presence of a chemical substance or mixture in the environment."

Please let me know if any questions. Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 07, 2016 4:51 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Re: SEPW TSCA TA RE: section 4 - Senate Counter

Sven - can we get a response to this one this morning, preferably by 10-11? Thanks.

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

From: Kaiser, Sven-Erik
Sent: Wednesday, April 6, 2016 12:26 PM
To: Freedhoff, Michal (Markey)
Cc: Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Re: SEPW TSCA TA RE: section 4 - Senate Counter

Michal,
Got it - checking. Thanks,
Sven

On Apr 6, 2016, at 12:25 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Quick question back to you:

We're maintaining current 4(a)(1) as you see. We'll explore the 6(a) issue there (we were hoping it was merely redundant but see from your TA that it is not).

But the question of changing data to information in 4(a)(1) – I was trying to be minimal in changes to that text, and so left in "data" in the backwards-looking parts of 4(a) that refer to the justifications for getting new information, but made the switch to the parts of 4(a)(1) that specifies what types of information EPA can REQUEST. But I'm still seeing your comment and am wondering if you can suggest a minor word change to address this (minor tweaks to (b)(2)(A) also happily accepted and perhaps even preferred)?

"The change from data to information is probably helpful, but it does not address the main source of ambiguity in TSCA as to the scope of section 4: the phrase "testing. . . on a chemical substance." This formulation could give rise to arguments that, for example, EPA cannot require monitoring for the presence of a chemical in the environment, because this is not testing on a chemical. Such a limited interpretation of "testing on a chemical" might be supported by (b)(2)(A), retained here, which describes the allowable types of tests in terms of toxicity and other attributes of the chemical itself, rather than in terms of its presence or absence."

Thanks
m

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Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 06, 2016 11:50 AM
To: Freedhoff, Michal (Markey)
Cc: Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: SEPW TSCA TA RE: section 4 - Senate Counter

Michal – Please see attached TA responding to the request on the draft Senate counter to the House offer on section 4. Note that there are track changes comments that might not show up on a phone. 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: Tuesday, April 05, 2016 2:34 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: section 4

Sven

Attached is a new Section 4 that we need TA on. Generally, it can be described as:

- Existing TSCA 4(a)(1) and 4(a)(2) (mostly)
- In addition to that, Senate text on other circumstances that allow testing, by rule or order or consent agreement
- Other changes to things like ITC and 4(f) that have been discussed/proposed by various parties
- All (I hope) the conforming changes the House offer removed or didn't do

Please give it a careful read and let us know of any issues.

Senate colleagues – note I did not strike and replace the animal testing language but just bracketed it to reflect ongoing discussions. Let me know if you want a different approach there.

Thanks
michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/29/2016 7:50:06 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request on section 6 replacement parts

Weekend scouting expedition?

On Feb 29, 2016, at 2:43 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

In case your team is interested, I found baby replacement part teething rings and bibs. ☺

https://us.britax.com/accessories/baby-carrier-bib/
http://www.amazon.com/BABYBJORN-Bib-Baby-Carrier-Pack/dp/B000CS9TGG
https://www.stokke.com/USA/en-us/w/accessories/3122.html

http://www.amazon.com/Sassy-Teething-Feeder-Replacement-Bags/dp/B000GUYCZI
https://store.mattel.com/ItemDetail.aspx?cat=140&item=64677
https://store.mattel.com/ItemDetail.aspx?cat=140&item=61756

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

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, February 25, 2016 4:24 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on section 6 replacement parts

Michal,
This responds to your technical assistance requests on section 6 replacement parts including the followup question about child specific items. 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
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202-566-2753

On Feb 8, 2016, at 6:53 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Additional question on this topic.

I know there is an MOU btw FDA and CPSC that describes the regulatory process for BPA in baby bottles. Does the same MOU cover the pthalates in the baby bottle nipples? If not, would that fall under "replacement parts" authority?

Would sippy cup lids or straws for straw cups fall under that authority, or is all of this FDA?

You can see where I'm going with this - if there are other examples I should be thinking about in addition to the couch seat cover, esp if there is a child-specific one, do let me know.

Thanks

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

From: Kaiser, Sven-Erik
Sent: Monday, February 8, 2016 5:18 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA Request on replacement parts

Michal – I'll run the additional info by folks and see how that changes things. Please let me know if any additional questions. Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 08, 2016 5:15 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on replacement parts

Thanks Sven

In response to the comments – there is no broader document that exists, let alone that can be sent, but assume that we are talking about a section 6 provision.

The House language exempts ALL replacement parts designed prior to the effective date – and thus captures all replacement parts MANUFACTURED before the effective date as well.

I am trying to find a way to soften the House language, so that it captures the car brake pad or airplane engine part, but NOT the replacement couch seat cushion cover or replacement pacifier nipple. You guys sent me an earlier draft that

would allow EPA to exempt replacement parts designed before the effective date following an affirmative finding that is similar to the language I sent. HOWEVER:

1) The House did not like that one bit. ☺
2) Even if the House did like that or my version, one would STILL presumably want to ensure that replacement parts that were manufactured prior to the effective date are exempted, even if such a finding (affirmative or not) were made.
3) That is why any final provision that doesn't exempt ALL replacement parts designed prior to the effective date would need the Senate text as well.

So what I am trying to propose is

- Manufactured by stays exempted
- Can we find a "designed by" provision that includes a presumption that the part would be exempted, UNLESS EPA makes a finding? If what I sent you doesn't do it, please suggest an alternative, and if you don't think your comment A3 works for that purpose, pls let me know.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 08, 2016 5:07 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on replacement parts

Michal,
Attached please find technical assistance that responds to your request on replacement parts. 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: Tuesday, February 02, 2016 10:29 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - replacement parts

Hi Sven

Your past TA provided an option to allow EPA to exempt replacement parts designed prior to the effective date of a TSCA regulation from that regulation if EPA found that the replacement parts would not be impracticable to replace/redesign. After receiving feedback from colleagues, I have re-drafted it to make the presumption be exemption, rather than the presumption being non-exemption. Can you take a look, suggest any changes and describe any concerns you might have with implementation?

Thanks
Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/21/2016 11:05:44 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on cost consideration alternatives
Attachments: Markey.TSCA TA.Options for introducing cost.docx

Flag: Follow up

Michal,
Please see attached TA responding to the request on cost consideration alternatives. We plan to follow this with additions to the options chart. 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: Friday, March 18, 2016 3:49 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Another TA request on 6(a) rules

Sven

Thanks for the table of alternatives on cost considerations in rulemaking. There was an interest in discussion today in seeing whether there is a way to flip the presumption of the House language in a way that said:

- epa identify remedies that address the unreasonable risk
- from those remedies, then somehow consider costs, whether by using the word cost-effective or some other word.

Can you help w some options (1 or more, however many occur to you), with eye to putting them into that chart? Ideally, I'd like options that fall closer to the Senate side rankings on both analytic burden and litigation risk but which helps the House feel that EPA will not choose the super-expensive unnecessary remedy.

Thanks
M

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

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.

Options for including cost-effectiveness in risk management

Set A—using the term cost-effectiveness, based on Senate offer structure

1. Add to 6(c)(2)(A)--

   "(vii) the cost-effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;"

2. Add the above to 6(C)(2)(A) and add the following at the end of the last sentence of 6(C)(2)(B)—

   "and shall generally give preference to requirements that are more cost-effective as determined based on the consideration described in 6(c)(2)(A)(vii)"

Commented [A1]: We use the phrase "more cost-effective" rather than "cost-effective", because we view the former as more in line with the typical understanding of cost-effectiveness. Unlike "cost-beneficial" – which can be applied as an absolute concept (an approach is either cost-beneficial or it is not) – EPA believes cost-effectiveness is typically understood and used in relative terms – i.e., in evaluating a range of options that achieve the safety standard, EPA would consider the relative costs of those options and generally prefer a less expensive option.

Set B—not using the term cost-effectiveness, based on Senate offer structure

1. Add to 6(c)(2)(A)—

"(vii) the efficiency with which the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator satisfy the requirement that a rule promulgated under section 6(a) ensures that the chemical substance does not present an unreasonable risk of injury to health or the environment under the conditions of use, as determined in accordance with subsection (b)(4)(A);"

Commented [A2]: Note that the use of this term gives EPA more flexibility than the use of "cost-effective." For example, it could be read to reference how quickly the requirements achieve the required results.

2. Add the above to 6(c)(2)(A) and add the following at the end of the last sentence of 6(~~c~~)(2)(B)—

   "and shall generally give preference to requirements that are more efficient in satisfying the requirement that a rule promulgated under section 6(a) ensures that the chemical substance does not present an unreasonable risk of injury to health or the environment under the conditions of use as determined in accordance with subsection (b)(4)(A)"

Set C —two versions of revision to House bill language, hewing closest to that language

Commented [A3]: Note that we have not attempted to integrate the Set C and D language into the Senate construct – e.g., we have not referenced back to subsection 4(b)(4)(A) to define "unreasonable risk". Conforming changes can be made if there is a desire to proceed with one of these approaches.

Version 1: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that requirements described in subsection (a) that are in addition to or different from the cost-effective requirements the Administrator was able to identify during the rulemaking process are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

Commented [A4]: Compared to the House bill version, this version clarifies that: 1. The scope of EPA's analysis is limited to the information described under subsection (A) (which includes "reasonably ascertainable economic consequences"); 2. (B) does not drive an open-ended requirement to identify all potentially cost-effective protective requirements; and 3. the requirements selected must eliminate the identified unreasonable risk. It does not "flip the presumption" in favor of cost-effective remedies, though; it weakens the presumption.

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.

Version 2: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective than the other requirements considered by the Administrator, except where the Administrator determines that one or more of the other requirements ~~requirements described in subsection (a) that are in addition to or different from the cost-effective requirements the Administrator was able to identify during the rulemaking process~~ are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

Commented [A5]: This version has the features described in Version 1, plus the added feature of presenting cost-effectiveness as a relative concept. This necessitated a fair amount of rewording, because it clarifies up front that only the range of options considered by EPA is at play.

Set D – more substantial revision to House bill language, to establish a preference rather than a presumption

(B) generally give preference to requirements that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective.

Commented [A6]: This is a softer version of 6(c)(1)(B). It establishes a general preference for more cost-effective requirements. EPA believes its decision to impose less cost-effective requirements could be subject to legal challenge, and that EPA would need to explain why it overcame the preference. But we believe the Agency's bar for doing so would be lower than the bar under the version above.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/11/2016 11:01:10 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on section 5 'unreasonable risk' and may/likely

Michal,
This responds to your TA request on the unreasonable risk finding.

Respecting an affirmative negative finding (i.e., one that would be used to justify restricting a new chemical substance), it would be easier for EPA to justify a determination that a chemical substance "may present" an unreasonable risk than to justify a determination a chemical substance is "likely to present" an unreasonable risk. "Likely" implies a greater degree of certainty about the effects of a chemical than "may present."

Respecting an affirmative positive finding (i.e., that a new chemical is OK to proceed to manufacture) note that there is no opposite-of-"may present" standard to be found under current TSCA. "Unlikely to present" an unreasonable risk is not the opposite finding, because a chemical substance could potentially meet both the "unlikely to present" an unreasonable risk standard and the "may present" an unreasonable risk standard. The opposite of the "may present" finding could perhaps be framed as: "There is not a reasonable basis to conclude that the chemical substance may present an unreasonable risk."

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

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 11, 2016 at 10:12:10 AM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: section 5 TA request - 'unreasonable risk' and may/likely

Sven

Existing TSCA section 5 refers to determinations that a chemical substance 'presents or will present' an unreasonable risk, and 'presents or may present' an unreasonable risk, depending on which part of Section 5 we are talking about.

S 697 alters this construct by including a safety standard definition, and switches the finding to "likely" or "not likely" to meet the safety standard.

If one were switching back to the 'unreasonable risk' lexicon and away from a 'safety standard' lexicon, but retaining the Senate requirement that EPA make affirmative determinations about new chemicals, does EPA see a difference between "presents or may present" and "is likely to present" an unreasonable risk? I do, in that I see "may present" as a lower bar that is consistent with current TSCA. I am interested in your team's views.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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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: 4/4/2016 2:36:31 AM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov; dimitri_karakitsos@epw.senate.gov
Subject: Sen. Markey TSCA TA on draft section 5
Attachments: sect 5 dnb version 4.docx; ATT00001.htm

Michal,
Attached is technical assistance requested on the draft section 5. The TA is based on the review we were able to complete over the weekend. We identified a fair number of issues with this draft and further review would likely identify additional issues. The attachment includes comments that may not be visible on a phone. Please let me know if any questions and if you would like to discuss.
Thanks,
Sven

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

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 31, 2016 at 8:18:09 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Cc: "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov>, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>, "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>
Subject: Section 5 - for review

Sven

Attached is new section 5 drafted to existing TSCA. You'll see a number of specific questions we have for you in comments. We have tried to identify all the potential for drafting challenges and deviations from Senate 5 policy – but we are sure you'll find some we missed. Please give this a very careful review for anything you think we may have overlooked, drafted oddly or wrong, etc. There is no intent to meaningfully alter policy here – we are simply shifting into a re-draft using base TSCA in response to a House request that we attempt to do so. Fast turn-around appreciated.

Thanks
Michal
<5-03-31-16-TOEPAv2.doc>

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

Internal x-refs where existing TSCA lettering/numbering changed have not been conformed pending review of text

(a) IN GENERAL.—(1) Except as provided in subsection (h), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless—

(i) 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 subsections (b), (e) or (f); and

(ii) the Administrator conducts a review of the notice, makes a determination under paragraph (3)(A), and takes any applicable action required under subsections (e) or (f).

(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,

Commented [GB1]: EPA TA: If reference to (e) and (f) is to be maintained in (a)(1), we suggest moving to a new (iii) so as not to mix with requirements relating to the section 5 submission, and to refer to requirements imposed by the Administrator under e and f, since e and f don't directly impose requirements.

Commented [GB2]: EPA TA: What does this mean? Appropriate?

Commented [A3]: EPA TA: As currently drafted, there is a complete ban on all manufacture pending the development of information (since a 3(B) determination is not a determination under paragraph (3)(A). We presume that's not really your intention, in light of the drafting of 3(B) and 5(e), which is contradictory. Note also that 5(e) requires no action on the part of the Administrator whatsoever: it is wholly discretionary authority to impose requirements on the manufacture pending development of information.

Intuiting from the overall structure of your draft, it seems you mean to say: "the Administrator conducts a review of the notice and either: (I) makes a determination under paragraph (3)(A) and takes any applicable action required under subsection (f); or (II) makes a determination under paragraph (3)(B) and [issues an order under (e) to regulate such manufacturing or processing]."

We're not entirely sure what your intentions are with respect to that bracketed language.

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(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) Before the end of the applicable period for review under paragraph (1), and subject to section 18, the Administrator shall review a notice received under paragraph (1) and—

(A) determine whether the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator, [under the conditions of use identified in the notice], and take applicable action under subsection (f); or

(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (b)(3).

(4) FAILURE TO ACT.—If the Administrator fails to complete its review of a notice received under paragraph (1) and make the determination required under paragraph (3) before the end of the applicable period for review under paragraph (1), including an extension pursuant to subsection (c), for reasons that cannot be attributed in whole or in part to actions or inactions of the submitter of the notice, the

Commented [A4]: EPA TA: This makes no sense. Section 18 is only about the preemption of state authority by federal authority. EPA wields federal authority, not state authority.

Commented [A5]: Question for EPA: In the past, you've told us that we should delete the "identified in the notice" language because EPA often is able to use information about similar existing chemicals to identify reasonably foreseeable conditions of use for new chemicals. We have bracketed the language here because we wonder whether EPA would typically reject or differently review a PMN for a manufacturer who is saying they are going to use the chemical for use X because EPA believes OTHER manufacturers might one day want to use the chemical for use Y? We wonder whether identified in the notice should stay here, but stay out in the SNUR part?

Commented [GB6]: EPA TA: We think it is important not to limit review to the uses identified in the notice. If the identified uses seem fine, and EPA therefore does nothing, the submitter is free to submit an NOC and then manufacture in any way he or she wants. EPA often uses 5(e) orders to address uses beyond those specified in notices.

Commented [GB7]: EPA TA: ? Appropriate?

Commented [A8]: EPA TA: Note that as drafted, a determination under (3)(B) doesn't lift the general bar on manufacturing under (1). Manufacture cannot commence pending the development of this additional information. We presume you didn't intend (1) to operate that way, in light of this language, and subsequent language.

Commented [A9]: We'd like your careful review of this to ensure that we capture only the appropriate circumstances in which this should occur

Commented [A10]: EPA TA: This redundant language is confusing. It suggests that if EPA merely failed to make a determination, but EPA *did* complete a review of the notice, then that would be sufficient action to avoid triggering the "failure to act" provisions. Isn't the determinative issue whether or not EPA makes a determination under paragraph (3)?

Administrator shall refund to the submitter of the notice any applicable fee charged to the submitter for review of the notice pursuant to section 26(b)(1). [Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this title.]

Commented [GB11]: EPA TA: We think it is valuable to be clear that the refund of money does not signal any change in obligations, including the EPA obligations the fees were paid to cover.

Commented [A12]: Is there any reason to think that this would not be the case absent this sentence?

(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)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.

(b) SUBMISSION OF INFORMATION.—

(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 for such substance pursuant to a rule, order or consent agreement under section 4 before the submission of such notice, such person shall submit to the Administrator such information 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

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(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule or order 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 submission of the information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

Commented [GB13]: EPA TA: This is not in section 4(b)(1)(B), and it changes the meaning. TSCA currently does not allow manufacture or processing by a person exempt from submitting test data until 90 days after the information is actually submitted; whereas this draft allows manufacture 90 days after the date the information was required to be submitted, whether it was submitted or not. Is that intentional?

(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 (5), and

(ii) is not required by a rule, order, or consent agreement under section 4 before the submission of such notice to submit information for such substance,

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

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes show that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

Commented [A14]: We believe we do not need to qualify this use of unreasonable risk in either clause here because it does not relate to an EPA determination or action of any sort. Correct us if we are wrong.

Commented [GB15]: EPA TA: This is up to the drafters, but it seems to us that it makes sense to ask the submitter to try to demonstrate what EPA will actually have to find – ie, no UR, without consideration of cost.

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

(3) If the Administrator determines under subsection (a)(3)(B) that additional information is necessary to make the determination under subsection (a)(3)(A), the Administrator—

(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

(C) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information;

(D) on receipt of information the Administrator finds supports the determination under subsection (a)(3)(A), shall promptly make the determination; and

(E) may take the actions specified in subsection (e).

(4) Information submitted under paragraph (1), (2) or (3) shall be made available, subject to section 14, for examination by interested persons.

(5)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator determines in accordance with subsection (a)(3)(A) 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.

Commented [GB16]: EPA TA: Although EPA must give the submitter opportunity to provide information, it is not obligated to do anything else – specifically, EPA is not required to get additional info under section 4, ever make an (a)(3)(A) determination (unless EPA gets information), or issue a 5(e) order. If EPA does not do these things, apparently the submitter will never be able to commence manufacture or processing. Is that the intent?

Commented [GB17]: EPA TA: This gives EPA limited authority to extend the review period, but why the need to extend if the submitter cannot commence anyway?

Commented [GB18]: EPA TA: This means EPA lists only chemicals that it finds meet the may present standard through the section 5 process. Currently, the main purpose of sec 5(b)(4) is to identify chemicals as to which EPA has concerns that will require the submission of data with a PMN or SNUN. If under the draft "may present" chemicals will be identified only through the sec 5 process, then what is the purpose of this section 5(b)(5)(A)?

(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—

(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.

(c) EXTENSION OF NOTICE AND REVIEW 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, subject to any applicable requirements under subsection (e) [or (f)] 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 [GB19]: EPA TA: Existing TSCA specifies that the Administrator shall consider "all relevant factors, including – ". Is there a reason (I) and (II) have been made exclusive? Other factors may be relevant to an unreasonable risk finding.

Commented [A20]: Senate staff don't agree on whether (f) is needed. Some of us believe that since (f) is what happens AFTER the review period ends or a determination is made it makes no sense to reference here. Others think there could be a scenario where a determination is made during an extension and we need to say it is ok for manufacture to commence if the restrictions under (f) are implemented. Request EPA TA on this point.

Commented [GB21]: EPA TA: We suggest retaining reference to (f), since it apparently is the intent that any manufacture or processing that occurs must be compliance with (f) requirements. Also, we don't see a basis to distinguish (e) from (f) in this regard.

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

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

(B) lists the conditions of use of such substance; and

Commented [GB22]: EPA TA: Conditions of use is defined to include not only intended but all reasonably foreseeable uses. Is that what you intend EPA to list? May be hard to do that within 5 days.

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any informationwhich 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 period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

(e) REGULATION WHEN AVAILABLE INFORMATION IS INSUFFICIENT.—(1)(A) If the Administrator determines that the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)(A) for a chemical substance or significant new use with respect to which notice is required by subsection (a), the Administrator may issue an order in accordance with subsection (f)(2), to take effect on the expiration of the notification and review period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of such substance, or manufacture or processing of the chemical substance for a significant new use, or to prohibit or otherwise restrict any combination of such activities.

(B) No person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use pursuant to this paragraph except in compliance with the restrictions specified in the order issued under subparagraph (A).

Commented [GB23]: EPA TA: A proposed order, right?

Commented [A24]: EPA TA: Note that 5(e) and 5(f) are now cross-referenced in an extraordinarily confusing fashion. Parts of the law governing 5(e) are now buried in 5(f), and parts of the law governing 5(f) are now buried in 5(e).

Commented [A25]: Questions for EPA. Note that we have not inserted a standard for the nature of the restrictions that need to be put into place. We have considered some options for how to do that, which include things like
"activities sufficient for the Administrator to ensure that the chemical substance or significant new use is not likely to present such a risk"
"activities sufficient for the Administrator to ensure that the chemical substance or significant new use is not likely to present an unreasonable risk"
"activities until the Administrator makes the determination in subsection (a)(3)(A)"
Our problem is that there is no "risk" defined here because the entire point is "we don't know yet, but we are pretty sure if you don't put it in the water you'll be fine making this until the test data comes back". We don't know how to define the standard of protection, and we also note that "may" and "not likely" are also not mutually exclusive. Appreciate your input here.

Commented [A26]: EPA TA: 5(e) regulation should be workable with exactly the same objective as 5(f) regulation ("not likely to present an unreasonable risk"). As you note below, "may present an unreasonable risk" and "not likely to present an unreasonable risk" are not mutually exclusive concepts. For exactly that reason, determining that the risk has exceeded some cutoff (e.g., "may present an unreasonable risk") is not an analytical pre-requisite to imposing restrictions sufficient to allow EPA to conclude that the chemical is "not likely to present an unreasonable risk." The new chemical review process is not analogous to the existing chemical review process, where the cutoff used to determine that regulation is necessary the flip-side of the objective for subsequent risk management regulation. Section 5 is dealing with prospective regulations to address uses that haven't even commenced: the target is simply what the Administrator finds necessary to conclude that she'll probably never need to take risk management action on an existing chemical substance that she let through the door under the new chemicals program..

Commented [A27]: EPA TA: But note: it is discretionary on EPA's part whether to issue such an order in the first place. What happens if EPA issues no such order? (B) does not resolve the question because it pre-supposes the existence of the order.

(C) Not later than 90 days after issuing an order under subparagraph (A), 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 order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—

Commented [A28]: Note here that the order relates to the conditions of use in the notice, and this would key off that – need to resolve.

Commented [GB29]: EPA TA: It seems like the best solution, per above comment, may be to drop the limitation above that the order pertain only to the conditions of use specified in the notice.

Commented [A30]: Leg counsel needs to conform rest of subsection x-refs to reflect new subparagraphs

Commented [GB31]: EPA TA: These limitations on EPA's authority to issue a 5(e) order make sense in current TSCA but not under the bill. Under TSCA, manufacture can commence without action by EPA, and Congress gave EPA limited time to act. Under the bill, the submitter apparently requires some EPA action before it can commence manufacture and/or processing. If EPA misses this 45-day deadline, then EPA apparently under this structure would not be able to issue the order that might allow manufacture/processing.

Commented [GB32]: EPA TA: In line with the preceding comment, the remainder of (e) does not work well with the bill structure. It makes sense in current TSCA, under which EPA (or a court) must stop a company from manufacturing or processing; it is confusing and serves no function under the bill, which requires affirmative EPA action prior to manufacture/processing. We have made some more specific comments below, but the whole structure is problematic.

A possible solution would be, in line with the Senate bill and offer, to drop (e) and require EPA to issue an order under what is now (f) any time EPA either makes a may present finding or lacks sufficient info, as necessary to make the unlikely to present finding.

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(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 [A33]: EPA TA: The standard for the judge to use in litigation is out of alignment with the findings EPA was itself supposed to make. They need to align, or else there will always be an incentive to litigate, in order to obtain a better This should be: "additional information is necessary to make the determination under subsection (a)(3)(A)."

(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 non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population 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.

Commented [A34]: EPA TA: The judicial standard here is out of alignment with the actual risk management standard. EPA didn't need to make a may present finding to justify the administrative rule ORDER?... why does it now need to show may present in court?

Perhaps it would work to say: "the injunction is [redacted] so that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A)."

Commented [A35]: EPA TA: This is no longer one of the criteria for issuing a 5(e) order. It should be deleted to conform.

(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 information 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 information 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 the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may present an unreasonable risk of injury to health or environment in accordance with subsection (a)(3)(A), —

(A) the Administrator shall issue an order, to take effect on the expiration of the notification and review period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, or to the significant new use, to prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, sufficient for the Administrator to determine that the chemical substance or significant new use is not likely to present such risk;

(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a

Commented [GB36]: EPA TA: This is the title from current TSCA 5(f) but doesn't fit well here because the order in the bill is premised on only a "may present" finding.

Commented [GB37]: EPA TA: (e) uses different language for this. Be consistent.

Commented [A38]: EPA TA: Why is this parenthetical necessary?

Commented [GB39]: EPA TA: Why can EPA regulate only mfr and processing in the case of a SNUN, but all activities in the case of a PMN? Current sec 5(e) is not so limited.

Commented [A40]: Question for EPA: may present and not likely to present are not mutually exclusive. Should we return to existing TSCA-like words "to the extent necessary to protect against such risk"?

Commented [A41]: EPA TA: The existing language is clear and workable. The fact that "may present" isn't the exact opposite of "not likely to present an unreasonable risk," shouldn't prevent EPA from implementing this as a risk management standard.

significant new use pursuant to this subsection except in compliance with the restrictions specified in the order; and

(C) not later than 90 days after issuing an order under subparagraph (A), 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 order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(2) In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator under paragraph (1) of this subsection or under subsection (e)(1)(A), the Administrator shall consider costs and other non-risk factors, and such an order may include—

(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).

(3) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are

Commented [GB42]: EPA TA: But EPA can't consider risk factors? Only cost and non-risk?

Commented [GB43]: EPA TA: Why is the authority to prohibit removed from here, and instead handled in a separate (f)(3), below? At least, that's our best read of what you are doing. That is very confusing. First of all, it is confusing (and seemingly incorrect) to say that EPA *must* issue an (f)(1) order, which cannot include a ban, and may issue an (f)(3) order to ban. If EPA issues an (f)(3) order, what does it put in the manadatory (f)(1) order? And more fundamentally, why create two different types of orders governed by different provisions rather than simply giving EPA authority to issue an order with appropriate conditions, subject to justification by EPA?

Commented [A44]: Question for EPA: do we need to add or change based on our 6(a) list in order to capture everything EPA currently can do?

Commented [A45]: EPA TA: Yes. 5(e) orders are now being limited to the particular restrictions available under 5(f)(2), and those apparently do not include the authority to prohibit. Aside from the prohibition issue, current 5(e) is not limited to the section 6 list under TSCA.

sufficient to address such risk identified in accordance with subsection (a)(3)(A), reduce potential exposure to the substance to the maximum extent practicable.

(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

(3)(A) The Administrator may—

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.

(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with

Commented [A46]: Different way to address the "may" and "not likely" can both be true at once problem. Does this work?

Commented [A47]: EPA TA: This is a less clear approach, because the reader has to infer what it means to "address the risk." Presumably the standard is restriction sufficient so that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A)."

Commented [A48]: Leg counsel to conform x-refs as needed in para (3)

Commented [A49]: EPA TA: This requires more work than just conforming x-refs by leg counsel. Per above comment, it is fundamentally confusing to create a mandatory and a discretionary order with the same objective.

Commented [GB50]: EPA TA: In line with comments on (f), the process involving proposed orders and/or EPA efforts to get judicial injunction does not make sense in a section that now requires EPA action for manufacture or processing to commence. EPA does not need to get an injunction; rather, the submitter is stopped until EPA acts. At least that's our understanding of your intent.

Commented [A51]: EPA TA: This judicial standard is out of alignment with how you've revised the underlying risk management objective of 5(f). You're trying to conform the judicial review language of 5(f) from current TSCA. Under 5(f) of current TSCA, though, EPA needs to make a "presents or will present" finding. The administrative analytical standard under 5(f)(A), however, is now not likely to present an unreasonable risk. It doesn't make sense for EPA to have to prove more in litigation than it was trying to prove to itself when issuing the original administrative order.

Just as the risk management standards of 5(e) and 5(f) can be the same, the judicial standards can be the same. We think the standard you're intending is: "the injunction is [redacted] so that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A)."

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, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use, 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.

Commented [A52]: Question for EPA: Ok to reference our language in section 6 that we use for REs that describes all of these instead of writing it all down twice?

Commented [A53]: EPA TA: As noted above, there's a broader problem here. Why is EPA proving in court that there is an unreasonable risk, when the original 5(f) order was founded on a "may present" finding?

(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).

(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use.

Commented [A54]: EPA TA: Same issue as noted above.

(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use

Commented [GB55]: EPA TA: Title doesn't seem right.

may present an unreasonable risk of injury to health or the environment is not justified, then notwithstanding any remaining portion of the period for review under subsection (a), (b), or (c) applicable to the manufacturing or processing of such substance or significant new use, the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use, and the Administrator shall publish a statement of the Administrator's finding . Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

Commented [GB56]: Suggested formulation: If the Administrator makes a determination under subsection (a)(3)(A) and does not determine that the chemical substance under review may present an unreasonable risk of injury to health or the environment,"

Commented [A57]: Question for EPA: This is our solution to the "may" and "not likely" can both be true at the same time problem for this subsection. Does it work? We can't say "does not determine" because that leaves open the potential that EPA just doesn't make a determination at all. We are trying to find words that say "EPA did what it was supposed to do and did not find "may present". Any issues w the words "find' or "findng"? Especially as it relates to any judicial reviewability implications? I don't think that the "safe" finding under Senate offer 5 met Bennet v Spear standards and I am not sure this is any different, but tell us if you disagree.

Commented [GB58]: EPA TA: This may be difficult to do. EPA does not control publication, and this effectively shortens the review period.

(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, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator for the specific uses identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

Commented [A59]: Should this be conditions of use? Our thinking was the application would be for specific uses and not for the breadth of uses EPA might consider when contemplating a SNUR. Tell us if we are wrong.

Commented [GB60]: EPA TA: We agree that the reference to specific uses makes sense, but not because of anything having to do with a SNUR. It seems to us that, if a party is seeking a partial section 5 exemptions, we would consider only the uses for which they are seeking the exemption, since the exemption would limit them to those.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

Commented [A61]: Leg counsel to conform internal X-refs here if needed

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information by the applicant on such substance would be duplicative of information which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such informationon such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

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

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by such person in complying with the requirement under subsection (b) (2) to submit such information, 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 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 informationto 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

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Administrator determines was necessary to develop such information

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, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator under the conditions of use.

Commented [A62]: We thought this one should be conditions of use since it is a broader exemption. Tell us if we are wrong.

Commented [dnb63]: EPA TA: The current language is fine. EPA could make the global finding for all conditions of use simply by analyzing the specific conditions of use submitted in an exemption request under the rule, and any other Section 5 exemptions that have already been issued for this chemical. Because there would be no other uses authorized, EPA would be in a position to make a global determination that exempting the specific uses in the exemption application would not present an unreasonable risk for any conditions of use.

(4) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the

manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(5) Immediately upon receipt of an application under paragraph (1) or (4) 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) 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 does not displace common law.

[15 U.S.C. 2604]

ED_002117_00008604-00020

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/29/2016 7:04:25 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA - slightly new Senate 14(c) construct

Michal - Got it, thanks. Please let me know if a call needed. Best,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 29, 2016 2:56 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA - slightly new Senate 14(c) construct

Sven

Could you please look at the following text? Basically, we are looking to address a House issue with the Senate 14 offer by going back to something that looks more like what the Senate reported out of EPW. We are particularly interested in EPA's take on whether there is conflict between the highlighted text portions. My own read of how this works is

- Health and safety studies get disclosed. No protecting them from disclosure until someone files a FOIA or makes another type of request. They go out.
- However, certain types of chem ID info (what currently gets statutory protection under TSCA) can be redacted from these studies.

PLs add your views, suggestions, etc as appropriate.

Thanks

michal

(c) Information Not Protected From Disclosure.—
(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:
(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—
(i) IN GENERAL.—Subject to clause (ii), subsection (a) does not prohibit the disclosure of—
(I) any health and safety study that is submitted under this Act with respect to—
(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or
(bb) any chemical substance or mixture for which—
(AA) testing is required under section 4; or (BB) a notification is required under section
5; or

(I) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

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: 4/17/2016 7:09:49 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sens. Udall and Merkley TSCA TA on section 18(b) and (c)
Attachments: 18-04-16-16 edits.doc

Jonathan and Adrian,
This TA responds to the questions on section 18(b) and (c) you raised along with those in the attachment.

Section 18(b)

We understand Richard's concern with the end-date for the preemption of enforcement, but think that the better reading of 18(b) is that the overall end date for preemption in 18(b)(1) cuts off the effect of the provisions of 18(b)(2). However, we don't think we can say an effort couldn't be made to take the tack that Richard is concerned about because there is no explicit end date in 18(b)(2)(B).

Before suggesting language to deal with it, we did want to point out that we actually think all of 18(b)(2) could be eliminated, as we don't think it's really necessary since we don't think there's a viable reading of 18(b)(1) that extends the prohibition on establishing new statutes or administrative actions to enforcement of pre-existing statutes or administrative actions. Section 18(b)(2)(A) is an attempt to clarify that the preemption of (b)(1) doesn't extend that far, but it's not really a necessary clarification. However, once the 18(b)(2)(A) clarification was inserted, presumably others sought to insert 18(b)(2)(B) to clarify the clarification, by making it clear that states couldn't enforce what they were prohibited from establishing in (b)(1). It was in the process of introducing that second-level limitation or clarification that the potential issue was introduced. Consequently, to us, the best solution would be to eliminate 18(b)(2) completely.

However, if there is not an appetite to do that, we think that language could be inserted after the word “enforce” in the second line of (b)(2)(B): ", before the termination of preemption pursuant to paragraph (1)," and that the phrase “after the date described in that subparagraph” should be deleted and replaced by “during the period of preemption described in paragraph (1).”

Section 18(c)

We agree with Richard’s concern that section 18(c) could be read to provide for a broader scope of preemption than is apparently intended, and we think his suggested language would address the issue.

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: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Sunday, April 17, 2016 12:44 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: FW: My comments on 18

Would appreciate your views on these comments, especially the third comment. (B3)

From: Richard Denison [mailto:rdenison@edf.org]
Sent: Sunday, April 17, 2016 12:37 PM
To: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Cc: joanna <joannaslaney@gmail.com>
Subject: RE: My comments on 18

Small additional change to resolve cross-ref issue I flagged, green-highlighted on p. 1

From: Richard Denison
Sent: Sunday, April 17, 2016 12:14 PM
To: Adrian Deveny (adrian_deveny@merkley.senate.gov); Jonathan Black (jonathan_black@tomudall.senate.gov)
Cc: joanna
Subject: My comments on 18
Importance: High

Edits in the attached.

A very impt needed change I have raised many times before is that flagged by comment B3

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

SEC. 18. ~~PREEMPTION~~STATE-FEDERAL RELATIONSHIP.

(a) ~~EFFECT ON STATE LAW.—~~

~~(1)~~ IN GENERAL.—

(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c), (d), (e), (f) and (g), and subject to paragraph (2), ~~nothing in this Act shall affect the authority of any~~ No State or political subdivision of a State may ~~to~~ establish or continue ~~in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture~~ to enforce any of the following:

(A) TESTING.—A statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

(i) a rule promulgated by the Administrator;

(ii) a consent agreement entered into 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 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 under section 6(d) [illegible] section 6(cd) for the 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 required notification pursuant to a rule promulgated under section 5.

(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—

(1) IN GENERAL.—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 under section 6(~~ba~~)(4~~2~~)(D) and ending on the date on which the deadline established pursuant to section 6(b)(4)(G)~~a~~) 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)~~a~~), whichever is earlier, no State or political subdivision of a State may establish a statute or

Commented [B1]: Reworded to cross-ref where effective date is set for a rule

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administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under 6(b)(1)(B)(i).

(2) EFFECT OF SUBSECTION.—

(A) IN GENERAL.—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).

(B) LIMITATION.—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 and before the date on which the deadline established pursuant to section 6(b)(4)(G) for completion of the risk evaluation expires, or before the date on which the Administrator publishes the risk evaluation under section 6(b)(4)(C)), whichever is earlier.

Commented [B2]: Language to end this prohibition for enforcement of actions taken after the pause lifts.

(c) Scope of Preemption.—Federal preemption under subsections (a) and (b) of statutes and administrative actions applicable to specific substances shall apply only to—

(1) with respect to subsection (a)(1)(A), the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;

(2) with respect to subsections (a)(1)(B) and (b)(1), 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 substance under section 6(b)(4)(D), or of any rule the Administrator promulgates pursuant to section 6(c); or

(3) with respect to subsection (a)(1)(C), the uses of such 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.

Commented [B3]: I sent this needed clarification around numerous times to all S staff and never heard back one way or the other. It and the insertions at the beginning of (2) and (3) are intended to address this problem:

Some are reading subsection (c) as indicating a broader-than-intended extent of preemption, e.g., that subparagraph (C) would preempt states from acting in any way on any uses of a chemical EPA had designated to be a significant new uses.

It's possible to read this as applying ANY of (1)-(3) here to ANY of (a)(1)(A)-(C), instead of them being one-to-one corresponding – which I know to have been the intent.

I think these changes are very impt to make

~~(2) Except as provided in subsection (b)—~~

~~(A) if the Administrator requires by a rule promulgated under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, establish or continue in effect a requirement for the testing of such substance or mixture for purposes similar to those for which testing is required under such rule; and~~

~~(B) if the Administrator prescribes a rule or order under section 5 or 6 (other than a rule imposing a requirement described in subsection (a)(6) of section 6) which is applicable to a chemical substance or mixture, and which is designed to protect against a risk of injury to health or the environment associated with such substance or mixture, no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect, any requirement which is applicable to such substance or mixture, or an article~~

~~containing such substance or mixture, and which is designed to protect against such risk unless such requirement (i) is identical to the requirement prescribed by the Administrator, (ii) is adopted under the authority of the Clean Air Act or any other Federal law, or (iii) prohibits the use of such substance or mixture in each State or political subdivision (other than its use in the manufacture or processing of other substances or mixtures).~~

(d) Exceptions.—

(1) NO PREEMPTION OF STATE STATUTES OR ADMINISTRATIVE ACTIONS.—

(A) IN GENERAL.— Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, 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, safety determination, safety assessment, scientific assessment, or any protection for public health or the environment that—

(i) 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;

(ii) implements a reporting, monitoring, disclosure, or information obligation for the chemical substance nor otherwise required by the Administrator under this Act or required under any other Federal law; or

(iii) 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 action—

(I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

(II)(aa) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the risk evaluation pursuant to section 6(b)(4)(D), but is inconsistent with the action of the Administrator; or

(bb) would cause a violation of the applicable action by the Administrator under section 5 or 6; or

(iv) subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.

(B) IDENTICAL REQUIREMENTS.—

(i) IN GENERAL.—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.

(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

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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.—Notwithstanding subsection (e)—

(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

(B) 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 Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after 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 ~~as~~ the selection of that ~~a~~ chemical substance selected for risk evaluations under section 6(b)(4)(E)(iv)(II).

Commented [B4]: A few edits for clarity

(e) Preservation of Certain State Laws.—

(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

(A) 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 before ~~August~~January 1, 2016~~5~~, 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

(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

(2) EFFECT OF SUBSECTION.—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.

(f) Waivers.—

(1) DISCRETIONARY EXEMPTIONS.—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 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 that—

(A) compelling conditions warrant granting the waiver to protect health or the environment;

(B) 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;

(C) 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

(D) 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 identified—

(i) consistent with the best available science;

(ii) using supporting studies conducted in accordance with sound and objective scientific practices; and

(iii) based on the weight of the scientific evidence.

(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~~B~~) 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~~C~~) 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) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator initiated a risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

(2) DETERMINATION OF A WAIVER REQUEST.—The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercised—

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(A) not later than 180 days after the date on which an application under paragraph (1) is submitted; and

(B) not later than 110 days after the date on which an application under paragraph (2) is submitted.

(4) FAILURE TO MAKE DETERMINATION.—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 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 or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.

(5) NOTICE AND COMMENT.—Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of a State shall be subject to public notice and comment.

(6) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of a State shall be—

(A) considered to be a final agency action; and

(B) subject to judicial review.

(7) DURATION OF WAIVERS.—A waiver granted under paragraph (2) or approved under paragraph (9) shall remain in effect until such time as the Administrator publishes the safety determination under section 6(a)(4).

(8) JUDICIAL REVIEW OF WAIVERS.—Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under 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.

(9) APPROVAL.—

(A) AUTOMATIC APPROVAL.—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.

(B) REQUIREMENTS.—Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadlines under paragraph (3)(B) shall not be considered final agency action or be subject to judicial review or public notice and comment.

(g) Savings.—

(1) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—

(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, 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

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statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

(2) NO EFFECT ON PRIVATE REMEDIES.—

(A) IN GENERAL.—Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, risk evaluation, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

(B) AUTHORITY OF COURTS.—This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, risk evaluations, scientific assessments, or orders issued pursuant to this Act.

~~(b) EXEMPTION.—Upon application of a State or political subdivision of a State the Administrator may by rule exempt from subsection (a)(2), under such conditions as may be prescribed in such rule, a requirement of such State or political subdivision designed to protect against a risk of injury to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if—~~

~~(1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under this Act described in subsection (a)(2), and~~

~~(2) the State or political subdivision requirement~~

~~(A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a)(2) and~~

~~(B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.~~

[15 U.S.C. 2617]

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/26/2016 6:30:34 PM
To: Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: Re: HEC min TSCA TA request on section 5 and 8

Yep- we're here

On Apr 26, 2016, at 2:29 PM, Cohen, Jacqueline <jackie.cohen@mail.house.gov> wrote:

Did we get back to you on this? 255.

-----Original Message-----
From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 26, 2016 12:14 PM
To: Fruci, Jean <Jean.Fruci@mail.house.gov>
Cc: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: HEC min TSCA TA request on section 5 and 8

Jean and Jacqueline,
We are okay with 2:30 pm at Ford. Room number? Thanks, Sven

On Apr 26, 2016, at 11:19 AM, Fruci, Jean <Jean.Fruci@mail.house.gov> wrote:

We would like you to come over to the Ford building to meet with us on pending language amending Sections 5 and 8 of TSCA this afternoon at either 2:30 or 3:00pm. Thanks.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 3:59:47 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on section 6 TA - House R language- followup

Michal,
This TA responds to the followup request on section 6 - House R language.

The solution to the section 6 issue, as you suggest, is straightforward: simply delete the reference to section 4 added in HLC to section 6(a)(1)(G). That would conform the text to current TSCA. With this reference gone, EPA would most likely interpret the new authority in section 4 -- allowing EPA to require testing as necessary to ensure compliance with a section 6(a) rule -- as providing *additional* authority to require testing beyond what is required in a section 6 rule -- for example, to address unforeseen circumstances that arise during implementation.

The section 4 issues could be addressed in various ways, depending on the desired outcome. Under the latest HLC, the requirements of 4(b) and 4(c) apply only to rules, not to orders or consent agreements. These would apply regardless of whether the rule was issued under the "old" may present/substantial production bases, or under one of the "new" bases (eg, to implement section 6 rules, for prioritization). Thus, the specification of standards and protocols, the requirement to reduce use of vertebrates, the specification of who must test, and the provisions regarding the reimbursement period and testing exemptions would apply only to rules, not orders. This does not necessarily present an issue or concern, with the exception of the "who is required to test" provisions (4(b)(3)).

Per earlier TA, these provisions prescribe who must test based on the finding made by EPA in imposing testing under existing TSCA 4(a). Because EPA will not make those findings for a test rule under the new authority -- and because orders and consent agreements under the new authority will not be subject to these provisions at all -- the law would provide no guidance as to whom EPA can impose testing obligations on under the new authority. This could create implementation issues for rule and orders, since it could be argued that Congress should specify whom EPA can impose obligations on. (It should not create an issue for consent agreements, since they are consensual.)

Here are two possible solutions:

1. Strike 4(b)(3) and insert: "A rule or order under subsection (a) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would be the simplest approach from an implementation perspective, in that it gives EPA authority in any test rule or order to impose test requirements on the manufacturers and/or processors that are most suited to conduct the testing.

2. Another approach involving less textual change would be to retain the existing 4(b)(3) but add a (C) as follows: "(C) A rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture

subject to the rule or order." This would require several minor conforming changes to (b)(3), which we could provide if you are interested in this approach. This approach would maintain the existing allocation of testing responsibilities under TSCA for rules under the "old" authority but add direction for rules and order under the "new" authority. Under either of these approaches, "rule" should be stricken from the title of (b).

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: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 23, 2016 at 5:15:41 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on section 6 TA - House R language

Thanks - is there a way to address?
In 6a I assume it would be to remove the language
In 4, I believe you've said in the past that the language in question doesn't work for orders/consent agreements.

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

From: Kaiser, Sven-Erik
Sent: Friday, April 22, 2016 4:47 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 6 TA - House R language

Michal,
This TA responds to the request on section 6 TA followup on House R language.

Section 4 requires a statement of need for testing, requires a tiered approach, and requires identification of protocols and methodologies. Those are certainly manageable in the context of a section 6 rule, but they impose some requirements that otherwise would not be imposed in section 6. There also may be some difficulty in applying the provisions in 4(b)(4) regarding expiration of the reimbursement period, since the section 6 rule may not have a fixed testing requirement or period for testing but rather may have a more open

ended obligation to conduct testing under circumstances specified in the rule. But these issues should be manageable.

The potentially more substantive issue is that the latest HLC version of section 4 we have seen does not provide any guidance on who can be made to test in a test rule or order under the new 4(a)(2) authority. But this is an issue with section 4 itself, and not unique to the incorporation of section 4 into section 6. TSCA 4(b)(3) requires that each test rule impose testing obligations on all manufacturers of the chemical substance, or all processors, or both, depending on which 4(a)(1) finding EPA makes to support the rule (may present, or substantial production/release/exposure). Specifically, it provides that "the following persons [all manufacturers and/or all processors] shall be required to conduct tests and submit data on a chemical substances or mixture subject to a rule under 4(a). . . .", and then lays out whether the entities required to test are the manufacturers or processors or both, depending on which 4(a)(1) finding was made. Because EPA will not be making one of these findings under 4(a)(2), the current 4(b)(3) is not a great fit, since it assumes that one of those findings will have been made to support each test rule.

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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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 22, 2016 1:50 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: question on your 6 TA from last night

1 (G) by striking "and monitor or conduct
2 tests" and inserting "or monitor or conduct
3 tests pursuant to section 4" [A1] in paragraph (4);
4 and

This was a House R request. What additional requirements will those be? btw, Senate agreed to add test orders to 4(a)(1) yesterday.

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

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EPA TA: This will suggest that EPA must follow any applicable section 4 requirements, as well as section 6 requirements, in imposing test requirements.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/29/2016 7:03:19 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA PBTs on New Chemicals

Michal- got it- line is open Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy

On Feb 29, 2016, at 1:59 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven:

Wanted to confirm EPA views of a proposed change to section 5 PBT language following on this older TA. Is the new alternative likely to result in a more stringent outcome than S 697? If not, can you suggest a tweak?
Thanks
Michal

Proposing to change from

> D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment, reduce potential exposure to the substance to the maximum extent practicable.

To

> D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—In selecting among prohibitions and other restrictions for a chemical substance that is a persistent and bioaccumulative substance, the Administrator shall act in a manner consistent with the TSCA Policy Statement on Persistent, Bioaccumulative and Toxic New Chemical Substances published by the Administrator in November 1999 (or a successor Policy Statement).

Michal Ilana Freedhoff, Ph.D.
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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, December 03, 2015 7:20 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA PBTs on New Chemicals

Michal,
This responds to your TA request on new chemical reviews. Please let me know if any additional questions
Thanks,

Sven

Question: If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so, and b) how long would scoring take (days, weeks, months, etc?)

a) **Yes, EPA would be able to score new chemicals in the same way it scores chemicals pursuant the TSCA Work Plan Methods document, and**
b) **The time to do so would not extend the PMN process beyond allotted 90-day deadline.**

However, we'd note that application of the New Chemical PBT policy referenced in previous TA is likely to be more stringent than the risk management standard included in the Senate PBT provision - "reduce exposure to the maximum extent practicable"

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, December 03, 2015 4:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on PBTs

Quick follow up for you – would be great to get this by 5 pm or shortly thereafter. If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so and b) how long would scoring take (days, weeks, months, etc?)

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

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

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 2:04 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on PBTs

Michal,

This responds to your TA requests on PBT determination and the follow on question about "maximum extent practicable".

1. Section 5 PBT language in S 697 requires EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

EPA currently reviews and categorizes new chemicals for persistence, bioaccumulation, and toxicity (PBT) characteristics under section 5 of TSCA in accordance with a policy statement published in 1999. A copy of the proposed and final policy is available on our website here. New chemicals are not currently scored "pursuant to" the 2012 Work Plan Chemicals Methods document. Because the language in 5(d)(4)(D) does not require a mandatory scoring of new chemicals for P or B pursuant to the Work Plan Chemicals Methods document, one possible outcome is that EPA never makes such a determination, and the specified risk management standard is never invoked.

EPA United States Environmental Protection Agency

Policy Statement on a New Chemicals Category for ...

On November 4, 1999, EPA issued its final policy

statement (64 FR 60194) on a category for Persistent Bioaccumulative and Toxic new chemicals.

Read more...

2. Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

As a purely linguistic matter, we do not see a significant difference between "to the extent practicable" and "to the maximum extent practicable" – the concept of "maximum" seems be implied in the first formulation. That having been said, arguments could certainly be raised that Congress' choice of the less explicit House formulation over the Senate formulation (in sections 5(d)(4)(D) and 6(d)(2)(B) of TSCA as modified by the Senate bill), indicates a choice to adopt a less demanding understanding of the extent to which EPA is required or authorized to reduce PBT exposure.

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

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

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Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:44 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Quick follow on on PBTs

Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

Thanks

Michal

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

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: November 24, 2015 at 10:11:33 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: PBT question

Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

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Washington, DC 20510

202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 5:54:51 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on 14(c)(B)(4) and 14(d)(1)(D)

Got it - thanks

Sven-Erik Kaiser
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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: Tuesday, March 15, 2016 1:42 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on 14(c)(B)(4) and 14(d)(1)(D)

Sorry, just 14(c)(4) – indenting got screwed up
CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is subject to disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 1:40 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on 14(c)(B)(4) and 14(d)(1)(D)

Michal – we're not seeing section 14(c)(B)(4) – what version is it in? Thanks,
Sven

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 11:28 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: More senate 14 qs

Are senate 14(c)(B)(4)
Or 14(d)(1)(D)
Needed? Redundant? In conflict with other parts of the section?
Thx

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: 2/11/2016 10:52:10 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
Subject: SEPW TSCA TA request on Inventory Reset
Attachments: SEPW.TSCA TA.Inventory Reset.docx

Dimitri,
The attached document responds to your TA request on the inventory reset. Please let me know if any additional questions. Thanks,
Sven

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

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Tuesday, February 09, 2016 9:54 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request

Morning Sven,

Hope everything is going well. Wanted to see if you all could give me thoughts or language on a few things in Section 8 of the Senate TSCA bill.

First would be how to possibly redraft the inventory reset provision. Its design was merely for EPA to publish the current inventory and through a simple hand raising exercise break it up into an "active" and "inactive" list based on responses from manufacturers and processors. What it was not supposed to do (and there seems to be a lot of concern and confusion) is create some massive reporting requirement where every use had to be registered or every company had to duplicate submittals – if one manufacturer or processor says something is active, that is it and it goes on the active list and everyone else is absolved of any responsibilities. This is not where EPA should be registering uses or getting all its exposure information, it is just to split the list into two categories in the easiest way possible.

Additionally I would be curious to get EPA's thoughts on whether 10 years is preferred/necessary for the time period going back or would something like 5 likely be sufficient for an "active" substance? This is also supposed to help inform the agency but not create some sort of retroactive penalty provision where if someone forgot they manufactured something 9 years ago and not 10 they get fined by the agency. 10 years may just be too long a timeframe.

Finally, there has been some concern that although we intended a simple notification to be required to move a chemical substance from the inactive list back to the active list this may be viewed as requiring a more stringent notification that was intended possibly even under Section 5. This again was not the intent, it was merely to let EPA know a chemical is now active and being manufactured so they should consider it eligible for prioritization and review as necessary. Any thoughts on how to make clearer this is just another hand raising exercise?

Any thoughts/assistance would be much appreciated and I am happy to discuss if folks are interested.

Thanks,

Dimtiri

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

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.] First would be how to possibly redraft the inventory reset provision. Its design was merely for EPA to publish the current inventory and through a simple hand raising exercise break it up into an "active" and "inactive" list based on responses from manufacturers and processors. What it was not supposed to do (and there seems to be a lot of concern and confusion) is create some massive reporting requirement where every use had to be registered or every company had to duplicate submittals – if one manufacturer or processor says something is active, that is it and it goes on the active list and everyone else is absolved of any responsibilities. This is not where EPA should be registering uses or getting all its exposure information, it is just to split the list into two categories in the easiest way possible.

We are not aware of any provision under § 8(b)(4) whereby the manufacturers and processors of chemical substances would be required to report information on a use-by-use basis or report any information on the uses of their chemical substances. The reference to "non-exempt commercial purpose" is a regulatory exemption for persons who may have manufactured or processed, but solely for non-commercial or exempt commercial purposes (e.g., non-isolated intermediates or R&D).

As EPA understands the current drafting, the information to be reported would be limited to:

- A notification that the submitter has manufactured or processed the chemical substance in the last 10 years. (§ 8(b)(4)(A))
- An indication whether the submitter wishes to maintain any existing claim it may have that the identity of the chemical substance is CBI. (§ 8(b)(4)(B)(ii))
- To the extent such CBI claims are being maintained, upfront substantiation for the claims.

Note: Because the hand-raising exercise is linked to a parallel program whereby EPA must affirmatively review (subject to some carve-outs) all the CBI claims for Chem ID being maintained (§ 8(b)(4)(D)) two raised hands for the same chemical substance are not necessarily duplicate submittals. This is because there may be Chem ID CBI claims at issue. If so, one party may wish to maintain its CBI claims even if another does not. Two parties may submit separate substantiation to maintain their separate CBI claims.

Appended to this TA are drafting changes that we believe accomplish the intent of your request: avoiding the imposition of any new reporting requirements and avoiding the need for more than one manufacturer or processor, per chemical substance, to "raise a hand" as a part of the reset process.

But we have not attempted to resolve the problems that these changes generate in connection with the CBI review provisions under section 8(b)(4). These could be addressed in a variety of ways. For example, the bill could establish a two-phase system where manufacturers and processors first go through the hand-raising exercise and then later go through a separate CBI re-assertion process if their chemical finds its way onto the active TSCA Inventory. We could

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.

provide further drafting assistance on this issue but we would need more direction regarding your intended objectives.

[2.] Additionally I would be curious to get EPA's thoughts on whether 10 years is preferred/necessary for the time period going back or would something like 5 likely be sufficient for an "active" substance? This is also supposed to help inform the agency but not create some sort of retroactive penalty provision where if someone forgot they manufactured something 9 years ago and not 10 they get fined by the agency. 10 years may just be too long a timeframe.

EPA does not have strong feelings on a 10-year versus a 5-year period of lookback for "active" chemical substances.

[3.] Finally, there has been some concern that although we intended a simple notification to be required to move a chemical substance from the inactive list back to the active list this may be viewed as requiring a more stringent notification that was intended possibly even under Section 5. This again was not the intent, it was merely to let EPA know a chemical is now active and being manufactured so they should consider it eligible for prioritization and review as necessary. Any thoughts on how to make clearer this is just another hand raising exercise?

We do not understand why a notice under section 8(b)(5) is being viewed by some as a "more stringent" notice than a PMN or SNUN, under section 5. The only information that is necessary is that the person intends to manufacture or process the chemical for some non-exempt commercial purpose. The particular non-exempt commercial purpose need not be identified. Unlike a PMN or SNUN, there is no requirement to submit additional information bearing on hazard, or conditions of use, or reasonably anticipated exposures.

As with the original inventory reset, there is a requirement here to notify and substantiate CBI claims for chemical identity which are being maintained. This is related to the parallel CBI review provisions of section 8(b)(4), as noted earlier.

***

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(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, by rule, shall establish a procedure wherebyrequire manufacturers and processors mayto notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has that they have manufactured or processed a chemical substance on the list published under paragraph (1) for a nonexempt commercial purpose during the 10-

Commented [A1]: Deadline is unnecessary since reporting is voluntary, and if anyone sends in a "late" submission for a chemical substance EPA would just add the chemical to the active list.

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.

year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which notices are received under clause (i), within 180 days of promulgation of the rule under clause (i), to be active substances on the list published under paragraph (1).

Commented [A2]: Instead of a deadline for anyone to submit a notice, just set a receipt deadline for EPA to rely on when making its initial cut as to active/inactive.

"(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i), within 180 days of promulgation of the rule under clause (i), to be inactive substances on the list published under paragraph (1).

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/29/2016 8:28:44 PM
To: Jonathan Black [jonathan_black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA Request on SDWA
Attachments: Udall TA -- Section 9 and RCRA -- OGC draft.docx; ATT00001.htm; [Untitled].pdf; ATT00002.htm

Jonathan,
Attached is technical assistance responding to your question about TSCA section 9 and SWDA. Please let me know if any additional questions. Thanks,
Sven

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

Further, Section 4(d) adds a requirement at the end of section 6(d)(2)(B) providing for a reasonable transition period for any rule promulgated under section 6(a).

Section 4(e) of the TSCA Modernization Act adds three new subsections to the end of TSCA section 6 to address three distinct areas.

First, under section 4(e), new section 6(g) bars the Administrator from considering costs and other non-health factors when deciding whether to initiate a rulemaking under subsection (a). The intention of the Committee is to ensure that the decision whether a regulation under 6(a) is required be limited to whether a chemical substance presents or will present an unreasonable risk as determined in section 6(b). The Committee intends that decisions applying the standard of regulation in section 6(a) and selecting any control measures to achieve that standard are made in the context of the economic, practical, and other considerations set out in section 6(c)(1).

Second, section 4(e) adds a new TSCA section 6(h) for cases in which the Administrator might find that any requirements to prevent a chemical substance or mixture from presenting an unreasonable risk are not cost-effective, but that a specific use of the chemical substance is critical or essential to prevent disruption to the national economy, national security, or critical infrastructure.

Section 6(h) allows the Administrator to grant a renewable exemption from such a requirement for a specific use for up to five years. To obtain an exemption, the Administrator must determine, pursuant to section 6(c)(1)(B), that the requirement is not cost-effective with respect to a specific use and must find that either the specific use is critical or essential, or the requirement as applied with respect to the specific use would significantly disrupt the national economy, national security, or critical infrastructure. An exemption must be preceded by a notice and comment period and supported by clear and convincing evidence. If the exemption is granted, EPA must then provide notice of the exemption, and the manufacturer or processor must notify known commercial purchasers. The Administrator is required to impose conditions on any use for which an exemption is granted in order to reduce risk from the chemical substance or mixture to the greatest extent feasible.

Finally, section 4(e) adds a new TSCA section 6(i) regarding Persistent, Bioaccumulative, and Toxic Chemicals (PBTs). First, new section 6(i) instructs the Administrator to publish a list, not later than nine months after the date of enactment, of chemicals the Administrator has a reasonable basis to conclude are persistent, bioaccumulative, and toxic. Subsection (i) excludes the placement on this list of metals, metal compounds, or chemical substances already regulated under TSCA section 6(e). The Committee hopes the Administrator will rely on its TSCA Work Plan Chemicals Methods Document published in February 2012 in identifying PBT candidate substances for listing. Upon its publication, either the Administrator or a chemical substance's manufacturer has ninety days to decide whether to initiate a risk evaluation under TSCA section 6(b) rather than further evaluation under section 6(i).

Second, no later than two years after the date of enactment, the Administrator is to designate as a PBT chemical of concern any chemical substance on the list: (1) that scores `high' for persistence or bioaccumulation and `high' or `moderate' in regard to the other, using the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012, and (2) where exposure is likely to the general population or a potentially exposed subpopulation identified by the Administrator. Last, the Administrator, subject to availability of appropriations, within two years of designating a chemical substance a PBT chemical of concern, must promulgate a rule under section 6(a), and in keeping with the rest of the factors in sections 6 and 9, to reduce, to the extent practicable, likely exposure to that PBT chemical.

These reforms to section 6 are intended to permit the Agency to identify unreasonable risks and address them effectively. To many members of the Committee, an important measure of TSCA reform proposals has been whether the proposal would enable EPA to take broader regulatory action to protect against unreasonable risks from asbestos. The Committee expects this legislation to enable that regulatory action.

Finally, while the phrase `unreasonable risk of injury' is not amended, it must be read in the context of the changes to section 6, including the functions and purposes delineated in subsections (a), (b), and (c).

Section 5. Relationship to other Federal laws

H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals. The Joint Explanatory Statement of the Committee of Conference for the legislation, which is now Title I of TSCA, clearly states that `[t]he conferees have drawn from both the Senate bill and the House amendment to assure that overlapping or duplicative regulation is avoided' and:

If the Administrator determines that a risk to health or the environment associated with a substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under authorities contained in other Federal laws, then the Administrator shall use such other authorities, unless the Administrator determines . . . it is in the public interest to use this Act.

This section adds a new paragraph to TSCA section 9(b) to help the Administrator decide whether using TSCA Title I or another Federal authority provided to the Administrator is `in the public interest.' Specifically, the new paragraph requires the Administrator to consider the relevant aspects of the risks posed by the chemical substance and compare the estimated costs of actions taken under Title I of TSCA or another Federal law with the relative efficiencies of protecting against the risk presented through actions taken under such laws. This new paragraph reflects language in section 6 current law that is removed by section 4 of the bill.

The Committee believes the added language will help to focus the Administrator's exercise of discretion regarding which statute to apply and to encourage decisions that avoid confusion, complication, and duplication. For example, if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the Administrator should use those authorities to protect against the risk. Likewise, while section 5 makes no amendment to TSCA section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety. Specifically, the Committee does not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls.

Section 6. Disclosure of data

Section 6 makes a number of changes to the way TSCA section 14 operates.

First, it authorizes three new classes of persons to receive information submitted to EPA and protected as confidential business information (CBI). These are State and local governments and tribal officials who request it for the purpose of administering or enforcing a law; Federal or State environmental professionals when responding to a release of a contaminant to the environment; and a treating physician or other health care professional for the purpose of diagnosing and treating an ailing person.

Second, the legislation requires persons receiving protected CBI to use the information only for the purpose for which it was obtained. Additionally, the legislation prohibits the disclosure of CBI to any person not authorized to receive it. Section 9 of the legislation, Conforming Amendments, makes a violation of these two requirements punishable through civil or criminal penalties or both. These sanctions are similar to penalties for unauthorized disclosure by Federal employees and Federal information protection laws that apply to the private sector, including the Health Insurance Portability and Accountability Act (42 USC 1320d-5).

Third, H.R. 2576 requires any manufacturer, processor, or distributor in commerce when submitting information to the Administrator to designate the information it believes qualifies for protection under the law. This designation, which applies only to information submitted to the Administrator after the date of enactment, must be made in writing and include: (1) a justification for each designation of confidentiality; (2) a certification that the information is not otherwise publically available; and (3) copies of all submitted information, one with the claimed CBI redacted and one with no redactions. In addition, information protected from public disclosure pursuant to these new requirements is required to be made public ten years after its initial grant of protection unless the requester submits a written renewal request that contains the necessary elements of the initial CBI protection request submission.

Section 11. Relationship to other Federal laws

Section 11 amends section 9 of TSCA, which provides EPA discretionary authority to refer a concern about an unreasonable risk of injury to another Federal Agency, when the authority to address the risk may be more efficiently or effectively regulated by the other Agency. For example, if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information. Section 11 conforms this authority to the provisions of S. 697. It further requires EPA to share information relevant to preventing or mitigating exposures or releases of a chemical substance under another Federal law with any relevant Federal agencies or offices within EPA.

Section 12. Research, development, collection, dissemination, and utilization of data

Section 12 makes a minor conforming amendment to section 10 of TSCA to ensure an appropriate reference to the Department of Health and Human Services.

Section 13. Exports

Section 13 of S. 697 amends the export notification requirements established in section 12 of TSCA. The amendments conform the export notification requirements to the requirements of the Act by requiring prior notice of exports of substances that are not likely to meet, or that do not meet, the safety standard and are subject to proposed or final restrictions. The section requires EPA to promulgate rules to implement the notification requirements.

The substitute strikes the amendments to section 13 of TSCA that were in S. 697 as introduced. Thus, S. 697 makes no changes to the current import requirements under TSCA.

Section 14. Confidential information

Section 14 of S. 697 amends section 14 of TSCA to make several important modifications to the process by which confidential business information (CBI) can be protected against disclosure or disclosed. In general, it is the Committee's intent to balance the need for protection from disclosure for information qualifying under the section b(4) exemption of the Freedom of Information Act (FOIA) (i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential") with the needs to ensure access to such information under appropriate conditions by those who need it to perform their duties, and to maximize public availability of health and environmental information relating to chemical substances in commerce. Striking a balance between protecting trade secrets and sensitive commercial and financial information and broadening access to information on chemicals is essential to encourage innovation and economic competitiveness within the chemical industry and those industries that use chemistry, while better informing the decisions made about chemicals by different levels of government, companies throughout the supply chain, and the general public.

Under this section, all information sought to be protected from disclosure must meet certain criteria, and all such claims must be

message:

From: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Date: January 13, 2016 at 3:00:33 PM EST
To: "Kaiser.Sven-Erik@epamail.epa.gov" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: Solid Waste Disposal

Hi Sven,

Attached are the Committee reports for the House and Senate TSCA bills. I'm curious if EPA has any comments on the direction both have taken about the disposal of chemicals and which statute should take precedence.

I'm also curious about what legislative language would look like in the event one were to propose clarification in statute that the Solid Waste Disposal Act should take precedence.

Thanks,
---Jonathan

Incoming TA: ***Attached are the Committee reports for the House and Senate TSCA bills. I'm curious if EPA has any comments on the direction both have taken about the disposal of chemicals and which statute should take precedence. I'm also curious about what legislative language would look like in the event one were to propose clarification in statute that the Solid Waste Disposal Act should take precedence.***

***

House Committee Report Language:

Excerpt from House Committee Report regarding § 9: "The Committee believes the added language will help to focus the Administrator's exercise of discretion regarding which statute to apply and to encourage decisions that avoid confusion, complication, and duplication. For example, if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the Administrator should use those authorities to protect against the risk. Likewise, while section 5 makes no amendment to TSCA section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety. Specifically, the Committee does not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls."

TA on House Committee Report Language Relating to Section 9:

The relevant portion of current TSCA section 9(b) currently contains two linked provisions.

- **First**, EPA when considering regulation under section 6, EPA is given discretion to make a determination that "a risk to health or the environment . . . could be eliminated or reduced to a sufficient extent by actions taken under authorities contained in [other Federal laws administered in whole or in part by the Administrator." This is the 'sufficient reduction' finding).
- If EPA makes the 'sufficient extent' finding, then EPA is required to use its non-TSCA authorities in lieu of its TSCA authorities, **unless EPA makes a second finding** that it is in the 'public interest' for EPA to use its TSCA authorities.

The House amendment to section 9(b) concerns the second finding (i.e., the 'public interest' finding). The bill adds particular analytical factors that EPA must consider before making a finding that it is in the 'public interest' to use TSCA, notwithstanding a prior 'sufficient reduction' finding. It does not appear that these analytical requirements apply to EPA's prior discretion to simply not make the 'sufficient reduction' finding in the first place.[1]

The Committee report explains that in the event EPA finds itself confronted with whether or not to make the 'public interest' finding (i.e., after having made a prior finding that action under the Solid Waste Disposal Act would 'sufficiently reduce' risk), then the Committee believes that EPA should not make the 'public interest' finding (i.e., EPA should instead "use those

[1] EPA notes that the original legislative history of TSCA reflected the conferees' view that the EPA's 'public interest' finding is not subject to substantive judicial review, except to review whether EPA examined its other authorities and presented the results of its examination. See TSCA Conference Report at 85. It is possible that the a failure to consider the specified analytical requirements at 9(b)(2) may be subject to judicial review, even if the outcome of the consideration remains unreviewable.

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authorities," meaning the SWDA authorities that are used in lieu of TSCA if EPA does not make the 'public interest' finding). This is a specification of the actual precedence of TSCA and SWDA when making the 'public interest' finding, quite distinct from the effect of the bill itself, which is merely to specify particular factors that must be considered when making such a finding (e.g., "compare the estimated costs and efficiencies.")

The House committee language also purports to be making a "similar[]" point with respect to TSCA section 9(a), that EPA should "respect . . . and defer to other agencies that have relevant responsibility," and should not take action that would "conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls." But EPA's discretion under 9(a) is not about how exactly to craft a TSCA 6(a) rule. Rather, it is whether to determine that an unreasonable risk "may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator," and thus trigger a mandatory referral to that other agency.[2] EPA finds the House committee language on 9(a) to be confusing, as its substance seems more related to EPA's crafting of a risk management regulation under TSCA than to a determination whether to entirely refer a chemical risk to a non-TSCA authority outside the Agency. Furthermore, it would be helpful if any obligation to refer a particular risk management action to a non-EPA, non-TSCA authority were more clearly reconciled with the strict deadlines under 6(b)(5)(C) to ensure that TSCA risk management rules are timely promulgated.

***

Senate Committee Report Language:
"Section 11 amends section 9 of TSCA, which provides EPA discretionary authority to refer a concern about an unreasonable risk of injury to another Federal Agency, when the authority to address the risk may be more efficiently or effectively regulated by the other Agency. For example, if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information. Section 11 conforms this authority to the provisions of S. 697."

TA on Senate Committee Report Language Relating to Section 9:
Among other amendments to TSCA section 9, the Senate bill adds section 9(e): "If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency."

EPA construes the Committee's language as an explanation of the implementation of new TSCA 9(e), rather than as a specification of the precedence of TSCA and SWDA when making a 'public interest' determination under TSCA 9(b). The Committee language does not appear to be referring to the finding under 9(b) that risk "could be could be eliminated or reduced ***to a sufficient extent***." (emphasis added)

***

[2] TSCA's original legislative history (TSCA Conference Report at 84) reflected the conferees' view that this determination is not subject to judicial review.

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TA to illustrate legislative language directing EPA to defer risk management action under TSCA, in favor of action under SWDA, when addressing risks stemming from the disposal of a chemical substance.

Edits to current TSCA:

(b) Laws administered by the Administrator.

(1) The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines 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 actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(2) So far as the Administrator has 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 actions taken under the authorities contained in the Solid Waste Disposal Act, the Administrator shall make no determination under paragraph (1) that it is in the public interest to use authority under this Act.

Commented [A1]: This would stop EPA from availing itself of the "public interest" option to use TSCA in lieu of SWDA, to the extent that there exists an EPA determination that SWDA would eliminate or sufficiently reduce the risk at issue.

This new provision raises some additional implementation questions about whether TSCA risk management deadlines under Section 6 would continue to apply, notwithstanding the fact that EPA is barred from using TSCA to address at least part of the risk in question (i.e., the part of the risk that could be addressed sufficiently by action under SWDA).

Note also that there is interpretive ambiguity about whether the "sufficient extent" standard set forth here is identical to the safety standard under section 6. This issue takes on heightened importance if one introduces circumstances (i.e., SWDA) where there would be no "public interest" exemption to 9(b)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/3/2016 10:37:30 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA - additional on nomenclature

Ok - got it. Will be after 5 (expected late tonight) and 4 (possibly tonight, maybe tomorrow). Thanks,
Sven

On Apr 3, 2016, at 6:18 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Some changes here. Won't address all your questions but I'm hoping the "without limitation" tweak helps. Let me know (after section 5 and 4).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)
<Nomenclature (4-2-16).docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 4:12:55 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on PBTs
Attachments: Markey.TSCA TA.PBT.4-12.docx

Michal,
This TA responds to the request on the revised PBT language.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

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

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

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 11, 2016 5:20 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: PBTS

I had made all of these changes before sending last time but must not have saved before sending. Pls use this version, and note that I changed many of the 6(c) references to 6(a) which should mean that both standards (necessary to reduce, and extent practicable) should be met, right? also got rid of “likely”, if you think I should restore pls note.

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.

( ) Chemicals That Are Persistent, Bioaccumulative, and Toxic.--

(1) Expedited Action.--Not later than ~~2~~ 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose a rule ~~under~~ in accordance with subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments —

(A) that the Administrator has a reasonable basis to conclude are toxic and with respect to persistence and bioaccumulation, scores high for one 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), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation ~~under section 4~~, initiated a ~~risk assessment~~review under section 5, or entered into a consent agreement under section 4 prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and

(B) exposure to which under the conditions of use is likely to the general population ~~or, to~~ a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) Final Rule.--Notwithstanding subsections (__), subject to ~~the availability of appropriations and~~ subsections __ and __ , not later than ~~2 years~~18 months after proposing a rule under paragraph (1), the Administrator shall promulgate a rule in accordance with subsection (c).

(3) In selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a) the Administrator shall, for each chemical substance for which a rule is proposed under paragraph (1), reduce exposure to the substance to the extent practicable.

(4) Relationship to subsection (b).--If, at any time prior to the date that is 90 days after the date on which the Administrator proposes the rule under paragraph (1), the Administrator makes a finding under subsection (__), or a manufacturer requests a risk evaluation under subsection (__), with respect to a chemical substance, such chemical substance shall not be subject to this subsection, except that any proposed ~~and/or~~ final rule promulgated in accordance with section 6(a) for such chemical substance shall reduce ~~likely~~ exposure to the extent practicable.

(~~3~~4) OTHER CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC OR CARCINOGENS.—

(A) In designating high priority substances pursuant to subsection (b), the Administrator shall give preference to—

(i) chemical substances that, with respect to persistence and bioaccumulation, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals

Commented [A1]: To EPA: added in 12 months for the exposure assessment. Better?

Commented [A2R1]: **EPA TA:** See response below. Whether or not EPA has to do a risk evaluation for each chemical substance as part of doing the 6(a) rule affects the answer.

Commented [A3]: To EPA: this should answer your q on whether it has to comply w goal of restrictions?

Commented [A4R3]: **EPA TA:** This helps to clarify that EPA is intended to both protect against and UR and reduce exposure to the maximum extent practicable. But does EPA need to do a risk evaluation? 6(a) pre-supposes that EPA knows what uses of the chemical present an unreasonable risk, and the only way to know what UR is is to do a risk evaluation.

There is a general awkwardness with this provision because you are re-purposing the framework of section 6(a) rulemaking to handle special risk management for PBTs. It is unclear what aspects of 6(a) rulemaking (if any) are superseded by the requirements of this subsection.

This is an issue that will be left to EPA interpretive discretion (and potentially litigation) if not explained in the statutory text.

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.

Methods Document published by the Administrator in February 2012 (or a successor scoring system) ;and

(ii) chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(B) In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

(C) For a chemical substance subject to subsection (a) and that 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 promulgated in a rule pursuant to subsection (a), reduce exposure to the substance to the extent practicable.

Retain expedited action provision in 6(c)

(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 paragraph and subsection (b)(4)(G) does not exceed two years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, 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), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/29/2016 1:40:13 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA followup on Sen. Udall TSCA TA on CBI - 14(c)(1)(B)

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: Tuesday, March 29, 2016 9:37 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: Sen. Udall TSCA TA on CBI - 14(c)(1)(B)

Sven – just checking to see if you believe that an edit along the lines of what is below (in 26(j)) would address the 14(c)(1)(B)(ii) concern raised, or if EPA believes that the "subject to section 14" would render the changes largely inoperative. Thanks
michal

AVAILABLILTY OF INFORMATION.—

(1) Subject to section 14, the Administrator shall make available to the public all notices, determinations, findings, rules, consent agreements, and orders by the Administrator, any tests required to be provided to the Administrator under the title, each risk evaluation upon its completion, including a nontechnical summary of each risk evaluation and the list of studies considered by the Administrator in carrying out each risk evaluation.

(2) In carrying out sections 4, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

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: Monday, March 28, 2016 4:18 PM
To: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)
Subject: Sen. Udall TSCA TA on CBI - 14(c)(1)(B)

Jonathan,
This TA responds to the request on 14(c)(1)(B)(i).

We agree that deleting 14(c)(1)(B)(i) would have no adverse implementation impact. If a chem ID claim was asserted consistent with 14(d), then 14(c)(1)(B)(i) wouldn't apply. If a chem ID claim was asserted inconsistent with 14(d), then it is already invalid, and 14(c)(1)(B)(i) adds nothing further. For the same reasons, as we have commented before, the *retention* of this provision may have adverse implementation impacts, since it might imply that information other than chem ID could be protectable even if the associated claim does not meet the requirements of section 14(d).

Deleting 14(c)(1)(B)(ii) would have an implementation impact unless there was substantial revision to 26(i)(2) to compensate for the deletion. Section 26(i)(2) is entirely "[s]ubject to section 14." That means the imperative to withhold under section 14 overrides any imperative to release under 26(i)(2). So long as that language on relative priority is retained, new language in 26(i)(2) cannot be used to neutralize the deletion of language in section 14. Also, the scope of materials subject to 26(i) is not the same as the scope of materials subject to 14(c)(1)(B)(ii). For example, the risk evaluation itself is not covered under 26(i), but it is covered under 14(c)(1)(B)(ii).

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

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, March 28, 2016 10:58 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: CBI request - 14(c)(1)(B)

Hi Sven,

In 14(c)(1)(B)

Does EPA feel (i) is redundant and can be removed without any real impact?
We are considering deleting (ii) as well, but making sure it is clearly stated in sec. 26. Concerns?

> (B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:
>
> (i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial

distribution, if the person submitting the information does not meet the requirements of subsection (d)

(ii) .A safety assessment developed, or a safety determination made, under section 6.

(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/9/2016 8:46:49 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on Section 5 - SNUR

Michal,
This TA responds to the request on section 5 and SNURs.

If we were to remove the provisions in 5(e)(4) and 5((f)((1)(C), can you confirm that EPA would still have the authority to do a SNUR, but just wouldn't be required to consider one and describe why it didn't do one? Not considering this right now but anticipate being asked to do so at some point. Response anytime today fine.

Response:
Yes, we can confirm that if you removed 5(e)(4) and 5(f)(1)(C), that would not prevent EPA from issuing SNURs. 5(e)(4) and 5(f)(1)(C) aren't the source of EPA's SNUR authority. The actual source of EPA's SNUR authority is section 5(a)(2). Deleting 5(e)(4) and 5(f)(1)(C) would have the effect of eliminating a *duty* for EPA to either exercise its 5(a)(2) authority or publish a statement explaining why not.

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

On Apr 9, 2016, at 6:07 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

If we were to remove the provisions in 5(e)(4) and 5((f)((1)(C), can you confirm that EPA would still have the authority to do a SNUR, but just wouldn't be required to consider one and describe why it didn't do one?
Not considering this right now but anticipate being asked to do so at some point. Response anytime today fine.
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: 4/7/2016 11:23:41 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: SEPW TSCA TA RE: section 4 - Senate Counter

Got it- thanks

On Apr 7, 2016, at 4:50 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven - can we get a response to this one this morning, preferably by 10-11? Thanks.

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

From: Kaiser, Sven-Erik
Sent: Wednesday, April 6, 2016 12:26 PM
To: Freedhoff, Michal (Markey)
Cc: Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Re: SEPW TSCA TA RE: section 4 - Senate Counter

Michal,
Got it - checking. Thanks,
Sven

On Apr 6, 2016, at 12:25 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Quick question back to you:

We're maintaining current 4(a)(1) as you see. We'll explore the 6(a) issue there (we were hoping it was merely redundant but see from your TA that it is not).

But the question of changing data to information in 4(a)(1) – I was trying to be minimal in changes to that text, and so left in "data" in the backwards-looking parts of 4(a) that refer to the justifications for getting new information, but made the switch to the parts of 4(a)(1) that specifies what types of information EPA can REQUEST. But I'm still seeing your comment and am wondering if you can suggest a minor word change to address this (minor tweaks to (b)(2)(A) also happily accepted and perhaps even preferred)?

"The change from data to information is probably helpful, but it does not address the main source of ambiguity in TSCA as to the scope of section 4: the phrase "testing. . . on a chemical substance." This formulation could give rise to arguments that, for example, EPA cannot require monitoring for the presence of a chemical in the environment, because this is not testing on a chemical. Such a limited interpretation of "testing on a chemical" might be supported by (b)(2)(A), retained here, which describes the allowable types of tests in terms of toxicity and other attributes of the chemical itself, rather than in terms of its presence or absence."

Thanks
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>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 06, 2016 11:50 AM
To: Freedhoff, Michal (Markey)
Cc: Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: SEPW TSCA TA RE: section 4 - Senate Counter

Michal – Please see attached TA responding to the request on the draft Senate counter to the House offer on section 4. Note that there are track changes comments that might not show up on a phone. 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: Tuesday, April 05, 2016 2:34 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: section 4

Sven

Attached is a new Section 4 that we need TA on. Generally, it can be described as:

- Existing TSCA 4(a)(1) and 4(a)(2) (mostly)
- In addition to that, Senate text on other circumstances that allow testing, by rule or order or consent agreement
- Other changes to things like ITC and 4(f) that have been discussed/proposed by various parties
- All (I hope) the conforming changes the House offer removed or didn't do

Please give it a careful read and let us know of any issues.

Senate colleagues – note I did not strike and replace the animal testing language but just bracketed it to reflect ongoing discussions. Let me know if you want a different approach there.

Thanks
michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/14/2016 9:05:36 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Checking the request list
Attachments: RDS_01_xml.pdf

Michal – how are you doing. I think we're caught up (for now). Am I missing anything? We have the attached - no specific request on that (for now). 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, April 14, 2016 12:41 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: some other stuff

Sven

Note that I have already identified some issues here and I am not currently requesting your careful review of this. I may later ask for review of separate sections as they are developed. I'm sending for your interest only. Section 14 TA much appreciated soon.

michal

[Discussion Draft]

PROPOSED AMENDMENT TO H.R. 2576, AS RECEIVED IN THE SENATE

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 "Frank R. Lautenberg Chemical Safety for the 21st Cen-
4 tury Act".

5 (b) TABLE OF CONTENTS.—The table of contents of
6 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. Voluntary risk evaluations.
Sec. 6. Regulation of hazardous chemical substances and mixtures.
Sec. 7. Imminent hazards.
Sec. 8. Reporting and retention of information.
Sec. 9. Relationship to other Federal laws.
Sec. 10. Disclosure of data.
Sec. 11. Effect on State law.
Sec. 12. Studies.
Sec. 13. Administration of the Act.
Sec. 14. State programs.
Sec. 15. Conforming amendments.

1 [**SEC. 2. FINDINGS, POLICY, AND INTENT.**

2 Section 2 of the Toxic Substances Control Act (15
3 U.S.C. 2601) is amended by striking "proposes to take"
4 and inserting "proposes as provided".]

5 **SEC. 3. DEFINITIONS.**

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

8 (1) by redesignating paragraphs (4) through
9 (14) as paragraphs (5) through (10) and (12)
10 through (16), respectively;

11 (2) by inserting after paragraph (3) the fol-
12 lowing:

13 ["(4) The term 'conditions of use' means the in-
14 tended, known, or reasonably foreseeable circumstances
15 under which the Administrator determines a chemical sub-
16 stance is manufactured, processed, distributed in com-
17 merce, used, or disposed of."; and]

18 (3) by inserting after paragraph (10), as so re-
19 designated, the following:

20 ["(11) The term 'potentially exposed or susceptible
21 subpopulation' means a group of individuals within the
22 general population identified by the Administrator who,
23 due to either greater susceptibility or greater exposure,
24 may be at greater risk than the general population of ad-
25 verse health effects from exposure to a chemical substance

or mixture, such as infants, children, pregnant women, workers, or the elderly.".]

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

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

(1) in subsection (a)(1)—

(A) in subparagraph (A)(iii), by striking "; or" and inserting a semicolon;

(B) in subparagraph (B)(iii), by striking "; and" and inserting "; or"; and

(C) by adding at the end the following:

"(C) testing of a chemical substance is necessary to conduct a risk evaluation under section 6(b); and";

(2) in the matter following subsection (a)(2), by inserting ", order, or consent agreement" after "by rule";

(3) in subsection (b)—

[(A) in paragraph (2)(A)—]

[(i) by striking "hierarchical tests" and inserting "tiered testing"; and]

[(ii) by adding at the end the following: "The Administrator shall reduce the use of animals in the testing of chem-

1 ical substances or mixtures, to the extent
2 practicable, by taking into consideration
3 existing toxicity information and the avail-
4 ability of validated alternative test proto-
5 cols that reduce or replace animal tests.";
6 and]
7 (B) in paragraph (5), by striking "para-
8 graph (1)(A) or (1)(B)" and inserting "para-
9 graph (1)(A), (1)(B), or (1)(C)";
10 [(4) in subsection (e), by adding at the end the
11 following:]
12 ["(3) In addition to recommendations made by the
13 committee under paragraph (1), the Administrator shall
14 consider the recommendations of Federal agencies regard-
15 ing the selection of chemical substances or mixtures for
16 testing under this section."; and]
17 [(5) by adding at the end the following:]
18 ["(h) REPORTS ON PROGRESS IN REDUCING THE
19 USE OF ANIMAL TESTING.—]
20 ["(1) IN GENERAL.—Not later than 2 years
21 after the date of enactment of the Frank R. Lauten-
22 berg Chemical Safety for the 21st Century Act, and
23 every 5 years thereafter, the Administrator shall
24 submit to Congress a report that describes the
25 progress made in reducing and replacing animal

1 tests through the use of validated alternative test
2 protocols for assessing risks of injury to health or
3 the environment of chemical substances or mix-
4 tures.]

5 [“(2) INCLUSION.—A report submitted under
6 this subsection shall include information regarding
7 the extent to which testing is conducted using infor-
8 mation developed through—]

9 [“(A) computational toxicology and
10 bioinformatics;]

11 [“(B) high-throughput screening meth-
12 ods;]

13 [“(C) testing of categories of chemical
14 substances;]

15 [“(D) tiered testing methods;]

16 [“(E) new or revised methods identified by
17 the Interagency Coordinating Committee on the
18 Validation of Alternative Methods; and]

19 [“(F) industry consortia that jointly de-
20 velop testing data for submission under this
21 title.”.]

22 **[SEC. 5. VOLUNTARY RISK EVALUATIONS.**

23 Section 5 of the Toxic Substances Control Act (15
24 U.S.C. 2604) is amended—]

1 [(1) by redesignating subsection (i) as sub-
2 section (j); and]
3 [(2) by inserting after subsection (h) the fol-
4 lowing:]
5 ["(i) VOLUNTARY RISK EVALUATIONS.—]
6 ["(1) IN GENERAL.—A manufacturer who is
7 required to submit a notice under subsection (a)(1)
8 for a chemical substance described in subsection
9 (a)(1)(A) may, in association with submission of
10 such notice, also request a risk evaluation under sec-
11 tion 6(b) for that chemical substance in accordance
12 with guidance issued under paragraph (2).]
13 ["(2) GUIDANCE.—Not later than 1 year after
14 the date of enactment of the Frank R. Lautenberg
15 Chemical Safety for the 21st Century Act, the Ad-
16 ministrator shall issue guidance specifying the data
17 needed to complete a risk evaluation pursuant to
18 paragraph (1). Such guidance may specify different
19 data requirements for different categories of chem-
20 ical substances.".]
21 **SEC. 6. REGULATION OF HAZARDOUS CHEMICAL SUB-**
22 **STANCES AND MIXTURES.**
23 (a) SCOPE OF REGULATION.—Section 6(a) of the
24 Toxic Substances Control Act (15 U.S.C. 2605(a)) is
25 amended—

(1) by striking "finds that there is a reasonable basis to conclude" and inserting "determines under subsection (b)";

(2) by inserting "or designates a chemical substance under subsection (i)(2)," before "the Administrator shall by rule"; and

(3) by striking "to protect adequately against such risk using the least burdensome requirements" and inserting "so that the chemical substance or mixture no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a [potentially exposed or susceptible subpopulation]".

(b) RISK EVALUATIONS.—Section 6(b) of the Toxic Substances Control Act (15 U.S.C. 2605(b)) is amended to read as follows:

"(b) RISK EVALUATIONS.—

"(1) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this subsection to determine whether or not a chemical substance presents or will present, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment.

"(2) APPLYING REQUIREMENTS.—The Administrator shall apply requirements with respect to a

1 chemical substance through a rule under subsection
2 (a) only if the Administrator determines through a
3 risk evaluation under this subsection, without con-
4 sideration of costs or other non-risk factors, that the
5 chemical substance presents or will present, in the
6 absence of such requirements, an unreasonable risk
7 of injury to health or the environment.

8 "(3) CONDUCTING RISK EVALUATIONS.—

9 "(A) REQUIRED RISK EVALUATIONS.—
10 [Subject to subparagraph (C),] the Adminis-
11 trator shall conduct and publish the results of
12 a risk evaluation under this subsection for a
13 chemical substance if—

14 "(i) the Administrator determines
15 that the chemical substance may present
16 an unreasonable risk of injury to health or
17 the environment because of potential haz-
18 ard and a potential route of exposure
19 under the [conditions of use]; or

20 "(ii) a manufacturer of the chemical
21 substance requests such a risk evaluation
22 in a form and manner prescribed by the
23 Administrator.

24 "(B) TSCA WORK PLAN CHEMICALS.—The
25 Administrator may, without making a deter-

1 mination under subparagraph (A)(i), conduct
2 and publish the results of a risk evaluation
3 under this subsection for a chemical substance
4 that, on the date of enactment of the Frank R.
5 Lautenberg Chemical Safety for the 21st Cen-
6 tury Act, is listed in the TSCA Work Plan for
7 Chemical Assessments published by the Admin-
8 istrator.

9 [“(C) LIMITATION.—]

10 [“(i) PERCENTAGE REQUIRE-
11 MENTS.—The Administrator shall ensure
12 that, of the chemical substances that un-
13 dergo a risk evaluation under this para-
14 graph (other than chemical substances de-
15 scribed in clause (ii)), the percentage of
16 chemical substances undergoing a risk
17 evaluation under clause (ii) of subpara-
18 graph (A) is—]

19 [“(I) not less than 25 percent, if
20 sufficient requests are made under
21 such clause; and]

22 [“(II) not more than 50 per-
23 cent.]

1 [“(ii) EXCLUSION.—In calculating
2 percentages under clause (i), the Adminis-
3 trator shall not consider—]
4 [“(I) chemical substances de-
5 scribed in subparagraph (B); or]
6 [“(II) chemical substances de-
7 scribed in section 5(a)(1)(A) for which
8 a risk evaluation is requested pursu-
9 ant to section 5(i).]
10 “(4) REQUIREMENTS.—In conducting a risk
11 evaluation under this subsection, the Administrator
12 shall—
13 “(A) integrate and assess information on
14 hazards and exposures for all of the [conditions
15 of use] of the chemical substance, including in-
16 formation that is relevant to specific risks of in-
17 jury to health or the environment and informa-
18 tion on [potentially exposed or susceptible sub-
19 populations];
20 “(B) not consider information on cost and
21 other factors not directly related to health or
22 the environment;
23 “(C) take into account, where relevant, the
24 likely duration, intensity, frequency, and num-

1 ber of exposures under the [conditions of use]
2 of the chemical substance;
3 "(D) describe the weight of the scientific
4 evidence for identified hazard and exposure;
5 "(E) consider whether the weight of the
6 scientific evidence supports the identification of
7 doses of the chemical substance below which no
8 adverse effects can be expected to occur; and
9 "(F) in the case of a risk evaluation re-
10 quested by a manufacturer under paragraph
11 (3)(A)(ii), ensure that the costs to the Environ-
12 mental Protection Agency, including contractor
13 costs, of conducting the risk evaluation are paid
14 for by the manufacturer.
15 "(5) DEADLINES.—
16 "(A) RISK EVALUATIONS.—The Adminis-
17 trator shall conduct and publish a risk evalua-
18 tion under this subsection for a chemical sub-
19 stance as soon as reasonably possible, subject to
20 the availability of resources, but not later
21 than—
22 "(i) 3 years after the date on which
23 the Administrator—
24 "(I) makes a determination
25 under paragraph (3)(A)(i); or

"(II) begins the risk evaluation under paragraph (3)(B); or

"(ii) in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), 2 years after the later of the date on which—

"(I) the manufacturer requests the risk evaluation; or

"(II) if applicable, the risk evaluation is initiated pursuant to subparagraph (B).

"(B) DEADLINE ADJUSTMENT.—If the Administrator receives more requests for risk evaluations under paragraph (3)(A)(ii) than the Administrator has resources to conduct by the deadline under subparagraph (A)(ii)(I) (taking into account the requirement in paragraph (4)(F)), [or if the number of such requests exceeds the percentage allowed under paragraph (3)(C),] the Administrator shall—

"(i)(I) initiate risk evaluations that exceed the Administrator's allotted resources as soon as resources for such risk evaluations are available; or

"(II) [in the case of a risk evaluation that exceeds the allowed percentage, initiate such risk evaluation in accordance with paragraph (3)(C)]; and

"(ii) not collect a fee under section 26 from the manufacturer for a risk evaluation until the Administrator initiates the risk evaluation.

"(C) SUBSECTION (a) RULES.—If, based on a risk evaluation conducted under this subsection, the Administrator determines, without consideration of costs or other non-risk factors, that a chemical substance presents or will present, in the absence of a rule under subsection (a), an unreasonable risk of injury to health or the environment, the Administrator shall—

"(i) propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A); and

"(ii) publish in the Federal Register a final rule not later than 2 years after the

1 date on which the risk evaluation regard-
2 ing such chemical substance is published
3 under subparagraph (A).
4 "(D) EXTENSION.—If the Administrator
5 determines that additional information is nec-
6 essary to make a risk evaluation determination
7 under this subsection, the Administrator may
8 extend the deadline under subparagraph (A) ac-
9 cordingly, except that the deadline may not be
10 extended to a date that is later than—
11 "(i) 90 days after receipt of such ad-
12 ditional information; or
13 "(ii) 2 years after the deadline being
14 extended under this subparagraph.
15 "(6) DETERMINATIONS OF NO UNREASONABLE
16 RISK.—
17 "(A) NOTICE AND COMMENT.—Not later
18 than 30 days before publishing a final deter-
19 mination under this subsection that a chemical
20 substance does not and will not present an un-
21 reasonable risk of injury to health or the envi-
22 ronment, the Administrator shall make a pre-
23 liminary determination to such effect and pro-
24 vide public notice of, and an opportunity for

1 comment regarding, such preliminary deter-
2 mination.
3 "(B) [POTENTIALLY EXPOSED OR SUSCEP-
4 TIBLE SUBPOPULATIONS].—The Administrator
5 shall not make a determination under this sub-
6 section that a chemical substance will not
7 present an unreasonable risk of injury to health
8 or the environment if the Administrator deter-
9 mines that the chemical substance, under the
10 [conditions of use], presents or will present an
11 unreasonable risk of injury to one or more [po-
12 tentially exposed or susceptible subpopula-
13 tions].
14 "(C) FINAL ACTION.—A final determina-
15 tion under this subsection that a chemical sub-
16 stance will not present an unreasonable risk of
17 injury to health or the environment shall be
18 considered a final agency action.
19 "(7) MINIMUM NUMBER.—Subject to the avail-
20 ability of appropriations, the Administrator shall ini-
21 tiate 10 or more risk evaluations under paragraphs
22 (3)(A)(i) or (3)(B) in each fiscal year beginning in
23 the fiscal year of the date of enactment of the Frank
24 R. Lautenberg Chemical Safety for the 21st Century
25 Act.".

1 (c) PROMULGATION OF SUBSECTION (a) RULES.—
2 Section 6(c) of the Toxic Substances Control Act (15
3 U.S.C. 2605(c)) is amended—
4 (1) by amending paragraph (1) to read as fol-
5 lows:
6 "(1) REQUIREMENTS FOR RULE.—In promul-
7 gating any rule under subsection (a) with respect to
8 a chemical substance or mixture, the Administrator
9 shall—
10 "(A) consider and publish a statement with
11 respect to—
12 "(i) the effects of the chemical sub-
13 stance or mixture on health and the mag-
14 nitude of the exposure of human beings to
15 the chemical substance or mixture;
16 "(ii) the effects of the chemical sub-
17 stance or mixture on the environment and
18 the magnitude of the exposure of the envi-
19 ronment to the chemical substance or mix-
20 ture;
21 "(iii) the benefits of the chemical sub-
22 stance or mixture for various uses; and
23 "(iv) the reasonably ascertainable eco-
24 nomic consequences of the rule, including
25 consideration of the likely effect of the rule

on the national economy, small business, technological innovation, the environment, and public health;

"(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risk;

"(C) based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, determine whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;

"(D) exempt replacement parts designed prior to the date of publication in the Federal

1 Register of the rule unless the Administrator
2 finds such replacement parts contribute signifi-
3 cantly to the identified risk, including identified
4 risk to identified [potentially exposed or sus-
5 ceptible subpopulations]; and
6 "(E) in selecting among prohibitions and
7 other restrictions to address an identified risk,
8 apply prohibitions or other restrictions to arti-
9 cles on the basis of a chemical substance or
10 mixture contained in the article only to the ex-
11 tent necessary to protect against the identified
12 risk.";
13 (2) in paragraph (2)—
14 (A) by inserting "PROCEDURES.—" before
15 "When prescribing a rule";
16 (B) by striking "provide an opportunity for
17 an informal hearing in accordance with para-
18 graph (3); (D)";
19 (C) by striking ", and (E)" and inserting
20 "; and (D)"; and
21 (D) by moving such paragraph 2 ems to
22 the right;
23 (3) by striking paragraphs (3) and (4) and re-
24 designating paragraph (5) as paragraph (3); and
25 (4) in paragraph (3) (as so redesignated)—

1 (A) by striking "Paragraphs (1), (2), (3),
2 and (4)" and inserting "APPLICATION.—Para-
3 graphs (1) and (2)"; and
4 (B) by moving such paragraph 2 ems to
5 the right.
6 (d) EFFECTIVE DATE.—Section 6(d)(2)(B) of the
7 Toxic Substances Control Act (15 U.S.C. 2605(d)(2)(B))
8 is amended by adding at the end the following: "Any rule
9 promulgated under subsection (a) shall provide for a rea-
10 sonable transition period.".
11 (e) NON-RISK FACTORS; CRITICAL USE EXEMP-
12 TIONS; PBT CHEMICALS.—Section 6 of the Toxic Sub-
13 stances Control Act (15 U.S.C. 2605) is amended by add-
14 ing at the end the following:
15 "(g) NON-RISK FACTORS.—The Administrator shall
16 not consider costs or other non-risk factors when deciding
17 whether to initiate a rulemaking under subsection (a).
18 "(h) CRITICAL USE EXEMPTIONS.—
19 "(1) CRITERIA FOR EXEMPTION.—The Admin-
20 istrator may grant an exemption from a requirement
21 of a subsection (a) rule for a specific use of a chem-
22 ical substance or mixture, if—
23 "(A) the requirement is not cost-effective
24 with respect to the specific use, as determined

1 by the Administrator pursuant to subsection
2 (c)(1)(B); and
3 "(B) the Administrator finds that—
4 "(i) the specific use is a critical or es-
5 sential use; or
6 "(ii) the requirement, as applied with
7 respect to the specific use, would signifi-
8 cantly disrupt the national economy, na-
9 tional security, or critical infrastructure.
10 "(2) PROCEDURE.—An exemption granted
11 under paragraph (1) shall be—
12 "(A) supported by clear and convincing
13 evidence;
14 "(B) preceded by public notice of the pro-
15 posed exemption and an opportunity for com-
16 ment; and
17 "(C) followed by notice of the granted ex-
18 emption—
19 "(i) to the public, by the Adminis-
20 trator; and
21 "(ii) to known commercial purchasers
22 of the chemical substance or mixture with
23 respect to which the exemption applies, by
24 the manufacturers and processors of such
25 chemical substance or mixture.

1 "(3) PERIOD OF EXEMPTION.—An exemption
2 granted under paragraph (1) shall expire after a pe-
3 riod not to exceed 5 years, but may be renewed for
4 one or more additional 5-year periods if the Admin-
5 istrator finds that the requirements of paragraph (1)
6 continue to be met.
7 "(4) CONDITIONS.—The Administrator shall
8 impose conditions on any use for which an exemp-
9 tion is granted under paragraph (1) to reduce risk
10 from the chemical substance or mixture to the great-
11 est extent feasible.
12 "(i) CHEMICALS THAT ARE PERSISTENT, BIO-
13 ACCUMULATIVE, AND TOXIC.—
14 "(1) IDENTIFICATION.—Not later than 9
15 months after the date of enactment of the Frank R.
16 Lautenberg Chemical Safety for the 21st Century
17 Act, the Administrator shall publish a list of those
18 chemical substances that the Administrator has a
19 reasonable basis to conclude are persistent, bio-
20 accumulative, and toxic, not including any chemical
21 substance that is a metal, a metal compound, or
22 subject to subsection (e).
23 "(2) CONFIRMATION OF CONCERN.—Not later
24 than 2 years after the date of enactment of the
25 Frank R. Lautenberg Chemical Safety for the 21st

1 Century Act, the Administrator shall designate as a
2 PBT chemical of concern each chemical substance
3 on the list published under paragraph (1)—
4 "(A) that, with respect to persistence and
5 bioaccumulation, scores high for one and either
6 high or moderate for the other, pursuant to the
7 TSCA Work Plan Chemicals: Methods Docu-
8 ment published by the Administrator in Feb-
9 ruary 2012; and
10 "(B) exposure to which is likely to the gen-
11 eral population or to a [potentially exposed or
12 susceptible subpopulation] identified by the Ad-
13 ministrator.
14 "(3) EXPEDITED ACTION.—Notwithstanding
15 subsection (b)(2), subject to the availability of ap-
16 propriations, not later than 2 years after designating
17 a chemical substance under paragraph (2), the Ad-
18 ministrator shall promulgate a rule under subsection
19 (a) with respect to the chemical substance to reduce
20 likely exposure to the extent practicable.
21 "(4) RELATIONSHIP TO SUBSECTION (b).—If,
22 at any time prior to the date that is 90 days after
23 the date on which the Administrator publishes the
24 list under paragraph (1), the Administrator makes a
25 finding under subsection (b)(3)(A)(i), or a manufac-

1 turer requests a risk evaluation under subsection
2 (b)(3)(A)(ii), with respect to a chemical substance,
3 such chemical substance shall not be subject to this
4 subsection.".

5 **[SEC. 7. IMMINENT HAZARDS.**

6 Section 7 of the Toxic Substances Control Act (15
7 U.S.C. 2606) is amended—]

8 [(1) in subsection (b)(1), by inserting "(as
9 identified by the Administrator without consider-
10 ation of costs or other non-risk factors)" after "from
11 the unreasonable risk"; and]

12 [(2) in subsection (f), by inserting ", without
13 consideration of costs or other non-risk factors"
14 after "widespread injury to health or the environ-
15 ment".]

16 **[SEC. 8. REPORTING AND RETENTION OF INFORMATION.**

17 Section 8 of the Toxic Substances Control Act (15
18 U.S.C. 2607) is amended—]

19 [(1) in subsection (a)—]

20 [(A) in paragraph (2), by striking the
21 matter that follows subparagraph (G);]

22 [(B) in paragraph (3), by adding at the
23 end the following:]

24 ["(C) Not later than 180 days after the date of en-
25 actment of the Frank R. Lautenberg Chemical Safety for

1 the 21st Century Act, and not less frequently than once
2 every 10 years thereafter, the Administrator, after con-
3 sultation with the Administrator of the Small Business
4 Administration, shall—]

5 [“(i) review the adequacy of the standards pre-
6 scribed under subparagraph (B); and]

7 [“(ii) after providing public notice and an op-
8 portunity for comment, make a determination as to
9 whether revision of the standards is warranted.”;
10 and]

11 [(C) by adding at the end the following:]

12 [“(4) ADMINISTRATION.—In carrying out this
13 section, the Administrator shall, to the extent fea-
14 sible—]

15 [“(A) not require reporting which is un-
16 necessary or duplicative;]

17 [“(B) minimize the cost of compliance
18 with this section and the rules issued there-
19 under on small manufacturers and processors;
20 and]

21 [“(C) apply any reporting obligations to
22 those persons likely to have information rel-
23 evant to the effective implementation of this
24 title.”; and]

1 [(2) in subsection (b), by adding at the end the
2 following:]
3 [“(3) NOMENCLATURE.—]]
4 [“(A) IN GENERAL.—In carrying out
5 paragraph (1), the Administrator shall—]
6 [“(i) maintain the use of Class 2 no-
7 menclature in use on the date of enact-
8 ment of the Frank R. Lautenberg Chem-
9 ical Safety for the 21st Century Act; and]
10 [“(ii) maintain the use of the Soap
11 and Detergent Association Nomenclature
12 System, published in March 1978 by the
13 Administrator in section 1 of addendum
14 III of the document entitled ‘Candidate
15 List of Chemical Substances’, and further
16 described in appendix A of volume I of the
17 1985 edition of the Toxic Substances Con-
18 trol Act Substances Inventory (EPA Docu-
19 ment No. EPA–560/7–85–002a).]
20 [“(B) MULTIPLE CAS NUMBERS.—For any
21 chemical substance appearing multiple times[,
22 as determined by the Administrator,] on the
23 list published under paragraph (1) under dif-
24 ferent Chemical Abstracts Service numbers, the
25 Administrator shall develop guidance recog-

1 nizing the multiple listings as a single chemical
2 substance.".]

3 **SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.**

4 Section 9 of the Toxic Substances Control Act (15
5 U.S.C. 2608) is amended—

6 [(1) in subsection (a)—]

7 [(A) in paragraph (1)—]

8 [(i) by inserting ", without consider-
9 ation of costs or other non-risk factors,"
10 after "basis to conclude"; and]

11 [(ii) by inserting "under the condi-
12 tions of use, including an unreasonable
13 risk to a potentially exposed or susceptible
14 subpopulation identified as relevant by the
15 Administrator," after "health or the envi-
16 ronment";]

17 [(B) in paragraph (2)—]

18 [(i) in subparagraph (A), by inserting
19 ", within the time period specified by the
20 Administrator in the report," after "issues
21 an order"; and]

22 [(ii) in subparagraph (B), by insert-
23 ing "responds within the time period speci-
24 fied by the Administrator in the report
25 and" before "initiates, within 90";]

1 [(C) by redesignating paragraph (3) as
2 paragraph (6); and]
3 [(D) by inserting after paragraph (2) the
4 following:]
5 ["(3) The Administrator shall take the actions de-
6 scribed in paragraph (4) if the Administrator makes a re-
7 port under paragraph (1) with respect to a chemical sub-
8 stance or mixture and the agency to which the report was
9 made does not—]
10 ["(A) issue the order described in paragraph
11 (2)(A) within the time period specified by the Ad-
12 ministrator in the report; or]
13 ["(B)(i) respond under paragraph (1) within
14 the time frame specified by the Administrator in the
15 report; and]
16 ["(ii) initiate action within 90 days of publica-
17 tion in the Federal Register of the response de-
18 scribed in clause (i).]
19 ["(4) If an agency to which a report is submitted
20 under paragraph (1) does not take the actions described
21 in subparagraph (A) or (B) of paragraph (3), the Admin-
22 istrator shall—]
23 ["(A) if a risk evaluation for a chemical sub-
24 stance included in the report has not been completed
25 under section 6, complete the risk evaluation;]

1 [“(B) if the Administrator has made a deter-
2 mination of unreasonable risk in accordance with
3 section 6(b)(1), initiate action under section 6(a)
4 with respect to the risk; or]
5 [“(C) take any action authorized or required
6 under section 7, as appropriate.]
7 [“(5) This subsection shall not relieve the Adminis-
8 trator of any obligation to complete a risk evaluation or
9 take any required action under section 6(a) or 7 to address
10 risks from the manufacture, processing, distribution in
11 commerce, use, or disposal of a chemical substance or mix-
12 ture, or any combination of those activities, that are not
13 identified in a report issued by the Administrator under
14 paragraph (1).”;]
15 (2) in subsection (b)—
16 (A) by striking “The Administrator shall
17 coordinate” and inserting “(1) The Adminis-
18 trator shall coordinate”; and
19 (B) by adding at the end the following:
20 “(2) In making a determination under paragraph (1)
21 that it is in the public interest for the Administrator to
22 take an action under this title with respect to a chemical
23 substance or mixture rather than under another law ad-
24 ministered in whole or in part by the Administrator, the
25 Administrator shall consider, based on information rea-

1 sonably available to the Administrator, the relative risks
2 and a comparison of the estimated costs and efficiencies
3 of the action to be taken under this title and an action
4 to be taken under such other law to protect against such
5 risk."; and

6 [(3) by adding at the end the following:]

7 ["(e) EXPOSURE INFORMATION.—In addition to the
8 requirements of subsection (a), if the Administrator ob-
9 tains information related to exposures or releases of a
10 chemical substance or mixture that may be prevented or
11 reduced under another Federal law, including a law not
12 administered by the Administrator, the Administrator
13 shall make such information available to the relevant Fed-
14 eral agency or office of the Environmental Protection
15 Agency.".]

16 **SEC. 10. DISCLOSURE OF DATA.**

17 Section 14 of the Toxic Substances Control Act (15
18 U.S.C. 2613) is amended—

19 (1) in subsection (a)—

20 (A) by striking "or" at the end of para-
21 graph (3);

22 (B) by striking the period at the end of
23 paragraph (4) and inserting a semicolon; and

24 (C) by adding after paragraph (4) the fol-
25 lowing new paragraphs:

"(5) may be disclosed to a State, local, or tribal government official upon request of the official for the purpose of administration or enforcement of a law; and

"(6) shall be disclosed upon request—

"(A) to a health or environmental professional employed by a Federal or State agency in response to an environmental release; or

"(B) to a treating physician or other health care professional to assist in the diagnosis or treatment of one or more individuals.";

(2) in subsection (b)(1), in the matter following subparagraph (B)—

(A) by striking "data which discloses" and inserting "data that disclose formulas (including molecular structures) of a chemical substance or mixture,";

(B) by striking "mixture or," and inserting "mixture, or,"; and

(C) by striking "the release of data disclosing";

(3) in subsection (c)—

(A) by striking the subsection heading and inserting "DESIGNATING AND SUBSTANTIATING CONFIDENTIALITY.—";

1 (B) by amending paragraph (1) to read as
2 follows: " (1)(A) In submitting information
3 under this Act after date of enactment of the
4 Frank R. Lautenberg Chemical Safety for the
5 21st Century Act, a manufacturer, processor, or
6 distributor in commerce shall designate the in-
7 formation which such person believes is entitled
8 to protection under this section, and submit
9 such designated information separately from
10 other information submitted under this Act. A
11 designation under this subparagraph shall be
12 made in writing and in such manner as the Ad-
13 ministrator may prescribe, and shall include—
14 "(i) justification for each designation of
15 confidentiality;
16 "(ii) a certification that the information is
17 not otherwise publicly available; and
18 "(iii) separate copies of all submitted infor-
19 mation, with one copy containing and one copy
20 excluding the information to which the request
21 applies.
22 "(B) Designations made under subparagraph
23 (A) after the date of enactment of the Frank R.
24 Lautenberg Chemical Safety for the 21st Century
25 Act shall expire after 10 years, at which time the in-

1 formation shall be made public unless the manufac-
2 turer, processor, or distributor in commerce has re-
3 asserted the claim for protection, in writing and in
4 such manner as the Administrator may prescribe, in-
5 cluding all of the elements required for the initial
6 submission.

7 "(C) Not later than 60 days prior to making in-
8 formation public under subparagraph (B), the Ad-
9 ministrator shall notify, as appropriate and prac-
10 ticable, the manufacturer, processor, or distributor
11 in commerce who designated the information under
12 subparagraph (A) of the date on which such infor-
13 mation will be made public unless [the Adminis-
14 trator determines that the information is entitled to
15 protection under this section].";

16 (C) in paragraph (2)—

17 (i) in subparagraph (A), by inserting
18 ", for a reason other than the expiration of
19 such designation pursuant to paragraph
20 (1)(B)," before "proposes to release"; and

21 (ii) in subparagraph (B)(i), by strik-
22 ing "or (4)" and inserting "(4), or (6)";
23 and

24 (D) by adding at the end the following:

1 [“(3)(A) Not later than 18 months after the date of
2 enactment of the Frank R. Lautenberg Chemical Safety
3 for the 21st Century Act, the Administrator shall, by rule,
4 establish a plan for consideration under this paragraph of
5 any information protected from public disclosure under
6 subsection (a) that was reported to or otherwise obtained
7 by the Administrator prior to the such date of enactment.]
8 [“(B) The plan established under subparagraph (A)
9 shall—]
10 [“(i) provide that the Administrator shall—]
11 [“(I) review all information described in
12 subparagraph (A);]
13 [“(II) based on such review, make a find-
14 ing regarding whether such information may no
15 longer qualify for protection under subsection
16 (a); and]
17 [“(III) if the Administrator finds a rea-
18 sonable basis to conclude that information may
19 no longer qualify for such protection, require
20 any person who has a claim for protection of
21 such information to reassert such claim by sub-
22 mitting and designating the information under
23 paragraph (1); and]

1 [“(ii) establish a schedule that ensures that,
2 not later than 5 years after the adoption of the plan,
3 the Administrator—]
4 [“(I) makes a finding under clause (i)(II)
5 with respect to all information described in sub-
6 paragraph (A);]
7 [“(II) requires reassertions under clause
8 (i)(III), as applicable; and]
9 [“(III) issues a notice under paragraph
10 (1)(C) for any information that is not entitled
11 to protection under this subsection (a).]
12 [“(C) The Administrator may, after public notice
13 and opportunity for comment, extend the deadline de-
14 scribed in subparagraph (B)(ii) for a period not to exceed
15 2 years if the Administrator determines that such exten-
16 sion is necessary based on the number of applicable claims
17 needing review under subparagraph (B)(i)(I) and the
18 available resources.]
19 [“(D) Information described in subparagraph (A)
20 with respect to which the Administrator does not require
21 reassertion under subparagraph (B)(i)(III) shall not be
22 entitled to protection from disclosure under subsection (a)
23 after the expiration of the 10-year period beginning on the
24 date of enactment of the Frank R. Lautenberg Chemical
25 Safety for the 21st Century Act, unless a person who has

1 a claim for such protection reasserts such claim by submit-
2 ting and designating the information under paragraph
3 (1).]

4 [“(E) Except as provided in subparagraph (D), in-
5 formation described in subparagraph (A) shall continue to
6 be protected from public disclosure unless the Adminis-
7 trator makes the information public as authorized under
8 paragraph (1).”; and]

9 (4) by adding at the end the following new sub-
10 sections:

11 “(f) PROHIBITION.—No person who receives informa-
12 tion as permitted under subsection (a) may use such infor-
13 mation for any purpose not specified in such subsection,
14 nor disclose such information to any person not authorized
15 to receive such information.

16 “(g) SAVINGS.—Nothing in this section shall be con-
17 strued to affect the applicability of State or Federal rules
18 of evidence or procedure in any judicial proceeding.”.

19 **SEC. 11. EFFECT ON STATE LAW.**

20 (a) IN GENERAL.—Section 18(a) of the Toxic Sub-
21 stances Control Act (15 U.S.C. 2617(a)) is amended—

22 (1) in paragraph (2)(A), by striking “; and”
23 and inserting a semicolon;

24 (2) by striking paragraph (2)(B) and inserting
25 the following:

1 "(B) if the Administrator makes a final deter-
2 mination under section 6(b) that a chemical sub-
3 stance will not present an unreasonable risk of in-
4 jury to health or the environment under the [condi-
5 tions of use], no State or political subdivision may,
6 after the date of publication of such determination,
7 establish or continue in effect any requirement that
8 applies to such chemical substance under the [condi-
9 tions of use] considered by the Administrator in the
10 risk evaluation under section 6(b), and is designed
11 to protect against exposure to such chemical sub-
12 stance under the [conditions of use], unless the re-
13 quirement of the State or political subdivision—
14 "(i) is adopted under the authority of a
15 Federal law; or
16 "(ii) is adopted to protect air or water
17 quality or is related to waste treatment or
18 waste disposal, except that this clause does not
19 apply to such a requirement if a provision of
20 this title, or an action or determination made
21 by the Administrator under this title, actually
22 conflicts with the requirement; and
23 "(C) if the Administrator imposes a require-
24 ment, through a rule or order under section 5 or 6,
25 that applies to a chemical substance or mixture

1 (other than a requirement described in section
2 6(a)(6)) and is designed to protect against a risk of
3 injury to health or the environment associated with
4 such chemical substance or mixture, no State or po-
5 litical subdivision may, after the effective date of
6 such requirement, establish or continue in effect any
7 requirement that applies to such chemical substance
8 or mixture (including a requirement that applies to
9 an article because the article contains the chemical
10 substance or mixture) and is designed to protect
11 against exposure to the chemical substance or mix-
12 ture either under the [conditions of use] considered
13 by the Administrator in the risk evaluation under
14 section 6(b) or from a use identified in a notice re-
15 ceived by the Administrator under section 5(a), or,
16 in the case of a requirement imposed pursuant to
17 section 6(i), is designed to protect against a risk of
18 injury considered by the Administrator in imposing
19 such requirement, unless the requirement of the
20 State or political subdivision—
21 "(i) is identical to the requirement imposed
22 by the Administrator;
23 "(ii) is adopted under the authority of a
24 Federal law; or

1 "(iii) is adopted to protect air or water
2 quality or is related to waste treatment or
3 waste disposal, except that this clause does not
4 apply to such a requirement if a provision of
5 this title, or an action or determination made
6 by the Administrator under this title, actually
7 conflicts with the requirement."; and
8 (3) by adding at the end the following:
9 "(3) In the case of an identical requirement described
10 in paragraph (2)(C)(i)—
11 "(A) a State may not assess a penalty for a
12 specific violation for which the Administrator has as-
13 sessed a penalty under section 16; and
14 "(B) if a State has assessed a penalty for a
15 specific violation, the Administrator may not assess
16 a penalty for that violation in an amount that would
17 cause the total of the penalties assessed for the vio-
18 lation by the State and the Administrator combined
19 to exceed the maximum amount that may be as-
20 sessed for that violation by the Administrator under
21 section 16.".
22 (b) SAVINGS.—Section 18 of the Toxic Substances
23 Control Act (15 U.S.C. 2617) is amended by adding at
24 the end the following:
25 "(c) SAVINGS.—

1 "(1) PRIOR STATE ACTIONS.—Nothing in this
2 title, nor any risk evaluation, rule, order, standard,
3 or requirement completed or implemented under this
4 title, shall be construed to preempt or otherwise af-
5 fect the authority of a State or political subdivision
6 of a State to continue to enforce any action taken
7 or requirement that has taken effect—
8 "(A) before August 1, 2015, under the au-
9 thority of a State law that prohibits or other-
10 wise restricts the manufacturing, processing,
11 distribution in commerce, use, or disposal of a
12 chemical substance; or
13 "(B) pursuant to a State law that was in
14 effect on August 31, 2003,
15 unless an action or determination made by the Ad-
16 ministrator under this title actually conflicts with
17 the action taken or requirement that has taken ef-
18 fect pursuant to such a State law.
19 "(2) TORT AND CONTRACT LAW.—Nothing in
20 this title, nor any risk evaluation, rule, order, stand-
21 ard, or requirement completed or implemented under
22 this title, shall be construed to preempt or otherwise
23 affect either Federal or State tort law or the law
24 governing the interpretation of contracts of any
25 State, including any remedy for civil relief, whether

1 under statutory or common law, including a remedy
2 for civil damages, and any cause of action for per-
3 sonal injury, wrongful death, property damage, or
4 other injury based on negligence, strict liability,
5 products liability, failure to warn, or any other legal
6 theory relating to tort law.

7 "(3) INTENT OF CONGRESS.—It is not the in-
8 tent of Congress that this title, or rules, regulations,
9 or orders issued pursuant to this title, be interpreted
10 as influencing, in either a plaintiff's or defendant's
11 favor, the disposition of any civil action for damages
12 in a State court, or the authority of any court to
13 make a determination in an adjudicatory proceeding
14 under applicable State law with respect to the ad-
15 missibility of evidence, unless a provision of this title
16 actually conflicts with the State court action.

17 "(4) APPLICATION.—For purposes of this title,
18 the term 'requirements' does not include civil tort
19 actions for damages under State law.".

20 (c) EFFECT OF ACTIONS BY ADMINISTRATOR.—
21 Nothing in this Act, or the amendments made by this Act,
22 shall be construed as changing the preemptive effect of
23 an action taken by the Administrator prior to the date
24 of enactment of this Act or under section 6(e) [of the
25 Toxic Substances Control Act].

[**SEC. 12. STUDIES.**

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.]

SEC. 13. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) in subsection (b)(1)—

(A) by striking "of a reasonable fee";

[(B) by inserting ", or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b), of a fee that is sufficient and not more than reasonably necessary" after "section 4 or 5";]

(C) by striking "this Act" and inserting "the provision of this title for which such fee is collected";

(D) by striking "Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100." and inserting "Such rules shall provide for lower fees for small business concerns."; and

[(E) by striking "submit the data and the cost to the Administrator of reviewing such data" and inserting "pay such fee and the cost to the Administrator of reviewing such data or

1 conducting such risk evaluation, as applica-
2 ble";]
3 (2) by adding at the end of subsection (b) the
4 following:
5 "(3) FUND.—
6 "(A) ESTABLISHMENT.—There is established in
7 the Treasury of the United States a revolving fund,
8 to be known as the TSCA Service Fee Fund (in this
9 paragraph referred to as the 'Fund'), consisting of
10 such amounts as are deposited in the Fund under
11 this paragraph.
12 "(B) COLLECTION AND DEPOSIT OF FEES.—
13 The Administrator shall collect the fees described in
14 paragraph (1) and deposit those fees in the Fund.
15 "(C) CREDITING AND AVAILABILITY OF
16 FEES.—On request by the Administrator, the Sec-
17 retary of the Treasury shall transfer from the Fund
18 to the Administrator amounts appropriated to pay
19 or recover the full costs incurred by the Environ-
20 mental Protection Agency, including contractor
21 costs, in carrying out the provisions of this title for
22 which the fees are collected under paragraph (1).
23 "(D) USE OF FUNDS BY ADMINISTRATOR.—
24 Fees authorized under this section shall be collected
25 and available for obligation only to the extent and in

1 the amount provided in advance in appropriations
2 Acts, and shall be available without fiscal year limi-
3 tation for use only in administering the provisions of
4 this title for which the fees are collected.

5 "(E) ACCOUNTING AND AUDITING.—

6 "(i) ACCOUNTING.—The Administrator
7 shall biennially prepare and submit to the Com-
8 mittee on Environment and Public Works of the
9 Senate and the Committee on Energy and Com-
10 merce of the House of Representatives a report
11 that includes an accounting of the fees paid to
12 the Administrator under this paragraph and
13 amounts disbursed from the Fund for the pe-
14 riod covered by the report, as reflected by fi-
15 nancial statements provided in accordance with
16 sections 3515 and 3521 of title 31, United
17 States Code.

18 "(ii) AUDITING.—

19 "(I) IN GENERAL.—For the purpose
20 of section 3515(c) of title 31, United
21 States Code, the Fund shall be considered
22 a component of a covered executive agency.

23 "(II) COMPONENTS OF AUDIT.—The
24 annual audit required in accordance with
25 sections 3515 and 3521 of title 31, United

1 States Code, of the financial statements of
2 activities carried out using amounts from
3 the Fund shall include an analysis of—
4 "(aa) the fees collected and
5 amounts disbursed under this sub-
6 section;
7 "(bb) the reasonableness of the
8 fees in place as of the date of the
9 audit to meet current and projected
10 costs of administering the provisions
11 of the title for which the fees are col-
12 lected; and
13 "(cc) the number of requests for
14 a risk evaluation made by manufac-
15 turers under section 6(b)(3)(A)(ii).
16 "(III) FEDERAL RESPONSIBILITY.—
17 The Inspector General of the Environ-
18 mental Protection Agency shall conduct
19 the annual audit described in subclause
20 (II) and submit to the Administrator a re-
21 port that describes the findings and any
22 recommendations of the Inspector General
23 resulting from the audit."; and
24 (3) by adding at the end the following:

1 "(h) SCIENTIFIC STANDARDS.—In carrying out sec-
2 tions 4, 5, and 6, to the extent that the Administrator
3 makes a decision based on science, the Administrator shall
4 consider, as applicable—
5 "(1) the extent to which the scientific and tech-
6 nical procedures, measures, methods, or models em-
7 ployed to generate the information are reasonable
8 for and consistent with the use of the information;
9 "(2) the extent to which the information is rel-
10 evant for the Administrator's use in making a deci-
11 sion about a chemical substance or mixture;
12 "(3) the degree of clarity and completeness with
13 which the data, assumptions, methods, quality assur-
14 ance, and analyses employed to generate the infor-
15 mation are documented;
16 "(4) the extent to which the variability and un-
17 certainty in the information, or in the procedures,
18 measures, methods, or models, are evaluated and
19 characterized; and
20 "(5) the extent of independent verification or
21 peer review of the information or of the procedures,
22 measures, methods, or models.
23 "(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Ad-
24 ministrator shall make decisions under sections 4, 5, and
25 6 based on the weight of the scientific evidence.

1 "(j) AVAILABILITY OF INFORMATION.—Subject to
2 section 14, the Administrator shall make available to the
3 public—
4 "(1) all notices, determinations, findings, rules,
5 and orders of the Administrator under this title; and
6 [[]"(2) any tests results required to be provided
7 to the Administrator under this title.[]]
8 "(k) POLICIES, PROCEDURES, AND GUIDANCE.—
9 "(1) DEVELOPMENT.—Not later than 2 years
10 after the date of enactment of the Frank R. Lauten-
11 berg Chemical Safety for the 21st Century Act, the
12 Administrator shall develop any policies, procedures,
13 and guidance the Administrator determines are nec-
14 essary to carry out the amendments to this Act
15 made by the Frank R. Lautenberg Chemical Safety
16 for the 21st Century Act [[]], including criteria the
17 Administrator will use to select chemical substances
18 for a determination under section 6(b)(3)(A)(i)[[]].
19 "(2) REVIEW.—Not later than 5 years after the
20 date of enactment of the Frank R. Lautenberg
21 Chemical Safety for the 21st Century Act, and not
22 less frequently than once every 5 years thereafter,
23 the Administrator shall—
24 "(A) review the adequacy of the policies,
25 procedures, and guidance developed under para-

1 graph (1), including with respect to animal,
2 nonanimal, and epidemiological test methods
3 and procedures for assessing and determining
4 risk under this title; and
5 "(B) revise such policies, procedures, and
6 guidance as the Administrator determines nec-
7 essary to reflect new scientific developments or
8 understandings.
9 "(l) REPORT TO CONGRESS.—
10 "(1) INITIAL REPORT.—Not later than 6
11 months after the date of enactment of the Frank R.
12 Lautenberg Chemical Safety for the 21st Century
13 Act, the Administrator shall submit to the Commit-
14 tees on Energy and Commerce and Appropriations
15 of the House of Representatives and the Committees
16 on Environment and Public Works and Appropria-
17 tions of the Senate a report containing an estimation
18 of—
19 "(A) the capacity of the Environmental
20 Protection Agency to conduct and publish risk
21 evaluations under subparagraphs (A)(i) and (B)
22 of section 6(b)(3), and the resources necessary
23 to initiate the minimum number of risk evalua-
24 tions required under section 6(b)(7);

"(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 6(b)(3)(A)(ii), the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

"(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

"(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 6(b).

"(2) SUBSEQUENT REPORTS.—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.".

[SEC. 14. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended by striking subsections (c) and (d).]

1 **SEC. 15. CONFORMING AMENDMENTS.**

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

4 (1) in subsection (b)—

5 (A) in paragraph (1), by striking "rule"
6 each place it appears and inserting "rule, order,
7 or consent agreement";

8 (B) in paragraph (2)(B), by striking
9 "rules" and inserting "rules, orders, and con-
10 sent agreements";

11 (C) in paragraph (3), by striking "rule"
12 each place it appears and inserting "rule, order,
13 or consent agreement"; and

14 (D) in paragraph (4)—

15 (i) by striking "rule under subsection
16 (a)" each place it appears and inserting
17 "rule, order, or consent agreement under
18 subsection (a)";

19 (ii) by striking "repeals the rule" each
20 place it appears and inserting "repeals the
21 rule or order or modifies the consent
22 agreement to terminate the requirement";
23 and

24 (iii) by striking "repeals the applica-
25 tion of the rule" and inserting "repeals or

1 modifies the application of the rule, order,
2 or consent agreement";
3 (2) in subsection (c)—
4 (A) in paragraph (1), by striking "rule"
5 and inserting "rule or order";
6 (B) in paragraph (2)—
7 (i) in subparagraph (A), by striking
8 "a rule under subsection (a) or for which
9 data is being developed pursuant to such a
10 rule" and inserting "a rule, order, or con-
11 sent agreement under subsection (a) or for
12 which data are being developed pursuant
13 to such a rule, order, or consent agree-
14 ment";
15 (ii) in subparagraph (B), by striking
16 "such rule or which is being developed pur-
17 suant to such rule" and inserting "such
18 rule, order, or consent agreement or which
19 is being developed pursuant to such rule,
20 order, or consent agreement"; and
21 (iii) in the matter following subpara-
22 graph (B), by striking "the rule" and in-
23 serting "the rule or order";

1 (C) in paragraph (3)(B)(i), by striking
2 "rule promulgated" and inserting "rule, order,
3 or consent agreement"; and
4 (D) in paragraph (4)—
5 (i) by striking "rule promulgated"
6 each place it appears and inserting "rule,
7 order, or consent agreement";
8 (ii) by striking "such rule" each place
9 it appears and inserting "such rule, order,
10 or consent agreement"; and
11 (iii) in subparagraph (B), by striking
12 "the rule" and inserting "the rule, order,
13 or consent agreement";
14 (3) in subsection (d), by striking "rule" and in-
15 serting "rule, order, or consent agreement"; and
16 (4) in subsection (g), by striking "rule" and in-
17 serting "rule, order, or consent agreement".
18 (b) SECTION 5.—Section 5 of the Toxic Substances
19 Control Act (15 U.S.C. 2604) is amended—
20 (1) in subsection (b)—
21 (A) in paragraph (1)(A)—
22 (i) by striking "rule promulgated"
23 and inserting "rule, order, or consent
24 agreement"; and

1 (ii) by striking "such rule" and insert-
2 ing "such rule, order, or consent agree-
3 ment";
4 (B) in paragraph (1)(B)—
5 (i) by striking "rule promulgated"
6 and inserting "rule or order"; and
7 (ii) by striking "the date of the sub-
8 mission in accordance with such rule" and
9 inserting "the required date of submis-
10 sion"; and
11 (C) in paragraph (2)(A)(ii), by striking
12 "rule promulgated" and inserting "rule, order,
13 or consent agreement";
14 (2) in subsection (d)(2)(C), by striking "rule"
15 and inserting "rule, order, or consent agreement";
16 and
17 (3) in subsection (h)(4), by striking "para-
18 graphs (2) and (3) of section 6(c)" and inserting
19 "paragraph (2) of section 6(c)".
20 (c) SECTION 6.—Section 6 of the Toxic Substances
21 Control Act (15 U.S.C. 2605) is amended—
22 (1) in subsection (d)(2)(B)—
23 (A) by striking ", provide reasonable op-
24 portunity, in accordance with paragraphs (2)
25 and (3) of subsection (c), for a hearing on such

1 rule," and inserting "in accordance with para-
2 graph (2) of subsection (c),"; and
3 (B) by striking "; and if such a hearing is
4 requested" and all that follows through "or re-
5 voke it." and inserting a period; and
6 (2) in subsection (e)(4), by striking "para-
7 graphs (2), (3), and (4) of subsection (c)" and in-
8 serting "paragraph (2) of subsection (c)".
9 (d) SECTION 7.—Section 7(a)(1) of the Toxic Sub-
10 stances Control Act (15 U.S.C. 2606(a)(1)) is amended,
11 in the matter following subparagraph (C), by striking "a
12 rule under section 4, 5, 6, or title IV or an order under
13 section 5 or title IV" and inserting "[a determination
14 under section 5 or 6,] a rule under section 4, 5, or 6 or
15 title IV, an order under section 4 or 5 or title IV, or a
16 consent agreement under section 4".
17 (e) SECTION 8.—Section 8(a)(3)(A)(ii)(I) of the
18 Toxic Substances Control Act (15 U.S.C.
19 2607(a)(3)(A)(ii)(I)) is amended by striking "or an order
20 in effect under section 5(e)" and inserting ", an order in
21 effect under section 4 or 5(e), or a consent agreement
22 under section 4".
23 (f) SECTION 9.—Section 9 of the Toxic Substances
24 Control Act (15 U.S.C. 2608) is amended—

1 (1) in subsection (a), by striking "section 6"
2 each place it appears and inserting "section 6(a)";
3 and
4 [(2) in subsection (d), by striking "Health,
5 Education, and Welfare" and inserting "Health and
6 Human Services".]
7 [(g) SECTION 10.—Section 10 of the Toxic Sub-
8 stances Control Act (15 U.S.C. 2609) is amended by strik-
9 ing "Health, Education, and Welfare" each place it ap-
10 pears and inserting "Health and Human Services".]
11 (h) SECTION 11.—Section 11(b)(2)(E) of the Toxic
12 Substances Control Act (15 U.S.C. 2610(b)(2)(E)) is
13 amended by striking "rule promulgated" and inserting
14 "rule promulgated, order issued, or consent agreement en-
15 tered into".
16 (i) SECTION 15.—Section 15(1) of the Toxic Sub-
17 stances Control Act (15 U.S.C. 2614(1)) is amended by
18 striking "(A) any rule" and all that follows through "or
19 (D)" and inserting "any requirement of this title or any
20 rule promulgated, order issued, or consent agreement en-
21 tered into under this title, or".
22 (j) SECTION 18.—Section 18(a)(2)(A) of the Toxic
23 Substances Control Act (15 U.S.C. 2617(a)(2)(A)) is
24 amended—

1 (1) by striking "rule promulgated" and insert-
2 ing "rule, order, or consent agreement"; and
3 (2) by striking "such rule" each place it ap-
4 pears and inserting "such rule, order, or consent
5 agreement".
6 (k) SECTION 19.—Section 19 of the Toxic Substances
7 Control Act (15 U.S.C. 2618) is amended—
8 (1) in subsection (a)—
9 (A) in paragraph (1)(A)—
10 (i) by striking "(A) Not later than 60
11 days after the date of the promulgation of
12 a rule" and inserting "Not later than 60
13 days after the date on which a rule is pro-
14 mulgated";
15 (ii) by inserting "or the date on which
16 an order is issued under section 4," before
17 "any person";
18 (iii) by striking "such rule" and in-
19 serting "such rule or order"; and
20 (iv) by striking "such a rule" and in-
21 serting "such a rule or order";
22 (B) by striking paragraph (1)(B);
23 (C) in paragraph (2), by striking "the
24 rule" and inserting "the rule or order"; and
25 (D) in paragraph (3)—

(i) in subparagraph (A), by striking "the rule" and inserting "the rule or order";

(ii) in subparagraph (B), by striking "a rule under section 4(a)" and inserting "a rule or order under section 4(a)";

(iii) in subparagraph (C), by striking "such rule" and inserting "such rule or order";

(iv) in subparagraph (D), by striking "such rule" and inserting "such rule or order"; and

(v) in subparagraph (E)—

(I) by striking "to such rule" and inserting "to such rule or order"; and

(II) by striking "the date of the promulgation of such rule" and inserting "the date on which such rule is promulgated or such order is issued";

(2) in subsection (b)—

(A) by striking "review a rule" and inserting "review a rule, or an order under section 4,";

1 (B) by striking "such rule" and inserting
2 "such rule or order";
3 (C) by striking "the rule" and inserting
4 "the rule or order";
5 (D) by striking "new rule" each place it
6 appears and inserting "new rule or order"; and
7 (E) by striking "modified rule" and insert-
8 ing "modified rule or order"; and
9 (3) in subsection (c)—
10 (A) in paragraph (1)—
11 (i) in subparagraph (A)—
12 (I) by striking "a rule" and in-
13 serting "a rule, or an order under sec-
14 tion 4"; and
15 (II) by striking "such rule" and
16 inserting "such rule or order"; and
17 (ii) in subparagraph (B)—
18 (I) in the matter preceding clause
19 (i), by striking "a rule" and inserting
20 "a rule or order";
21 (II) in clause (i)—
22 (aa) by inserting "or an
23 order under section 4," before
24 "the standard for review";

(bb) by striking "such rule" and inserting "such rule or order";

(cc) by striking "the rule" and inserting "the rule or order"; and

(dd) by striking the semicolon and inserting "; and"; and

(III) by striking clause (ii) and redesignating clause (iii) as clause (ii); and

(B) in paragraph (2), by striking "any rule" and inserting "any rule or order".

(l) SECTION 20.—Section 20(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2619(a)(1)) is amended by striking "order issued under section 5" and inserting "order issued under section 4 or 5".

(m) SECTION 21.—Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "order under section 5(e) or (6)(b)(2)" and inserting "order under section 4 or 5(e)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)"

1 and inserting "order under section 4 or 5(e)";
2 and
3 (B) in paragraph (4)(B)—
4 (i) in the matter preceding clause (i),
5 by striking "order under section 5(e) or
6 6(b)(2)" and inserting "order under sec-
7 tion 4 or 5(e)";
8 (ii) in clause (i), by striking "order
9 under section 5(e)" and inserting "order
10 under section 4 or 5(e)"; and
11 (iii) in clause (ii), by striking "or an
12 order under section 6(b)(2)".
13 (n) SECTION 24.—Section 24(b)(2)(B) of the Toxic
14 Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is
15 amended—
16 (1) by inserting "and" at the end of clause (i);
17 (2) by striking clause (ii); and
18 (3) by redesignating clause (iii) as clause (ii).
19 ⟦(o) SECTION 26.—Section 26(e) of the Toxic Sub-
20 stances Control Act (15 U.S.C. 2625(e)) is amended by
21 striking "Health, Education, and Welfare" each place it
22 appears and inserting "Health and Human Services".⟧
23 (p) SECTION 27.—Section 27(a) of the Toxic Sub-
24 stances Control Act (15 U.S.C. 2626(a)) is amended—

1 [(1) by striking "Health, Education, and Wel-
2 fare" and inserting "Health and Human Services";
3 and]
4 (2) by striking "rules promulgated" and insert-
5 ing "rules, orders, or consent agreements".
6 (q) SECTION 30.—Section 30(2) of the Toxic Sub-
7 stances Control Act (15 U.S.C. 2629(2)) is amended by
8 striking "rule" and inserting "rule, order, or consent
9 agreement".

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display-inline="no-display-inline">Section 2 of the Toxic Substances Control Act (15
U.S.C. 2601) is amended by striking <quote>proposes to take</quote> and inserting
<quote>proposes as provided</quote>. </text></section>
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U.S.C. 2602) is amendedâ€"</text>
<paragraph id="H07884C863493449D96D6AB47ECB075DA"><enum>(1)</enum><text>by
redesignating paragraphs (4) through (14) as paragraphs (5) through (10) and (12)
through (16), respectively;</text></paragraph>
<paragraph id="H8E599FA278074AE889A565524DB3E295"><enum>(2)</enum><text>by inserting
after paragraph (3) the following:</text>
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style="OLC">
<paragraph id="H020FF52D4D8D4D0495574F0C00763A41" indent="up1"
commented="yes"><enum>(4)</enum><text display-inline="yes-display-inline">The term
<term>conditions of use</term> means the intended, known, or reasonably foreseeable
circumstances under which the Administrator determines a chemical substance is
manufactured, processed, distributed in commerce, used, or disposed
of.</text></paragraph><after-quoted-block>; and</after-quoted-block></quoted-

block></paragraph>
<paragraph id="H61EE9FD2334D4EF596F079681F2445E2"><enum>(3)</enum><text>by inserting after paragraph (10), as so redesignated, the following:</text>
<quoted-block display-inline="no-display-inline" id="HF6DE4F656BF2490E85457D64DCAC91F8" style="OLC">
<paragraph id="H1E5AD26C1C8B4B39B47FC5D9B1D6A054" indent="up1" commented="yes"><enum>(11)</enum><text display-inline="yes-display-inline">The term <term>potentially exposed or susceptible subpopulation</term> means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.</text></paragraph><after-quoted-block>.</after-quoted-block></quoted-block></paragraph></section>
<section commented="no" id="H81B19D4B278140DAB96CD1403FC45F1A"><enum>4.</enum><header>Testing of chemical substances and mixtures</header><text display-inline="no-display-inline">Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amendedâ€"</text>
<paragraph commented="no" id="H2C3C0ADED1174261AE8F75C374089D31"><enum>(1)</enum><text display-inline="yes-display-inline">in subsection (a)(1)â€"</text>
<subparagraph commented="no" id="HB77262E41AE44AE3B51348885FE3E07D"><enum>(A)</enum><text>in subparagraph (A)(iii), by striking <quote>; or</quote> and inserting a semicolon;</text></subparagraph>
<subparagraph commented="no" id="HD363ED79F1F045CBB4CADC2DB325DA7A"><enum>(B)</enum><text>in subparagraph (B)(iii), by striking <quote>; and</quote> and inserting <quote>; or</quote>; and</text></subparagraph>
<subparagraph commented="no" id="H15FC86A3D1D54EE7897C1E2529874DBF"><enum>(C)</enum><text>by adding at the end the following:</text>
<quoted-block display-inline="no-display-inline" id="H509F3B3B6CB34D618541A5BB72BA0184" style="OLC">
<subparagraph commented="no" id="H2D149D7F1F1E4E3C94633E5A0C5EF765" indent="up1"><enum>(C)</enum><text display-inline="yes-display-inline">testing of a chemical substance is necessary to conduct a risk evaluation under section 6(b); and</text></subparagraph><after-quoted-block>; </after-quoted-block></quoted-block></subparagraph></paragraph>
<paragraph commented="no" id="HB67797865E504220B9FACAA469017119"><enum>(2)</enum><text>in the matter following subsection (a)(2), by inserting <quote>, order, or consent agreement</quote> after <quote>by rule</quote>; </text> </paragraph>
<paragraph id="H92F9B9A8075744699A8667BB7664D1C5" commented="no"><enum>(3)</enum><text display-inline="yes-display-inline">in subsection (b)â€"</text>
<subparagraph id="HB2282947A53F4D408962C10D215CA907" commented="yes"><enum>(A)</enum><text display-inline="yes-display-inline">in paragraph (2)(A)â€"</text>
<clause id="HED24698550D141FEA1912C7D81D4812A" commented="yes"><enum>(i)</enum><text>by striking <quote>hierarchical tests</quote> and inserting <quote>tiered testing</quote>;

and</text></clause>
<clause id="HF454FE3A605945DDA561964468E03B53"
commented="yes"><enum>(ii)</enum><text>by adding at the end the following: <quote>The Administrator shall reduce the use of animals in the testing of chemical substances or mixtures, to the extent practicable, by taking into consideration existing toxicity information and the availability of validated alternative test protocols that reduce or replace animal tests.</quote>; and</text></clause></subparagraph>
<subparagraph id="H59993753D2AC49CE886BFF4D566DAB64"
commented="no"><enum>(B)</enum><text>in paragraph (5), by striking <quote>paragraph (1)(A) or (1)(B)</quote> and inserting <quote>paragraph (1)(A), (1)(B), or (1)(C)</quote>; </text></subparagraph></paragraph>
<paragraph id="HED11AFF7AC6041708502773DADABE1D4"
commented="yes"><enum>(4)</enum><text>in subsection (e), by adding at the end the following:</text>
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<paragraph id="H55AB0112C3124ED88D03F6F28167DF2F" indent="up1"
commented="yes"><enum>(3)</enum><text display-inline="yes-display-inline">In addition to recommendations made by the committee under paragraph (1), the Administrator shall consider the recommendations of Federal agencies regarding the selection of chemical substances or mixtures for testing under this section. </text></paragraph><after-quoted-block>; and</after-quoted-block></quoted-block></paragraph>
<paragraph id="H73379F9602414AE8967EE484896C9067"
commented="yes"><enum>(5)</enum><text>by adding at the end the following: </text>
<quoted-block style="OLC" id="HA9AA6CB9C0D14D379F28A147BA11FA98" display-inline="no-display-inline">
<subsection id="HC4AB16CFDFC9479A9AC7A0C71B5B19D9"
commented="yes"><enum>(h)</enum><header>Reports on progress in reducing the use of animal testing</header>
<paragraph id="H5A6F6CB690E04A8B80DB3E0F75A5A974"
commented="yes"><enum>(1)</enum><header>In general</header><text>Not later than 2 years after the date of enactment of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>, and every 5 years thereafter, the Administrator shall submit to Congress a report that describes the progress made in reducing and replacing animal tests through the use of validated alternative test protocols for assessing risks of injury to health or the environment of chemical substances or mixtures. </text></paragraph>
<paragraph id="HCA0473EC145B408CBB31A01B3C5449C4"
commented="yes"><enum>(2)</enum><header>Inclusion</header><text>A report submitted under this subsection shall include information regarding the extent to which testing is conducted using information developed throughâ€"</text>
<subparagraph id="HED2DE593CBB44056A1D05B724E6D1F11"
commented="yes"><enum>(A)</enum><text>computational toxicology and bioinformatics;</text></subparagraph>
<subparagraph id="HAB7248FB6C174962AFBBB18298B10E9B"
commented="yes"><enum>(B)</enum><text>high-throughput screening methods;
</text></subparagraph>
<subparagraph id="H092B314D480B4C78A3733753899DB3BD"

commented="yes"><enum>(C)</enum><text>testing of categories of chemical substances;
</text></subparagraph>
<subparagraph id="HE16E86BF7CE344CD8F6277B36DD469F6"
commented="yes"><enum>(D)</enum><text>tiered testing methods; </text></subparagraph>
<subparagraph id="H21BC7C54784A46BABC851330E3B7103B"
commented="yes"><enum>(E)</enum><text>new or revised methods identified by the
Interagency Coordinating Committee on the Validation of Alternative Methods; and
</text></subparagraph>
<subparagraph id="H28CDC940DB2D4D51B35FA81E5C3A0636"
commented="yes"><enum>(F)</enum><text>industry consortia that jointly develop testing
data for submission under this
title.</text></subparagraph></paragraph></subsection><after-quoted-block>.</after-
quoted-block></quoted-block></paragraph></section>
<section id="H149E957D6C87411D98B5E5776993BEEF"
commented="yes"><enum>5.</enum><header>Voluntary risk evaluations</header><text
display-inline="no-display-inline">Section 5 of the Toxic Substances Control Act (15
U.S.C. 2604) is amendedâ€"</text>
<paragraph id="H2C737371D2584E4EA975F22DA256B647"
commented="yes"><enum>(1)</enum><text>by redesignating subsection (i) as subsection
(j); and</text></paragraph>
<paragraph id="HE2DDDEAEE12E4726AF9E1B89B3FD9438"
commented="yes"><enum>(2)</enum><text>by inserting after subsection (h) the following:
</text>
<quoted-block style="OLC" id="H6851F9B1E1F64D66A0AC378250CAAC8B" display-inline="no-
display-inline">
<subsection id="H5B764D9EAE374892AF0C061161502E36"
commented="yes"><enum>(i)</enum><header>Voluntary risk evaluations</header>
<paragraph id="HAE6E7388E11E41B1A8B60BE240ED4D7B"
commented="yes"><enum>(1)</enum><header>In general</header><text>A manufacturer who is
required to submit a notice under subsection (a)(1) for a chemical substance described
in subsection (a)(1)(A) may, in association with submission of such notice, also
request a risk evaluation under section 6(b) for that chemical substance in accordance
with guidance issued under paragraph (2).</text></paragraph>
<paragraph id="H9904E42BC9494C298003102D60570BEF" display-inline="no-display-inline"
commented="yes"><enum>(2)</enum><header>Guidance</header><text>Not later than 1 year
after the date of enactment of the <short-title>Frank R. Lautenberg Chemical Safety for
the 21st Century Act</short-title>, the Administrator shall issue guidance specifying
the data needed to complete a risk evaluation pursuant to paragraph (1). Such guidance
may specify different data requirements for different categories of chemical
substances. </text></paragraph></subsection><after-quoted-block>.</after-quoted-
block></quoted-block></paragraph></section>
<section id="HE884AC04CF864C1CB512FA9183C39138"><enum>6.</enum><header>Regulation of
hazardous chemical substances and mixtures</header>
<subsection id="HFB81FA7DB41440FFB88A6F3424755197"><enum>(a)</enum><header>Scope of
regulation</header><text display-inline="yes-display-inline">Section 6(a) of the Toxic
Substances Control Act (15 U.S.C. 2605(a)) is amendedâ€"</text>
<paragraph id="HBA1B20F0BB8B47E088DFC632DCCD6CF1"><enum>(1)</enum><text>by striking
<quote>finds that there is a reasonable basis to conclude</quote> and inserting

<quote>determines under subsection (b)</quote>;</text></paragraph>
<paragraph commented="no"
id="H4F123CCD53334259848E23AAC55ABB94"><enum>(2)</enum><text>by inserting <quote>or designates a chemical substance under subsection (i)(2),</quote> before <quote>the Administrator shall by rule</quote>; and</text></paragraph>
<paragraph id="H3AAF58FB3CFF48BAA8FF14F82A34C07D"><enum>(3)</enum><text>by striking <quote>to protect adequately against such risk using the least burdensome requirements</quote> and inserting <quote>so that the chemical substance or mixture no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a <inline-comment display="yes">potentially exposed or susceptible subpopulation</inline-comment></quote>.</text></paragraph></subsection>
<subsection id="HC34DCAF40D614E64A87DB19A59AED680"><enum>(b)</enum><header>Risk evaluations</header><text display-inline="yes-display-inline">Section 6(b) of the Toxic Substances Control Act (15 U.S.C. 2605(b)) is amended to read as follows:</text>
<quoted-block display-inline="no-display-inline" id="H54B5D852831B40A8AC8B85139F8606AE" style="OLC">
<subsection id="HBE891550C9A34AF1BEB5AC992F07D1EF"><enum>(b)</enum><header>Risk evaluations</header>
<paragraph id="HE740DB2D9BF041418634DC6A3842159B"><enum>(1)</enum><header>In general</header><text display-inline="yes-display-inline">The Administrator shall conduct risk evaluations pursuant to this subsection to determine whether or not a chemical substance presents or will present, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment.</text></paragraph>
<paragraph commented="no"
id="HC040F12D21D7447BA1C76633882C4B96"><enum>(2)</enum><header>Applying requirements</header><text display-inline="yes-display-inline">The Administrator shall apply requirements with respect to a chemical substance through a rule under subsection (a) only if the Administrator determines through a risk evaluation under this subsection, without consideration of costs or other non-risk factors, that the chemical substance presents or will present, in the absence of such requirements, an unreasonable risk of injury to health or the environment.</text></paragraph>
<paragraph commented="no"
id="H436894CAB1194BA29B8E196B455FA8A7"><enum>(3)</enum><header>Conducting risk evaluations</header>
<subparagraph commented="no"
id="HDD2C822D3AF7433487866F7CB9DA6B28"><enum>(A)</enum><header>Required risk evaluations</header><text><inline-comment display="yes">Subject to subparagraph (C),</inline-comment> the Administrator shall conduct and publish the results of a risk evaluation under this subsection for a chemical substance ifâ€"</text>
<clause commented="no" id="HB0DC2299E51F46B487CFD0851A0F4239"><enum>(i)</enum><text>the Administrator determines that the chemical substance may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the <inline-comment display="yes">conditions of use</inline-comment>; or</text></clause>
<clause commented="no" id="H6B0C9909B50A468C8F9AD687CC80265F"><enum>(ii)</enum><text display-inline="yes-display-inline">a manufacturer of the chemical substance requests such a risk evaluation in a form and manner prescribed by the

Administrator.</text></clause></subparagraph>
<subparagraph commented="no"
id="H9EED00C4EADC4BD38E36E94999D3C101"><enum>(B)</enum><header>TSCA Work Plan
chemicals</header><text display-inline="yes-display-inline">The Administrator may,
without making a determination under subparagraph (A)(i), conduct and publish the
results of a risk evaluation under this subsection for a chemical substance that, on
the date of enactment of the <short-title>Frank R. Lautenberg Chemical Safety for the
21st Century Act</short-title>, is listed in the TSCA Work Plan for Chemical
Assessments published by the Administrator.</text></subparagraph>
<subparagraph id="HF37BD232BBEF437F913B9D88B6D385E8"
commented="yes"><enum>(C)</enum><header>Limitation</header>
<clause id="HF8A0AD24F36F4808B2FC5E823C85FA7B" display-inline="no-display-inline"
commented="yes"><enum>(i)</enum><header>Percentage requirements</header><text>The
Administrator shall ensure that, of the chemical substances that undergo a risk
evaluation under this paragraph (other than chemical substances described in clause
(ii)), the percentage of chemical substances undergoing a risk evaluation under clause
(ii) of subparagraph (A) isâ€"</text>
<subclause id="H72DAACE9D1064F5EAE03AFF8E2AF88FB"
commented="yes"><enum>(I)</enum><text>not less than 25 percent, if sufficient requests
are made under such clause; and</text></subclause>
<subclause id="H55D8A8C24CFA4B29BE8ADA70DA4330F2"
commented="yes"><enum>(II)</enum><text>not more than 50
percent.</text></subclause></clause>
<clause id="H3099D4A0AABB42719531049E3F1D4B89"
commented="yes"><enum>(ii)</enum><header>Exclusion</header><text display-inline="yes-
display-inline">In calculating percentages under clause (i), the Administrator shall
not considerâ€"</text>
<subclause id="H8AEC835D80E348138581709FF2000281"
commented="yes"><enum>(I)</enum><text>chemical substances described in subparagraph
(B); or</text></subclause>
<subclause id="H713F7B59C89F4EFE9D1DE94C89B01947"
commented="yes"><enum>(II)</enum><text>chemical substances described in section
5(a)(1)(A) for which a risk evaluation is requested pursuant to section
5(i).</text></subclause></clause> </subparagraph> </paragraph>
<paragraph commented="no"
id="HEFF900BDCEBC49189D51447D9D6EAF8B"><enum>(4)</enum><header>Requirements</header><te
xt>In conducting a risk evaluation under this subsection, the Administrator
shallâ€"</text>
<subparagraph commented="no"
id="HEC06FEFE1E9A4488BBDFC4EF6905023B"><enum>(A)</enum><text display-inline="yes-
display-inline">integrate and assess information on hazards and exposures for all of
the <inline-comment display="yes">conditions of use</inline-comment> of the chemical
substance, including information that is relevant to specific risks of injury to health
or the environment and information on <inline-comment display="yes">potentially exposed
or susceptible subpopulations</inline-comment>;</text></subparagraph>
<subparagraph commented="no"
id="HCE12CC49EC0B4B8C8A3AD6404A09FB8B"><enum>(B)</enum><text display-inline="yes-
display-inline">not consider information on cost and other factors not directly related

to health or the environment;</text></subparagraph>
<subparagraph commented="no"
id="H2A280E8EEC884EC4BB910A55CFEEDBBB"><enum>(C)</enum><text>take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the <inline-comment display="yes">conditions of use</inline-comment> of the chemical substance;</text></subparagraph>
<subparagraph commented="no"
id="H07D1F01F866E45C1BF22877F1DAFFEFC"><enum>(D)</enum><text>describe the weight of the scientific evidence for identified hazard and exposure;</text></subparagraph>
<subparagraph commented="no"
id="HD9D07112B149463CAC6A089C5E35EB34"><enum>(E)</enum><text>consider whether the weight of the scientific evidence supports the identification of doses of the chemical substance below which no adverse effects can be expected to occur;
and</text></subparagraph>
<subparagraph id="H70C39AB55517431382EEA1C956A03D90"><enum>(F)</enum><text>in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), ensure that the costs to the Environmental Protection Agency, including contractor costs, of conducting the risk evaluation are paid for by the
manufacturer.</text></subparagraph></paragraph>
<paragraph
id="HEB23781001C247C88E0279B4C5B06F95"><enum>(5)</enum><header>Deadlines</header>
<subparagraph id="H7B675CCC103A4BE3AABF0AE052EC7CD3"><enum>(A)</enum><header>Risk evaluations</header><text display-inline="yes-display-inline">The Administrator shall conduct and publish a risk evaluation under this subsection for a chemical substance as soon as reasonably possible, subject to the availability of resources, but not later thanâ€"</text>
<clause commented="no" id="H3296F4DAF3E24A718E70998A21C2B1E5"><enum>(i)</enum><text display-inline="yes-display-inline">3 years after the date on which the Administratorâ€"</text>
<subclause commented="no"
id="HC90F1753EFB64A6FA14EC60D135EB59E"><enum>(I)</enum><text>makes a determination under paragraph (3)(A)(i); or</text></subclause>
<subclause commented="no"
id="HAB779631943145E0AB26E21A8FBDAE75"><enum>(II)</enum><text>begins the risk evaluation under paragraph (3)(B); or</text></subclause></clause>
<clause commented="no" id="H14337EB1324A43E8A60F2C71A8589FA7"><enum>(ii)</enum><text>in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), 2 years after the later of the date on whichâ€"</text>
<subclause commented="no"
id="HD29B012D3E7F41B9A4BAC53A4B3C8839"><enum>(I)</enum><text>the manufacturer requests the risk evaluation; or</text></subclause>
<subclause commented="no"
id="H2136AA34B3CF4395B1A9C547662B50A6"><enum>(II)</enum><text>if applicable, the risk evaluation is initiated pursuant to subparagraph
(B).</text></subclause></clause></subparagraph>
<subparagraph commented="no"
id="H8C3C1F54E82645579344A0F39A6297CF"><enum>(B)</enum><header>Deadline adjustment</header><text display-inline="yes-display-inline">If the Administrator

receives more requests for risk evaluations under paragraph (3)(A)(ii) than the Administrator has resources to conduct by the deadline under subparagraph (A)(ii)(I) (taking into account the requirement in paragraph (4)(F)), <inline-comment display="yes">or if the number of such requests exceeds the percentage allowed under paragraph (3)(C),</inline-comment> the Administrator shallâ€"</text>
<clause commented="no" id="HB3F6D0040E5043B4BA031653F18FF18A"><enum>(i)</enum>
<subclause id="HC61FA4EE01C94824848142606DC79FFF" display-inline="yes-display-inline"><enum>(I)</enum><text>initiate risk evaluations that exceed the Administratorâ€™s allotted resources as soon as resources for such risk evaluations are available; or</text></subclause>
<subclause id="H00E9CCB4129948959157B8385E00501A" indent="up1"><enum>(II)</enum><text><inline-comment display="yes">in the case of a risk evaluation that exceeds the allowed percentage, initiate such risk evaluation in accordance with paragraph (3)(C)</inline-comment>; and</text></subclause></clause>
<clause commented="no" id="H2ABE19434D3B42E4A46E25BA37B6EC00"><enum>(ii)</enum><text>not collect a fee under section 26 from the manufacturer for a risk evaluation until the Administrator initiates the risk evaluation.</text></clause></subparagraph>
<subparagraph commented="no" id="H122151CC368549D2B5F8538E4AB5527D"><enum>(C)</enum><header>Subsection <enum-in-header>(a)</enum-in-header> rules</header><text display-inline="yes-display-inline">If, based on a risk evaluation conducted under this subsection, the Administrator determines, without consideration of costs or other non-risk factors, that a chemical substance presents or will present, in the absence of a rule under subsection (a), an unreasonable risk of injury to health or the environment, the Administrator shallâ€"</text>
<clause commented="no" id="HDE821E97661944D7AB72F4A511C4CB66"><enum>(i)</enum><text>propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A); and</text></clause>
<clause commented="no" id="H68C6D01E62B448708C322E1EE094E6F7"><enum>(ii)</enum><text display-inline="yes-display-inline">publish in the Federal Register a final rule not later than 2 years after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A).</text></clause></subparagraph>
<subparagraph commented="no" id="H7C8BE0538DB145B9BE389A2CE5531C64"><enum>(D)</enum><header>Extension</header><text>If the Administrator determines that additional information is necessary to make a risk evaluation determination under this subsection, the Administrator may extend the deadline under subparagraph (A) accordingly, except that the deadline may not be extended to a date that is later thanâ€"</text>
<clause commented="no" id="HD9C6D19E9DDB49F8A34359AB69D9E8C7"><enum>(i)</enum><text>90 days after receipt of such additional information; or</text></clause>
<clause commented="no" id="HD15DD65D195643D78E6876123F395F80"><enum>(ii)</enum><text>2 years after the deadline being extended under this subparagraph.</text></clause></subparagraph></paragraph>
<paragraph id="H237095B0AE8D4AF5B784BE1D96BCEF64"><enum>(6)</enum><header>Determinations of no

unreasonable risk</header>
<subparagraph commented="no"
id="H36B1BBE969C14523A0EE1545284A56A0"><enum>(A)</enum><header>Notice and
comment</header><text display-inline="yes-display-inline">Not later than 30 days before
publishing a final determination under this subsection that a chemical substance does
not and will not present an unreasonable risk of injury to health or the environment,
the Administrator shall make a preliminary determination to such effect and provide
public notice of, and an opportunity for comment regarding, such preliminary
determination.</text></subparagraph>
<subparagraph id="H27A62EA0F42B42CF935B89EF22DFE521"
commented="no"><enum>(B)</enum><header><inline-comment display="yes">Potentially
exposed or susceptible subpopulations</inline-comment></header><text display-
inline="yes-display-inline">The Administrator shall not make a determination under this
subsection that a chemical substance will not present an unreasonable risk of injury to
health or the environment if the Administrator determines that the chemical substance,
under the <inline-comment display="yes">conditions of use</inline-comment>, presents or
will present an unreasonable risk of injury to one or more <inline-comment
display="yes">potentially exposed or susceptible subpopulations</inline-
comment>.</text></subparagraph>
<subparagraph id="H35E1068463864918ABE6AC106886531D"><enum>(C)</enum><header>Final
action</header><text>A final determination under this subsection that a chemical
substance will not present an unreasonable risk of injury to health or the environment
shall be considered a final agency action.</text></subparagraph></paragraph>
<paragraph commented="no"
id="H7E4E87D3C5944F2883DA12A5644F0D0F"><enum>(7)</enum><header>Minimum
number</header><text display-inline="yes-display-inline">Subject to the availability of
appropriations, the Administrator shall initiate 10 or more risk evaluations under
paragraphs (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the
date of enactment of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st
Century Act</short-title>.</text></paragraph> </subsection><after-quoted-
block>.</after-quoted-block></quoted-block></subsection>
<subsection id="H0F5928EB29BC49858A9B2279DED9AF1E"><enum>(c)</enum><header>Promulgation
of subsection <enum-in-header>(a) </enum-in-header>rules</header><text display-
inline="yes-display-inline">Section 6(c) of the Toxic Substances Control Act (15 U.S.C.
2605(c)) is amendedâ€"</text>
<paragraph id="HC71F47D889FC4FA982C15C68F15C179F"><enum>(1)</enum><text>by amending
paragraph (1) to read as follows:</text>
<quoted-block display-inline="no-display-inline" id="HB031A1A411614398B7EC7A024DF2C446"
style="OLC">
<paragraph id="HCFC55A6214DB40748A0A3C8E2DCCC70F"><enum>(1)</enum><header>Requirements
for rule</header><text display-inline="yes-display-inline">In promulgating any rule
under subsection (a) with respect to a chemical substance or mixture, the Administrator
shallâ€"</text>
<subparagraph id="HC279065FAAFB4068AEAB2BA1E2674C24"><enum>(A)</enum><text>consider and
publish a statement with respect toâ€"</text>
<clause id="HB88ED8CBA5454586BD42DF439F5B9CCD"><enum>(i)</enum><text display-
inline="yes-display-inline">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;</text></clause>
<clause id="HE663E59BB8D942708CBB86C122181DB0"><enum>(ii)</enum><text display-inline="yes-display-inline">the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to the chemical substance or mixture;</text></clause>
<clause id="H77D2F57DD89C474EABEB9D59149A7A49"><enum>(iii)</enum><text display-inline="yes-display-inline">the benefits of the chemical substance or mixture for various uses; and</text></clause>
<clause id="H0F4ECCE075CA4BB286D0A4D10DDC0D39"><enum>(iv)</enum><text>the reasonably ascertainable economic consequences of the rule, including consideration of the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;</text></clause></subparagraph>
<subparagraph commented="no" id="H1624701A61584945895DAF741510621E"><enum>(B)</enum><text display-inline="yes-display-inline">impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risk;</text></subparagraph>
<subparagraph id="H1553476EDD14459FBCC8CBFF5CC54428"><enum>(C)</enum><text display-inline="yes-display-inline">based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, determine whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;</text></subparagraph>
<subparagraph commented="no" id="H94E63726205F4F0AB096EFBE2B2A3C8D"><enum>(D)</enum><text display-inline="yes-display-inline">exempt replacement parts designed prior to the date of publication in the Federal Register of the rule unless the Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to identified <inline-comment display="yes">potentially exposed or susceptible subpopulations</inline-comment>; and</text></subparagraph>
<subparagraph commented="no" id="HA5F4B66F9B96450FA174B2C5F78D5E37"><enum>(E)</enum><text display-inline="yes-display-inline">in selecting among prohibitions and other restrictions to address an identified risk, apply prohibitions or other restrictions to articles on the basis of a chemical substance or mixture contained in the article only to the extent necessary to protect against the identified risk.</text></subparagraph></paragraph><after-quoted-block>;</after-quoted-block></quoted-block></paragraph>
<paragraph id="H7CC60D3D21AE49A690E622CE018CFA1E"><enum>(2)</enum><text>in paragraph (2)â€"</text>
<subparagraph id="H0E53F10EC49143F993515EC2A1734C82"><enum>(A)</enum><text>by inserting <quote><header-in-text level="paragraph" style="OLC">Procedures.</header-in-text>â€"</quote> before <quote>When prescribing a rule</quote>;</text></subparagraph>
<subparagraph id="H885FC2CF399E4E1DA653D87027B6C2F0"><enum>(B)</enum><text>by striking <quote>provide an opportunity for an informal hearing in accordance with paragraph (3);

(D)</quote>;</text></subparagraph>
<subparagraph id="HAF2E429FB9FB470FB5E4D645719D0495"><enum>(C)</enum><text>by striking <quote>, and (E)</quote> and inserting <quote>; and (D)</quote>; and</text></subparagraph>
<subparagraph commented="no" id="H2BE473B70E0748529FF4634003500338"><enum>(D)</enum><text>by moving such paragraph 2 ems to the right;</text></subparagraph></paragraph>
<paragraph commented="no" id="H88DBC72FF56448E3A5576B87660F1611"><enum>(3)</enum><text>by striking paragraphs (3) and (4) and redesignating paragraph (5) as paragraph (3); and</text></paragraph>
<paragraph id="H118EFA59589B48488125FC1B8057C3FB"><enum>(4)</enum><text>in paragraph (3) (as so redesignated)â€"</text>
<subparagraph commented="no" id="H7F8B684973D54528822ABA5F182F2247"><enum>(A)</enum><text>by striking <quote>Paragraphs (1), (2), (3), and (4)</quote> and inserting <quote><header-in-text level="paragraph" style="OLC">Application.â€"</header-in-text>Paragraphs (1) and (2)</quote>; and</text></subparagraph>
<subparagraph id="HC842299F4BEC45F88FF95C7C62C5D94D"><enum>(B)</enum><text display-inline="yes-display-inline">by moving such paragraph 2 ems to the right.</text></subparagraph></paragraph></subsection>
<subsection id="HFC13B70E51D8447A8C651ADA1AB153EF"><enum>(d)</enum><header>Effective date</header><text display-inline="yes-display-inline">Section 6(d)(2)(B) of the Toxic Substances Control Act (15 U.S.C. 2605(d)(2)(B)) is amended by adding at the end the following: <quote>Any rule promulgated under subsection (a) shall provide for a reasonable transition period.</quote>.</text></subsection>
<subsection commented="no" id="HE7E57D3D59C74E5F89E474847EB8BAB6"><enum>(e)</enum><header>Non-Risk factors; critical use exemptions; PBT chemicals</header><text display-inline="yes-display-inline">Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended by adding at the end the following:</text>
<quoted-block display-inline="no-display-inline" id="HCC0D5795F59C4FEBB2263B92A6B235BD" style="OLC">
<subsection commented="no" id="H7DAB4D803D6D4139B40DBF841427C142"><enum>(g)</enum><header>Non-Risk factors</header><text display-inline="yes-display-inline">The Administrator shall not consider costs or other non-risk factors when deciding whether to initiate a rulemaking under subsection (a).</text></subsection>
<subsection commented="no" id="H3D2757649DE24B41BE984D7F15641E72"><enum>(h)</enum><header>Critical use exemptions</header>
<paragraph commented="no" id="HD7F6E0A210724AA68F2C4ADCC8090045"><enum>(1)</enum><header>Criteria for exemption</header><text display-inline="yes-display-inline">The Administrator may grant an exemption from a requirement of a subsection (a) rule for a specific use of a chemical substance or mixture, ifâ€"</text>
<subparagraph commented="no" id="H694290A699EA406A9E969E9641E84E06"><enum>(A)</enum><text>the requirement is not cost-effective with respect to the specific use, as determined by the Administrator

pursuant to subsection (c)(1)(B); and</text></subparagraph>
<subparagraph commented="no"
id="HA446BBB9480946029853E2F963FBBD8B"><enum>(B)</enum><text>the Administrator finds
thatâ€"</text>
<clause commented="no" id="H80289882EA3C4C558F925FB56123FE86"><enum>(i)</enum><text>the
specific use is a critical or essential use; or</text></clause>
<clause commented="no" id="HBD50942B3CF249E7AE50DC5D276FDB04"><enum>(ii)</enum><text
display-inline="yes-display-inline">the requirement, as applied with respect to the
specific use, would significantly disrupt the national economy, national security, or
critical infrastructure.</text></clause></subparagraph></paragraph>
<paragraph commented="no"
id="H896A3FAD60204DB5A0306CF9DD50C9E5"><enum>(2)</enum><header>Procedure</header><text
display-inline="yes-display-inline">An exemption granted under paragraph (1) shall
beâ€"</text>
<subparagraph commented="no"
id="HFAFB0DDBA0B74698B5AF88576F137959"><enum>(A)</enum><text>supported by clear and
convincing evidence;</text></subparagraph>
<subparagraph commented="no"
id="H2460F14A8F104BE9BD6AA29FB223FA7B"><enum>(B)</enum><text>preceded by public notice
of the proposed exemption and an opportunity for comment; and</text></subparagraph>
<subparagraph commented="no"
id="HC0337799874A4CBBB3B07BC4E0B9FACB"><enum>(C)</enum><text>followed by notice of the
granted exemptionâ€"</text>
<clause commented="no" id="H56E4737E410E4257AED45B422180630B"><enum>(i)</enum><text>to
the public, by the Administrator; and</text></clause>
<clause commented="no" id="HE1364DE1CCAC4330A2A8FC75B5A452C9"><enum>(ii)</enum><text
display-inline="yes-display-inline">to known commercial purchasers of the chemical
substance or mixture with respect to which the exemption applies, by the manufacturers
and processors of such chemical substance or
mixture.</text></clause></subparagraph></paragraph>
<paragraph commented="no"
id="HDD4C34AAD351438DB1DE488301993226"><enum>(3)</enum><header>Period of
exemption</header><text display-inline="yes-display-inline">An exemption granted under
paragraph (1) shall expire after a period not to exceed 5 years, but may be renewed for
one or more additional 5-year periods if the Administrator finds that the requirements
of paragraph (1) continue to be met.</text></paragraph>
<paragraph commented="no"
id="H02E7CE52FBE045209378255D7E28CB68"><enum>(4)</enum><header>Conditions</header><text
display-inline="yes-display-inline">The Administrator shall impose conditions on any
use for which an exemption is granted under paragraph (1) to reduce risk from the
chemical substance or mixture to the greatest extent
feasible.</text></paragraph></subsection>
<subsection id="H69D3E7D808254B3AB0718AFF6214F592"><enum>(i)</enum><header>Chemicals
that are persistent, bioaccumulative, and toxic</header>
<paragraph
id="H347CD17C59C34BD29E187C099B2538D3"><enum>(1)</enum><header>Identification</header><
text display-inline="yes-display-inline">Not later than 9 months after the date of
enactment of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century

Act</short-title>, the Administrator shall publish a list of those chemical substances that the Administrator has a reasonable basis to conclude are persistent, bioaccumulative, and toxic, not including any chemical substance that is a metal, a metal compound, or subject to subsection (e).</text></paragraph>
<paragraph commented="no" id="H407CDB8139C6402A9B1CDF7E41307065"><enum>(2)</enum><header>Confirmation of concern</header><text display-inline="yes-display-inline">Not later than 2 years after the date of enactment of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>, the Administrator shall designate as a PBT chemical of concern each chemical substance on the list published under paragraph (1)â€"</text>
<subparagraph commented="no" id="HE042689106704E359C02264DB3C93280"><enum>(A)</enum><text display-inline="yes-display-inline">that, with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals: Methods Document published by the Administrator in February 2012; and</text></subparagraph>
<subparagraph commented="no" id="H93030FC5696B4244AF7D45350F162B00"><enum>(B)</enum><text display-inline="yes-display-inline">exposure to which is likely to the general population or to a <inline-comment display="yes">potentially exposed or susceptible subpopulation</inline-comment> identified by the Administrator.</text></subparagraph></paragraph>
<paragraph commented="no" id="H35C83E03EC514E27B03CC05D9B65D2D1"><enum>(3)</enum><header>Expedited action</header><text display-inline="yes-display-inline">Notwithstanding subsection (b)(2), subject to the availability of appropriations, not later than 2 years after designating a chemical substance under paragraph (2), the Administrator shall promulgate a rule under subsection (a) with respect to the chemical substance to reduce likely exposure to the extent practicable.</text></paragraph>
<paragraph commented="no" id="H94572F82E1D94F9EAF61AA752355AB04"><enum>(4)</enum><header>Relationship to subsection <enum-in-header>(b)</enum-in-header></header><text display-inline="yes-display-inline">If, at any time prior to the date that is 90 days after the date on which the Administrator publishes the list under paragraph (1), the Administrator makes a finding under subsection (b)(3)(A)(i), or a manufacturer requests a risk evaluation under subsection (b)(3)(A)(ii), with respect to a chemical substance, such chemical substance shall not be subject to this subsection.</text></paragraph></subsection>
<after-quoted-block>.</after-quoted-block></quoted-block></subsection></section>
<section id="H3E4C682716D044CC9D89C55244E6AA4B" commented="yes"><enum>7.</enum><header>Imminent hazards</header><text display-inline="no-display-inline">Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amendedâ€"</text>
<paragraph id="H9EE52A926FC34AADA0A77C66135346AA" commented="yes"><enum>(1)</enum><text>in subsection (b)(1), by inserting <quote>(as identified by the Administrator without consideration of costs or other non-risk factors)</quote> after <quote>from the unreasonable risk</quote>; and</text></paragraph>
<paragraph id="HD13F99E163354B1091CB94A5048EF80C" commented="yes"><enum>(2)</enum><text>in subsection (f), by inserting <quote>, without

consideration of costs or other non-risk factors</quote> after <quote>widespread injury to health or the environment</quote>.</text> </paragraph></section>
<section id="H98F7F4BB61EF4F7C8AB3F4B1B1EEDB09" commented="yes"><enum>8.</enum><header>Reporting and retention of information</header><text display-inline="no-display-inline">Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amendedâ€"</text>
<paragraph id="H4BDF8C603BF540568B37CBCD1AB345F1" commented="yes"><enum>(1)</enum><text>in subsection (a)â€"</text>
<subparagraph id="H205195DF2E424A248615CFFFD9DF1EDD" commented="yes"><enum>(A)</enum><text>in paragraph (2), by striking the matter that follows subparagraph (G);</text></subparagraph>
<subparagraph id="HF9A02E2002454EA09929F25FF7053306" commented="yes"><enum>(B)</enum><text>in paragraph (3), by adding at the end the following:</text>
<quoted-block style="OLC" id="H99BC6F0694BC4AE6BED7B316BE824DD7" display-inline="no-display-inline">
<subparagraph id="HE153BB90F0904B8DAB8287ED6BEDF135" indent="up2" commented="yes"><enum>(C)</enum><text display-inline="yes-display-inline">Not later than 180 days after the date of enactment of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>, and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shallâ€"</text>
<clause id="H4DD1C31C6CC843C38CF8C5C1B18417AD" commented="yes"><enum>(i)</enum><text>review the adequacy of the standards prescribed under subparagraph (B); and</text></clause>
<clause id="H4BEFED506FDD49F9B4BAE345EE14E5EE" commented="yes"><enum>(ii)</enum><text>after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted.</text> </clause></subparagraph><after-quoted-block>; and</after-quoted-block></quoted-block></subparagraph>
<subparagraph id="H3D670F79E65E459182BD48A25402DA66" commented="yes"><enum>(C)</enum><text>by adding at the end the following:</text>
<quoted-block style="OLC" id="H489763FDD889423F92EF330CF2A7756B" display-inline="no-display-inline">
<paragraph id="H57D076946DCD4EE5B7D1298A73D8A506" commented="yes"><enum>(4)</enum><header>Administration</header><text display-inline="yes-display-inline">In carrying out this section, the Administrator shall, to the extent feasibleâ€"</text>
<subparagraph id="HBD2ADB9A63B544C8A587FF0B05AD3D70" commented="yes"><enum>(A)</enum><text>not require reporting which is unnecessary or duplicative; </text></subparagraph>
<subparagraph id="H166A188988D54AAD931464DED75DDE31" commented="yes"><enum>(B)</enum><text>minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and</text></subparagraph>
<subparagraph id="H9B3FCD571B4A42AC8C8FC4A4321D1273" commented="yes"><enum>(C)</enum><text>apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this

title.</text></subparagraph></paragraph><after-quoted-block>; and</after-quoted-block></quoted-block></subparagraph></paragraph>
<paragraph id="H48004871CD294BB0B0B7DC41BBCD6E71" commented="yes"><enum>(2)</enum><text>in subsection (b), by adding at the end the following:</text>
<quoted-block style="OLC" id="HD1EBA4B70DE34D6AA4627FF959ED59A0" display-inline="no-display-inline">
<paragraph id="H924348D1A4644479937F3611C7E15963" display-inline="no-display-inline" commented="yes"><enum>(3)</enum><header>Nomenclature</header>
<subparagraph id="HB3E39893C27D4FDF8AF118A10F6563D7" commented="yes"><enum>(A)</enum><header>In general</header><text>In carrying out paragraph (1), the Administrator shallâ€"</text>
<clause id="H01202C93575A4A3B9C001ABAAEC7B0B2" commented="yes"><enum>(i)</enum><text>maintain the use of Class 2 nomenclature in use on the date of enactment of the <short-title>Frank R. Lautenberg Chemical Safety for the 21st Century Act</short-title>; and</text></clause>
<clause id="H77E4F28204BC4106826D028D1633788A" commented="yes"><enum>(ii)</enum><text>maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled <quote>Candidate List of Chemical Substances</quote>, and further described in appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPAâ€"560/7â€"85â€"002a).</text></clause> </subparagraph>
<subparagraph id="H7F1981A334AA4C91B8EFE71F8B4E3AFF" commented="yes"><enum>(B)</enum><header>Multiple CAS numbers</header><text>For any chemical substance appearing multiple times<inline-comment display="yes">, as determined by the Administrator,</inline-comment> on the list published under paragraph (1) under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.</text></subparagraph> </paragraph><after-quoted-block>.</after-quoted-block></quoted-block></paragraph> </section>
<section commented="no" id="H1F89180CD13542F386CEB45C6C0E7C3F"><enum>9.</enum><header>Relationship to other Federal laws</header><text display-inline="no-display-inline">Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amendedâ€"</text>
<paragraph id="HA7525AB9CAF64C6BB76C0DD245B550A6" commented="yes"><enum>(1)</enum><text>in subsection (a)â€"</text>
<subparagraph id="HCE59E69823894B10A8EF385D54841EC6" commented="yes"><enum>(A)</enum><text>in paragraph (1)â€"</text>
<clause id="HC07BBBE86DE7476EBFDB1D55746EBAEA" commented="yes"><enum>(i)</enum><text>by inserting <quote>, without consideration of costs or other non-risk factors,</quote> after <quote>basis to conclude</quote>; and</text></clause>
<clause id="HB0329669B1914D83B57674F3CEAEEF3E" commented="yes"><enum>(ii)</enum><text>by inserting <quote>under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator,</quote> after <quote>health or the environment</quote>;</text></clause></subparagraph>
<subparagraph id="H376B84FA77FA4BAF82D7EE206CCCC5A3"

commented="yes"><enum>(B)</enum><text>in paragraph (2)â€"</text>
<clause id="HEBBF67BD53EC412DA9587EC73C30C162" commented="yes"><enum>(i)</enum><text>in subparagraph (A), by inserting <quote>, within the time period specified by the Administrator in the report,</quote> after <quote>issues an order</quote>; and</text></clause>
<clause id="H361B3D97B1004F89A7536BA043531F51" commented="yes"><enum>(ii)</enum><text>in subparagraph (B), by inserting <quote>responds within the time period specified by the Administrator in the report and</quote> before <quote>initiates, within 90</quote>;</text></clause> </subparagraph>

<subparagraph id="HCC76973E83EB4328A1010A152D359768" commented="yes"><enum>(C)</enum><text>by redesignating paragraph (3) as paragraph (6); and</text></subparagraph>
<subparagraph id="HF5E87BC517BE4D1EA78B12ED76DDEAE3" commented="yes"><enum>(D)</enum><text>by inserting after paragraph (2) the following:</text>
<quoted-block style="OLC" id="H5C98D304479641778DC17D7C09FF2B4A" display-inline="no-display-inline">
<paragraph id="H15DDA0936FB14C37BBCB51550ED5DFA5" indent="up1" commented="yes"><enum>(3)</enum><text>The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does notâ€"</text>
<subparagraph id="HF239DCFE2DB04D2295A33C5CDA6EF89A" commented="yes"><enum>(A)</enum><text>issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or</text></subparagraph>
<subparagraph id="H2D7DCBCAE9E3491ABFF716C9D2EEF8C9" commented="yes"><enum>(B)</enum>
<clause id="H8CCBF1CD56774C059C717A5C98E2FCB6" display-inline="yes-display-inline" commented="yes"><enum>(i)</enum><text>respond under paragraph (1) within the time frame specified by the Administrator in the report; and</text></clause>
<clause id="H3364910CB8734726BF09650FABD2B15F" indent="up1" commented="yes"><enum>(ii)</enum><text>initiate action within 90 days of publication in the Federal Register of the response described in clause (i).</text></clause></subparagraph></paragraph>
<paragraph id="HB358003D2D7D413AB6827912401632CC" indent="up1" commented="yes"><enum>(4)</enum><text>If an agency to which a report is submitted under paragraph (1) does not take the actions described in subparagraph (A) or (B) of paragraph (3), the Administrator shallâ€"</text>
<subparagraph id="H3DA960EA4C3643A29D11A05194866735" commented="yes"><enum>(A)</enum><text>if a risk evaluation for a chemical substance included in the report has not been completed under section 6, complete the risk evaluation;</text></subparagraph>
<subparagraph id="HBC91A7BF52174E668FE220978ADE5530" commented="yes"><enum>(B)</enum><text>if the Administrator has made a determination of unreasonable risk in accordance with section 6(b)(1), initiate action under section 6(a) with respect to the risk; or </text></subparagraph>
<subparagraph id="H9A4479259D584116A2DD73756BFC33E3"

commented="yes"><enum>(C)</enum><text>take any action authorized or required under section 7, as appropriate.</text></subparagraph></paragraph>
<paragraph id="H860387C77CAB48EDB98E9DC89660EE24" indent="up1" commented="yes"><enum>(5)</enum><text>This subsection shall not relieve the Administrator of any obligation to complete a risk evaluation or take any required action under section 6(a) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).</text></paragraph><after-quoted-block>;</after-quoted-block></quoted-block></subparagraph></paragraph>
<paragraph id="HDC9B2AAF47504912B8E1AB36A45A850E"><enum>(2)</enum><text>in subsection (b)â€"</text>
<subparagraph id="HA24C0C3907E648D4B623DEA2F366D998" commented="no"><enum>(A)</enum><text>by striking <quote>The Administrator shall coordinate</quote> and inserting <quote>(1) The Administrator shall coordinate</quote>; and</text></subparagraph>
<subparagraph id="HB6C0FD3CF7DE4D9982C28C731CE6CD8B" commented="no"><enum>(B)</enum><text>by adding at the end the following:</text>
<quoted-block display-inline="no-display-inline" id="H7A331A6A0103410BB71122AC2155519A" style="OLC">
<paragraph commented="no" id="HA95F1DDD5E7B47BDB6D14E4561371E15" indent="up1"><enum>(2)</enum><text display-inline="yes-display-inline">In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, the relative risks and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk.</text></paragraph><after-quoted-block>; and</after-quoted-block></quoted-block></subparagraph></paragraph>
<paragraph id="HE81FC91AF6234028ADC72AAA87C82B17" commented="yes"><enum>(3)</enum><text>by adding at the end the following: </text>
<quoted-block style="OLC" id="H4C159927C6724BDDA9F5BFA20F95C34D" display-inline="no-display-inline">
<subsection id="HB3DFED8D70A1471FA2F8FDC4C2A20CC1" commented="yes"><enum>(e)</enum><header>Exposure information</header><text display-inline="yes-display-inline">In addition to the requirements of subsection (a), if the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.</text></subsection><after-quoted-block>.</after-quoted-block></quoted-block></paragraph></section>
<section id="H731513B0ED7E48268B7CD6D87B8076D0"><enum>10.</enum><header>Disclosure of data</header><text display-inline="no-display-inline">Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amendedâ€"</text>
<paragraph id="H8C0AE9B2DAF342AB986DA4285650D598"><enum>(1)</enum><text>in subsection (a)â€"</text>