

Senator Carper's QFRs to EPA nominees

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Michael Dourson, nominee to be Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (OCSPP) of the U.S. Environmental Protection Agency

1. For decades, both Republican and Democratic administrations alike have had written policies limiting White House contacts with agencies that have investigatory and enforcement responsibilities. These policies have recognized that even a simple phone call from the White House to an agency inquiring about or flagging a specific matter can upset the evenhanded application of the law. I recently learned that Devon Energy, a strong political supporter of Administrator Pruitt's, informed the EPA just 5 days after Mr. Pruitt was sworn in as Administrator that it was no longer willing to install air pollution technology or pay a high penalty to EPA for its illegal air emissions of cancer-causing benzene and other chemicals. We also know that Trump family casinos, hotels and golf courses have been the subject of EPA enforcement actions for violations of the Clean Air Act and Clean Water Act.
 - a. Do you agree that it is essential that in making decisions, EPA's OCSPP must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?
 - b. Will you commit to restricting communications between OCSPP and the White House staff regarding specific matters under the authority of OCSPP?
 - c. Will you commit to ensuring the staff of OCSPP is familiar with those restrictions?
 - d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OCSPP staff, including you, occur?
2. Recently, EPA conducted "anti-leaking" training for its employees¹. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.

5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against

¹ https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089_story.html?utm_term=.e2bfc5e54d95

whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of. ... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences- (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation... " In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

- a. If you are confirmed, will you commit to protect the rights of all career employees in OCSPP to make lawful disclosures, including their right to speak with Congress?
 - b. Will you commit to communicate employees' whistleblower rights via email to all OCSPP employees within a week of being sworn in?
3. Recently, EPA decided not to revoke all the remaining tolerances for chlorpyrifos as had been proposed by the Obama Administration.
- a. Do you believe that EPA should ever use epidemiological studies as a basis for the agency to conclude that it cannot make a determination that exposure to a substance can occur with a "reasonable certainty of no harm" under the Federal Food, Drug and Cosmetic Act (FFDCA)? If so, when? If not, please fully describe the reasons why not.
 - b. One of the complicating factors surrounding the proposed Obama Administration's ban on the remaining uses of chlorpyrifos was the assertion made by some that there is uncertainty associated with the level of chlorpyrifos that causes an adverse health effect and debate about which biological endpoint should be used to define what an "adverse" health effect should be. If EPA cannot make a "reasonable certainty of no harm" finding under the FFDCA for a substance, how would you suggest EPA resolve such uncertainties in order to comply with both FFDCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)?
4. EPA currently uses a 10-fold safety factor to account for the added risks mutagenic carcinogenic chemicals pose to vulnerable sub-populations. Will you commit to continue this approach? If not, please provide a specific explanation for when, why and how you would deviate from this approach.

5. EPA often uses a safety adjustment factor when it writes rules that protect people from exposure to chemicals. That factor accounts for the interspecies variability between the effect of the chemical on an animal that is measured in laboratory tests and the predicted effect of the chemical on people.
 - a. If you are confirmed, will you commit to continue to support this approach?
 - b. If not, how would you propose to account for interspecies differences between a chemical's measured effect on an animal and its predicted effect on a human?

6. One argument that is often made to justify less protective chemical safety standards is to set an adverse effect end-point that is 'more adverse' than other end-points. For example, it would take higher exposure levels to a chemical for the chemical to actually cause cancer than it would for a biochemical marker that is a known precursor to cancer to be observed. Using cancer as the end-point in this scenario would allow for a less stringent safety standard for that chemical to be set.
 - a. Generally speaking, if there is an end-point that is a precursor or otherwise predictive of a serious illness or risk of acute toxicity, is there ever a scenario in which EPA should regulate to protect against the precursor end-point rather than the more serious one? If so, please describe such scenarios. If not, please fully explain why not.
 - b. Additionally, if it is your view that safety standards should not seek to prevent effects that are known to be predictive of more serious ones, please explain your views on whether the FDA should continue to approve cholesterol-lowering medications or whether it should simply focus its efforts on ways to better treat heart attacks. If you believe that preventive medicine should continue to be developed and approved, why are your views different for chemical safety standards?

7. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:
 - a) When EPA first submitted the proposed repeal rule to OMB, the draft stated that the agency would undertake a new cost-benefit analysis as part of the second step of its process.
 - b) OMB interpreted EPA's first proposal to mean that the rule's repeal would not avoid any costs to industry or have any economic impact at all. EPA's political staff then directed the career staff to undertake a new economic analysis. In response to this direction from OMB, EPA career staff reportedly changed the table included in the 2015 rule to i) reflect 2016 dollars instead of 2014 dollars, ii) convert "annual costs incurred" under the Clean Water Rule to "annual costs avoided" due to its repeal and iii) convert "annual benefits gained" under the Clean Water Rule to "annual benefits forgone" due to its repeal. This new table was sent to OMB on June 8, 2017.

- c) OMB correctly concluded from EPA's June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this 'problem' by simply deleting the majority of the benefits of the rule from the table and re-submitting it to OMB, which they did².

The direction that was reportedly provided to the EPA career staff to make the various revisions to what was submitted to OMB was verbal, not written. If you are confirmed, do you commit to ensure that career staff in OCSPP will receive appropriately documented, rather than verbal, direction from political officials before they take action? If not, why not?

8. Thank you for your response to my pre-hearing questions. I have some follow-up questions.
- a. In the spreadsheet you provided that listed sponsors, project description and project type information, there are several entities that seem incorrect. For each of these, please explain the apparent discrepancy, and if any of these entries are errors, please submit a corrected version of the spreadsheet in excel format:
 - i. Several entries that list the American Chemistry Council as its sponsor as "collaborative" rather than "private sector;"
 - ii. Listing an entry in which the California Chamber of Commerce is the sponsor as "non-profit" rather than "private sector;"
 - iii. Listing an entry in which the CEFIC is the sponsor as a "collaboration" rather than "private sector;"
 - iv. Listing an entry in which Concurrent Technologies Corporation is the sponsor as "government" rather than "private sector;"
 - v. Listing an entry in which EPRI is the sponsor as a "collaboration" rather than "private sector;"
 - vi. Listing an entry in which ICL-IP is the sponsor as a "collaboration" rather than "private sector;"
 - vii. Listing an entry in which ILSI-NA is the sponsor as "non-profit" rather than "private sector;"
 - viii. Listing an entry in which Lockheed Martin Corporation is the sponsor as "government" rather than "private sector;"
 - ix. Listing an entry in which McKenna, Long and Aldridge is the sponsor as "government" rather than "private sector;"
 - x. Listing an entry in which Silicones Environment Safety & Health Council is the sponsor as "non-profit" rather than "private sector;"
 - xi. Listing an entry in which Summit Technology is the sponsor as "government" rather than "private sector;"
 - xii. Listing an entry in which ToxServices is the sponsor as "government" rather than "private sector;"
 - xiii. Listing an entry in which the Vinyl Acetate Council is the sponsor as a "collaboration" rather than "private sector"; and

² https://www.epa.gov/sites/production/files/2017-06/documents/economic_analysis_proposed_step1_rule.pdf
See Table 1

- xiv. Listing an entry in which Waste Management is the sponsor as a “collaboration” rather than “private sector”.
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- b. Please identify the “multiple sponsors” listed for each entry on this spreadsheet and indicate the percentage of funding received from each sponsor.
 - c. Please describe the criteria you used to designate an entity as a “non-profit,” how you defined “sponsor” and how you defined “project “type”.
 - d. In the “Summary of billed hours” table, there is no designation for government-sponsored work for TERA for 1995-2015. Could you provide a new table that includes this information?
 - e. In the spreadsheet that includes this chart, you seem to have calculated the percentage of work done by sector by counting the number of projects you classified as falling under each sector and dividing by the total number of projects listed. This does not reflect relative funding for projects in each sector, however. Please provide a detailed breakdown of the percentage of total funding received for projects included in each sector, using the corrected version of the table requested in c.
 - f. In the chart, the work on the Kids+Chemical Safety website is described as: “Develop a kids risk webpage, in part.” The project is listed as a collaborative twice, once with the American Chemistry Council (ACC) as the sponsor and once with the Combined Federal Campaign (CFC) as the sponsor. Did the CFC hire or pay TERA to develop the website? If not, what was their specific sponsorship role? If so, how long after ACC hired TERA to develop the website did CFC contribute? What percentage of the costs of developing the website were paid for by the CFC? Did the CFC itself fund the website, or was it donations through a CFC listing? If so, were these donations from the federal government?
9. The following questions refer to the chart I used during the hearing (attached). For each chemical listed on this chart, please provide a complete description of:
- a. The year(s) in which you, TERA or other TERA employees were funded to work on the chemical.
 - b. The name of the entity or entities that provided such funding, and the funding amount. If the activity was a collaboration, please list all collaborators as well as the amount of funding each collaborator contributed to the effort.
 - c. The type of activity (risk assessment, peer review, research paper, presentation, litigation support, etc) that was funded and the deliverables provided to the sponsor.
10. Do you believe that there is a safe level of exposure to perchlorate for i) a pregnant woman, and ii) a toddler, with serious iodine deficiencies, and if so, what is it? Do you believe that there is a safe level of exposure to perchlorate for i) a pregnant woman, and ii) a toddler, who gets insufficient iodine according to World Health Organization guidelines, and if so, what is it?

11. On September 21, 2017, the Consumer Product Safety Commission (CPSC) approved a petition³ that called for CPSC to write regulations requiring the removal of organohalogen flame retardants from four types of consumer products.
- a. An argument against the petition is that EPA is currently reviewing flame retardants under TSCA. Do you agree that EPA is currently undertaking a risk evaluation on only the Cyclic Aliphatic Bromide Cluster flame retardants (i.e. only one class) and that EPA is required by law to complete this risk evaluation and finishing a regulation (if needed) by November 29, 2021?
 - b. According to EPA's website⁴, "the hexabromocyclodecanes (HBCD cluster) in the cyclic aliphatic bromide cluster consists of the following chemicals: Hexabromocyclododecane; 1,2,5,6,9,10-Hexabromocyclododecane; and 1,2,5,6-Tetrabromocyclooctane. Two of these chemicals are used as flame retardants, no uses for 1,2,5,6-tetrabromocyclooctane have been identified. The primary use of the two chemicals is in expanded polystyrene foam (EPS) and extruded polystyrene foam (XPS) in the building and construction industry for thermal insulation boards and laminates for sheathing products. They are also used in plastics (additive) and textiles (back-coating). In the United States, the HBCD cluster was historically used as a flame retardant in the back coating of textiles; however, research and information gathering indicates that the HBCD cluster is no longer used in consumer textile applications outside of the automotive industry." Do you agree that this type of flame retardant is generally not used in consumer products such as children's products, furniture, mattresses and the casings surrounding electronics? If not, why not?
12. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by *any* Member of the Environment and Public Works Committee? If not, why not?
13. Before the end of the last Administration, EPA proposed to ban some uses of three dangerous chemicals using its new Toxic Substances Control Act authority. TCE is a probable carcinogen that is found in drinking water all across the country. Accidental exposures to MC, which is used in paint and furniture strippers, has killed at least 56 people since 1980. And a second chemical used in paint strippers, NMP, is dangerous for pregnant women to be exposed to. Some have suggested that these bans should not be finalized, saying instead that EPA should study the uses of these chemicals for three more years before proposing a rule. Do you disagree that more exposures, more illnesses and maybe even more deaths would probably occur as a result of a three year delay in these proposed bans? If so, on what basis? If EPA has already determined that some uses of these chemicals are dangerous, how could one justify the extra time, taxpayer dollars and risk to human health that would occur by studying these same uses for three additional years instead of acting to finalize the bans now?

³ http://earthjustice.org/sites/default/files/files/FHSA-Petition%20_revised_6-30-15.pdf

⁴ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-cyclic-aliphatic-bromide-cluster-hbcd>

14. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily⁵. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?

15. Section 26 of the newly enacted TSCA states that:

“(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.— With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6.”

Page 1 of Attachment 1 is an email sent by EPA on March 17, 2016, the substance of which was shared with the bipartisan and bicameral negotiators of the Toxic Substances Control Act. It states that EPA “just discovered a technical issue that will have significant policy implications for EPA’s ongoing work under Section 6. As currently drafted, both Senate and House bills could frustrate EPA’s ability to timely manage risks that have been (or may be) identified in our current Work Plan risk assessments.” The email goes on to describe several risk assessments on chemical substances (TCE, NMP, MC and 1-BP) that had been completed or were near completion by EPA, and stated that “EPA is *not* looking at all the conditions of use for these chemicals. This approach, which might be characterized as a *partial* risk evaluation or *partial* safety determination, we see as simply not contemplated under the Senate and House bills. The section 6 structure in both bills would require EPA to assess a chemical in its entirety, based on all conditions of use – not just a subset of those uses.” EPA then went on to state that if it were to move forward with rulemakings to restrict or ban some or all of these substances (which it has subsequently proposed to do), there would be some risk that the rules would be found to be inconsistent with the new statutory requirement to assess all conditions of use. EPA said that it would “welcome an opportunity to work with you on a drafting solution to this issue.”

- a. Do you agree with EPA’s March 17, 2016 view that if it had moved forward with these partial risk evaluations and rulemakings absent explicit statutory authority to do so even though the risk evaluations had not considered all conditions of use, that EPA could have been sued for not complying with the law’s requirements? If not, please provide specific reasons why not.
- b. Pages 2 and 3 of Attachment 1 consist of April 2, 2016 Technical Assistance from EPA that was provided to the Senate on a drafting solution to address the problem identified by EPA on March 17, 2016. Do you agree that this language, which is also drafted as an amendment to Section 26, bears a close resemblance to the language that was enacted into law, and, like the enacted text, provides EPA with statutory authority to complete rulemakings on the chemical substances on which it completed risk assessments prior to

⁵ <https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView>

the enactment of the new law even though the risk assessments were not undertaken for all conditions of use? If not, please provide specific reasons why not.

16. The newly enacted TSCA, for new chemicals, states that:

“(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—(1)(A)

If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use; or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator shall issue an order, to take effect on the expiration of the applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.”

Attachment 2 consists of a portion of EPA’s Technical Assistance on an April 7, 2016 draft of Section 5 of TSCA that EPA provided to the Senate. Comment A7 provides EPA’s views on section 5(e). This comment noted a change from previous drafts, observing that the draft allowed manufacture of a new chemical to proceed even if EPA did not have enough information to determine whether it posed an unreasonable risk. This is because the draft as written allowed for manufacture to proceed if EPA *either* took steps to obtain sufficient information about the chemical substance (but before it received and evaluated that information) OR if it imposed a risk management order. EPA also suggested some edits to this draft to restore the “functionality of the prior draft,” which ensured that manufacture could not proceed unless/until the information about the chemical substance was sufficient and EPA made the necessary risk determination, or in compliance with an EPA-issued order to protect against unreasonable risk under the conditions of use while the information was being developed. Do you agree that the statute requires EPA to issue an order to protect against an unreasonable risk a new chemical substance may pose under the conditions of use, either while information EPA needs to assess the chemical substance is developed, or if EPA determines that the substance may present an

unreasonable risk under the conditions of use, or if 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? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

17. Section 5(f)(4) of TSCA states that:

“(4) TREATMENT OF NONCONFORMING USES.—Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.”

Attachment 3 is an April 9, 2016 email from EPA providing responses to questions on the April 7 draft included in Attachment 2. The email asks whether the removal of provisions 5(e)(4) and 5(f)(1)(C) in that draft would also remove EPA’s requirement to consider whether to issue a Significant New Use Rule (SNUR) when it issued orders to a submitter of a pre-manufacturing notice (PMN) (and explain its decision if it chose not to do so). EPA responded in the affirmative. Do you agree that the enacted law retained the April 7 draft’s requirement to consider whether to issue a Significant New Use Rule (SNUR) when EPA has issued an order to a submitter of a pre-manufacturing notice (PMN) (and explain its decision if it chooses not to do so)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

18. The newly enacted TSCA requires EPA, for existing chemicals that are designated a high-priority chemical substance or otherwise designated for a risk evaluation, to:

“conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.”

In the statute, ‘conditions of use’ is defined as:

“the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”

Attachment 4 is a December 12, 2016 (post-enactment) email conveying Technical Assistance from EPA that responded to several questions posed about how EPA was required to do risk evaluations for a chemical substance under the conditions of use. Do you agree with EPA's responses to these questions as well as the narrative that precedes the specific responses to questions? If not, please provide specific reasons why not, indicating in your response how your views are consistent with the statutory text excerpted above (or, as applicable, how EPA's responses are inconsistent with the statutory text excerpted above).

19. Attachment 5 is a document that includes EPA's technical assistance and observations that compared an April 12 2016 Senate draft of section 5 to an April 18, 2016 House draft.
 - a. On pages 2 and 15, EPA provides comments related to the 90-day period for review of a PMN. Do you agree that the enacted law includes text that reflects EPA's input in these comments? If not, please provide specific reasons why not, using statutory text to explain your reasoning.
 - b. On Page 14, EPA notes the deletion of the requirement not to consider costs or other non-risk factors when considering section 5(h) exemption requests. Do you agree that the enacted law retained this deletion in this subsection, but included the requirement in sections 5(a), 5(e) and 5(f)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

20. Attachment 6 consists of EPA's comments to a draft of Senate section 5 dated around April 12, 2016.
 - a. EPA's comment A22 notes the absence of the requirement not to consider costs or other non-risk factors when considering section 5(h) exemption requests. Do you agree that the enacted law does not include the requirement in this subsection, but does include the requirement in subsections 5(a), 5(e) and 5(f)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.
 - b. Do you agree that while this same EPA comment identifies one inconsistency between the above-described text that is absent from subsection 5(h) but appears throughout the rest of section 5, it does not identify another difference, namely the presence of the term "specific uses identified in the application" in subsection 5(h) versus the term "conditions of use" that appears throughout the rest of section 5? If not, why not?

21. Attachment 7 consists of EPA's comments to an April 3, 2016 Senate draft of section 5.
 - a. On page 1, EPA observes 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." Do you agree that the enacted law requires EPA to either prohibit manufacture or issue an order to mitigate against potential risk while information is being developed by a manufacturer? If not, please provide specific reasons why not, using statutory text to explain your reasoning.
 - b. On page 2, EPA responds to a question posed by Senate staff, stating "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.” Do you agree that the enacted statute requires EPA to review the conditions of use (as that term is defined in the statute) of a chemical substance when it reviews a PMN as EPA advised the Senate in this comment? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

- c. On page 9, EPA says that “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.” Do you agree that the enacted statute incorporated EPA’s proposed ‘best solution’ and did not limit orders only to the conditions of use specified in the notice? If not, please provide specific reasons why not, using statutory text to explain your reasoning.
 - d. A second EPA comment on page 9 states that “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.” Do you agree that the enacted text retains section 5(e) and also requires EPA to issue an order any time EPA either makes a may present finding or lacks sufficient information before manufacturing can commence? If not, please provide specific reasons why not, using statutory text to explain your reasoning.
 - e. On page 16, EPA responds to a question from Senate staff about whether, in the 5(h) exemptions section, it makes sense to deviate from the rest of the section’s references to ‘conditions of use’ and instead limit EPA’s exemption determination to the uses of the chemical substance identified in the exemption request. EPA responds by stating “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.” Do you agree that the enacted statute follows EPA’s advice to retain the authority for EPA to consider just the uses of a chemical substance included in an exemption request, but does not make the same limiting change anywhere else so as not to so limit its review of all conditions of use of a chemical substance subject to a PMN? If not, please provide specific reasons why not, using statutory text to explain your reasoning.
22. In our private meeting, you described your work on perchlorate as an example where the safety standard you suggested at the time (2004) was based on older science, and said that at that time, you actually recommended a level that was more protective than the one industry was recommending. Isn’t it true that in 2012, seven years after EPA recommended its drinking water reference dose for perchlorate, you wrote a paper⁶ that suggested the removal of the three-fold safety factor designed to protect pregnant women, which, if adopted, means the reference dose would be 8.6 times less protective than EPA’s?

Chart referenced in question 9

Science for Sale

Chemical & Known Harms	EPA/Agency Safe Level	Dourson "Safe" Level
1,4-Dioxane <i>(Likely carcinogen)</i>	0.35 ppb	1000x higher
1-Bromopropane <i>(Neurotoxin)</i>	0.3 – 10 ppm	2 – 67x higher
PFOA <i>(Thyroid disruption)</i>	.07 ppb	2,143x higher
TCE <i>(Carcinogen)</i>	2 µg/m ³	1.5 – 15x higher
Perchlorate <i>(Thyroid disruption)</i>	0.7 µg/kg/day	8.6x higher
Chlorpyrifos <i>(Neurotoxin)</i>	.0017 – 0.3 µg/kg/day	33–5,882x higher
Alachlor degradates <i>(Liver, kidney damage)</i>	20 – 70 ppb	80 – 280x higher
Acetochlor degradates <i>(Thyroid, reproductive disruption)</i>	100 – 300 ppb	4.7 – 14x higher
Diacetyl <i>(Severe lung damage)</i>	5 – 10 ppb	20 – 40x higher
Acrylamide <i>(Neurotoxin, likely carcinogen)</i>	.002 mg/kg/day	10 – 25x higher

William L. Wehrum, nominee to be Assistant Administrator for the Office of Air and Radiation (OAR) of the U.S. Environmental Protection Agency

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 - a. Do you agree that it is essential that in making decisions, EPA's OAR must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?
 - b. Will you commit to restricting communications between OAR and the White House staff regarding specific matters under the authority of OAR?
 - c. Will you commit to ensuring the staff of OAR is familiar with those restrictions?
 - d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OAR staff, including you, occur?

2. Recently, EPA conducted "anti-leaking" training for its employees⁷. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.

5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of. ... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences- (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency

⁷ https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089_story.html?utm_term=.e2bfc5e54d95

to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation... " In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

- a. If you are confirmed, will you commit to protect the rights of all career employees in OAR to make lawful disclosures, including their right to speak with Congress?
 - b. Will you commit to communicate employees' whistleblower rights via email to all OAR employees within a week of being sworn in?
3. In the wake of Hurricane Irma, at least 11 deaths and numerous injuries have been reported in Florida due to accidental carbon monoxide poisoning from gasoline-powered portable generators.⁸ One additional death has also been reported in North Carolina, along with other injuries throughout the Southeastern United States.⁹ Many of these deaths and injuries could have been prevented had stronger safety standards been in place for portable gasoline generators. In November 2016, the U.S. Consumer Product Safety Commission (CPSC), following years of work on the issue, voted to issue a Notice of Proposed Rulemaking (NPRM) to implement a mandatory safety standard for portable generators.¹⁰ Since then, Administrator Pruitt and Acting CPSC Chairman Buerkle have separately opined that section 213 of the Clean Air Act precludes CPSC action.
- a. Section 213 of the Clean Air Act is intended to regulate emissions from non-road engines or vehicles when the EPA determines that such emissions "are significant contributors to ozone or carbon monoxide concentrations in more than 1 area which has failed to attain the national ambient air quality standards for ozone or carbon monoxide." In your opinion, would the occasional indoor use of portable generators following a power outage be likely to be a significant contributor to ambient carbon monoxide concentrations in more than 1 area that has failed to attain the national ambient air quality standards for carbon monoxide? Why or why not?
 - b. There are currently no areas in the United States that have failed to attain the national ambient air quality standards for carbon monoxide, and this has been the case since 2010¹¹. As a matter of law, could section 213 of the Clean Air Act be used to regulate carbon monoxide emissions due to the indoor use of portable generators if there are no areas in the United States that fail to attain the national ambient air quality standards for carbon monoxide? Why or why not?

⁸ <http://www.miamiherald.com/news/weather/hurricane/article174097351.html> <http://www.sun-sentinel.com/news/weather/hurricane/sfl-carbon-monoxide-deaths-20170914-story.html>

⁹ <http://www.charlotteobserver.com/news/article173612361.html>

¹⁰ <https://www.federalregister.gov/documents/2016/11/21/2016-26962/safety-standard-for-portable-generators>

¹¹ <https://www.epa.gov/green-book/green-book-carbon-monoxide-1971-area-information>

4. Your public financial disclosure material lists, among others, several clients such as the American Petroleum Institute and others that are trade or other associations that consist of individual member companies. For each such association or organization listed on your financial disclosure form, please provide a complete list of the individual companies and other entities that comprise its members.
5. In addition to employees or representatives of the trade associations or organizations listed as your clients, have you met or otherwise communicated with employees or representatives of the companies that are members of the associations or organizations as part of your work for the client itself? If so, which ones?
6. Your ethics agreement states that you “will not participate personally and substantially in any particular matter involving specific parties in which I know a former client of mine is a party or represents a party for a period of one year after I last provided service to that client, unless I am first authorized to participate, pursuant to 5 C.F.R. 2635.502(d).”
 - a. Please provide a list of all such particular matters involving specific parties that you will either need to recuse yourself from or seek authorization to participate in. For each such particular matter, please also indicate whether you plan to seek authorization to participate.
 - b. If that list does not include particular matters involving the list of individual companies and other entities described in question 4, why not?
 - c. 5 C.F.R 2635.502(a) states that
“where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee in accordance with paragraph (d) of this section.”

Do you agree that your representation of numerous industry clients in litigation to repeal or weaken EPA regulations would cause a reasonable person with knowledge of the relevant facts to question your impartiality if you are confirmed and continue to participate either in the litigation or in an administrative action designed to accomplish the identical outcome – repeal or weakening of an EPA regulation – that the litigation sought to accomplish? Why or why not?

7. Do you intend to participate in non-public meetings with your former clients or their member companies (as applicable) if you are confirmed, even if the meetings are about the repeal or weakening of the very same EPA regulations you sought, on behalf of those clients, to repeal or weaken through litigation? If so, please explain why this would not

cause a reasonable person with knowledge of the relevant facts to question your impartiality in the matter at hand.

8. Your Ethics Agreement also states that you will either recuse yourself from or seek authorization to participate in “any particular matter involving specific parties in which I know the law firm [Hunton & Williams] is a party or represents a party.” Please provide a list of all the EPA-related particular matters involving specific parties in which Hunton & Williams is a party or represents a party, and indicate whether you plan to seek authorization to participate in each such matter.
9. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:
 - a) When EPA first submitted the proposed repeal rule to OMB, the draft stated that the agency would undertake a new cost-benefit analysis as part of the second step of its process.
 - b) OMB interpreted EPA’s first proposal to mean that the rule’s repeal would not avoid any costs to industry or have any economic impact at all. EPA’s political staff then directed the career staff to undertake a new economic analysis. In response to this direction from OMB, EPA career staff reportedly changed the table included in the 2015 rule to a) reflect 2016 dollars instead of 2014 dollars, b) convert “annual costs incurred” under the Clean Water Rule to “annual costs avoided” due to its repeal and c) convert “annual benefits gained” under the Clean Water Rule to “annual benefits forgone” due to its repeal. This new table was sent to OMB on June 8, 2017.
 - c) OMB correctly concluded from EPA’s June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this ‘problem’ by simply deleting the majority of the benefits of the rule from the table and re-submitting it to OMB, which they did¹².

The direction that was reportedly provided to the EPA career staff to make the various revisions to what was submitted to OMB was verbal, not written. If you are confirmed, do you commit to ensure that career staff in OAR will receive appropriately documented, rather than verbal, direction from political officials before they take action? If not, why not?

10. As Attorney General of Oklahoma, Administrator Pruitt copied and pasted materials sent to him by industry onto his own letterhead and sent them to EPA. Similarly, when you last served in EPA’s air office, language drafted by your old law firm found its way into

¹² https://www.epa.gov/sites/production/files/2017-06/documents/economic_analysis_proposed_step1_rule.pdf
See Table 1

an EPA mercury regulation that you helped write. You also repeatedly prevented EPA employees from verifying the public health benefits of reducing mercury exposure.

- a. If confirmed, do you commit that you will not allow industry to exert an undue influence on any of the regulatory and policy efforts you will be charged with leading? If not, why not?
 - b. Do you commit not to censor or exclude the dedicated and knowledgeable career EPA staff? If not, why not?
11. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by any Member of the Environment and Public Works Committee? If not, why not?
12. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily¹³. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?
13. In 2006, when you were last nominated to lead the Office of Air and Radiation (OAR), the then-Bush Administration requested for FY 2007 \$1.33 billion (adjusting to 2017 dollars) for State and Tribal Assistance Grants, of which \$250 million (in 2017 dollars) was for Air and Radiation programs. Earlier this year, the Trump Administration requested for FY 2018 \$597 million, of which \$168 million was for Air and Radiation programs. This is more than 50% less for the STAG program in general, and almost 1/3 less for Categorical Grants for OAR programs.
- a. Did you support the request for FY 2007, and do you support the request for FY 2018? Why, or why not?
 - b. If you support both the requested levels in FY 2007 and FY 2018, why do you believe that a 1/3 cut to the funding levels in FY 2018 from FY 2017 levels is appropriate?
14. How many legal cases have you filed, or joined others in filing against the EPA, since leaving the agency? Please provide a full list with the outcome of each case, including those cases in which the court disagreed with your argument, agreed with your argument, and those in which the court refused to hear the matter.
15. You've represented industry in at least thirty-one cases against the EPA since you left the agency. Can you name one Clean Air Act regulation that was promulgated by the Obama Administration – not a voluntary or grant program – that you do support and why? If you support more than one, please name these as well.
16. Delaware is already seeing the adverse effects of climate change with sea level rise, ocean acidification, and stronger storms. While all states will be harmed by climate change, the adverse effects will vary by state and region. Would you comment on why

¹³ <https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView>

it is imperative that we have national standards to reduce carbon pollution? If you do not believe it is imperative, why not?

17. In a *per curiam* opinion, the U.S. Circuit Court of Appeals for the District of Columbia affirmed the Endangerment Finding and the U.S. Supreme Court declined to issue a writ of certiorari on the D.C. Circuit's decision. The Endangerment Finding set in motion EPA's legal obligations to set greenhouse gas emissions standards for mobile and stationary sources, including those established by the Clean Power Plan in August 2015.¹⁴ During an exchange with Senator Gillibrand during Administrator Pruitt's confirmation hearing before the Environment and Public Works Committee, he stated, "I believe that the EPA, because of the *Mass v. EPA* case and the endangerment finding, has obligations to address the CO₂ [carbon dioxide] issue."
 - a. Do you agree with Administrator Pruitt's statement?
 - b. If the Clean Power Plan is withdrawn, and if confirmed, how will you lead the agency to fulfill its legal obligations to address climate change?
18. EPA policy prohibits the use of non-EPA e-mail accounts and instructs employees to: "not use any outside e-mail system to conduct official Agency business. If, during an emergency, you use a non-EPA e-mail system, you are responsible for ensuring that any e-mail records and attachments are saved in your office's recordkeeping system." When last at the EPA, did you ever use personal email to conduct official EPA business? Did you ever use an email alias to conduct official EPA business when you last served at the agency? Do you commit that if confirmed, you will not use an email alias or use personal email addresses to conduct EPA business?
19. Clean car standards save consumers money at the pump and help reduce oil imports. Automakers are complying with vehicle standards ahead of schedule. If confirmed, will you commit to support, defend and enforce EPA's current programs to address greenhouse gas emissions from vehicles?
20. For the most part, patients and their families only participate in scientific trials and studies once they know their privacy - and any resulting health-related information - will remain confidential and secure. If confirmed, do you commit to respecting confidentiality agreements that exist between researchers and their subjects? Will you protect the health information of the thousands of people that have participated in health studies in the past?
21. In December 2007, President Bush's EPA proposed to declare greenhouse gases as a danger to public welfare through a draft Endangerment Finding, stating, "The Administrator proposes to find that the air pollution of elevated levels of greenhouse gas (GHG) concentrations may reasonably be anticipated to endanger public welfare...Carbon dioxide is the most important GHG (greenhouse gas) directly emitted by human activities, and is the most significant driver of climate change."¹⁵

¹⁴ <https://www.epa.gov/climatechange/us-court-appeals-dc-circuit-upholds-epas-action-reduce-greenhouse-gases-under-clean>

¹⁵ https://insideclimatenews.org/sites/default/files/2007_Draft_Proposed_Endangerment_Finding.pdf

- a. Do you agree with these statements, if not, why not?
 - b. Did you participate in drafting the proposed Bush Endangerment Finding document in any way? If so, how?
22. When you last served in the EPA OAR office, did the EPA ever propose to disapprove state mercury emissions control programs that were stronger than the Clean Air Mercury? If so, please provide how many times this happened and what your role was in these actions. Please also provide how this fits in Administrator Pruitt's views of "cooperative federalism."
23. The Rule of Law Defense Fund is an affiliate of the Republican Attorneys General Association. Have you ever contributed any money or time to the Rule of Law Defense Fund?
24. Have you ever contributed any money or time to two election fundraising groups, Oklahoma Strong PAC and Liberty 2.0 PAC?
25. How many legal cases have you filed, or joined others in filing, that involved the Renewable Fuel Standard, biofuels or biodiesel since leaving the EPA? Please provide a summary of your argument and the outcome of each case, including those cases in which the court disagreed with your argument.
26. Have you ever argued in court, or been part of a legal argument, that the Renewable Fuel Standard, as being implemented by the EPA, will lead to an increase in the overall demand for corn, which will lead to an increase in the price of corn? If so, please cite the case and the data used for the argument.
27. In your 2005 EPW confirmation hearing, you answered a question, with the following, "I was barred for 1 year starting September 29, 2001, from participating in the particular matters listed in Attachment A of the memorandum and from taking official action on any particular matter in which my former clients, listed in Attachment B, were or represented a party to the matter. The ethics memorandum also addressed the general rulemakings on which I had represented various clients...With respect to the ethylene MACT rule and the semiconductor MACT rule, he [Kenneth J. Wernick, EPA's then Alternate Agency Ethics Official] concluded that it would be prudent for me not to handle these matters during my first year at EPA. Subsequent to that time, there was no bar to my participating as an EPA official in these rulemakings... In accordance with the ethics memorandum referenced above, I refrained for 1 year starting September 29, 2001, from participating in the particular matters identified by the memorandum and from taking official action with respect to any particular matter involving the entities listed in the memorandum. I also did not participate in the ethylene and semiconductor MACT rules in my first year at EPA."¹⁶
- a. Please provide a full list of the cases you filed, joined others in filing, or participated in some way related to the ethylene and semiconductor MACT rules prior to you joining the EPA in 2001. Please include any other work that

¹⁶ <https://www.gpo.gov/fdsys/pkg/CHRG-109shrg42275/pdf/CHRG-109shrg42275.pdf>

you may have done while employed at Latham and Watkins – or any other organization – prior to coming to the EPA in 2001 that was related to the ethylene and semiconductor MACT rules.

- b. What led Kenneth J. Wernick, EPA's then Alternate Agency Ethics Official to conclude it wouldn't "be prudent" for you to handle the ethylene MACT rule and the semiconductor MACT rule during your first year at EPA?
 - c. In 2001, what other issues and rulemakings did you have to recuse yourself for one year to meet the ethical standards set by the EPA?
28. How many legal cases have you filed, or joined others in filing, since leaving the EPA that challenged rules the Obama EPA had to re-write because the courts said the original rules written by the Bush Administration were illegal?
29. On July 8, 2003, Jeff Holmstead, then-EPA Assistant Administrator for Air and Radiation provided the following remarks in his written testimony to the House Energy and Air Quality Subcommittee of the Energy and Commerce Committee, "Clear Skies would also reduce mercury emissions from power plants. EPA is required to regulate mercury because EPA determined that mercury emissions from power plants pose an otherwise unaddressed significant risk to health and the environment, and because control options to reduce this risk are available."¹⁷ At the time Mr. Holmstead provided these remarks, you were serving as his chief counselor within the EPA OAR office.
- a. Did you agree at the time with Mr. Holmstead's determination, if so why? If not, why not?
 - b. Did you ever provide legal counsel to Mr. Holmstead, or others within the EPA, that helped provided the legal basis for these remarks?
 - c. Do you agree with Mr. Holmstead's remarks today?
30. On July 8, 2003, Jeff Holmstead, then-EPA Assistant Administrator for Air and Radiation provided the following remarks in his written testimony to the House Energy and Air Quality Subcommittee of the Energy and Commerce Committee: "Mercury, a potent toxin, can cause permanent damage to the brain and nervous system, particularly in developing fetuses when ingested in sufficient quantities. People are exposed to mercury mainly through eating fish contaminated with methylmercury... EPA estimates that 60% of the mercury falling on the U.S. is coming from current man-made sources. Power generation remains the largest man-made source of mercury emissions in the United States...Mercury that ends up in fish may originate as emissions to the air. Mercury emissions are later converted into methylmercury by bacteria. Methylmercury accumulates through the food chain: fish that eat other fish can accumulate high levels of methylmercury".¹⁸ At the time Mr. Holmstead provided these remarks, you were serving as his chief counselor within the EPA OAR office.
- a. Did you have any involvement in the drafting of these remarks? If so, what was your involvement?

¹⁷ https://archive.epa.gov/ocir/hearings/testimony/108_2003_2004/web/pdf/2003_0708_jh.pdf

¹⁸ https://archive.epa.gov/ocir/hearings/testimony/108_2003_2004/web/pdf/2003_0708_jh.pdf

- b. Did you agree at the time with Mr. Holmstead's remarks, if so why? If not, why not?
 - c. Do you still agree with Mr. Holmstead's remarks today? If not, why not?
31. In the *White Stallion Energy Center v. EPA, February 2012*, industry argued, "the record does not support EPA's findings that mercury, non-mercury HAP metals, and acid gas HAPs [hazardous air pollutants] pose public health hazards."¹⁹ Do you agree with this statement? Did you have any involvement with this case, if so, please explain.
32. On April 17, 2012, Dr. Jerome Paulson, Chair, Council on Environmental Health, American Academy of Pediatrics, testified before the EPW Committee, stating, "Methyl mercury causes localized death of nerve cells and destruction of other cells in the developing brain of an infant or fetus. It interferes with the movement of brain cells and the eventual organization of the brain...The damage it [methylmercury] causes to an individual's health and development is permanent and irreversible. ...There is no evidence demonstrating a "safe" level of mercury exposure, or a blood mercury concentration below which adverse effects on cognition are not seen. Minimizing mercury exposure is essential to optimal child health."²⁰
- a. Do you agree with the American Academy of Pediatrics' finding on the importance of minimizing mercury exposures for child health? If not, please cite the scientific studies that support your disagreement.
 - b. Do you agree the record supports EPA's findings that mercury, non-mercury hazardous air pollutant metals, and acid gas hazardous air pollutants emitted from uncontrolled power plants pose public health hazards? If not, why not?
33. On July 8, 2003, Jeff Holmstead, then-EPA Assistant Administrator for Air and Radiation provided the following remarks in his written testimony to the House Energy and Air Quality Subcommittee of the Energy and Commerce Committee, "We have not developed methodologies for quantifying or monetizing all the expected benefits of Clear Skies...These estimates [for Clear Skies] do not include the many additional benefits that cannot currently be monetized but are likely to be significant, such as human health benefits from reduced risk of mercury emissions, and ecological benefits from improvements in the health of our forests, lakes, and coastal waters."²¹ At the time Mr. Holmstead provided these remarks, you were serving as his chief counselor within the EPA OAR office.
- a. Did you have any involvement in the drafting of these remarks? If so, what was your involvement?
 - b. Did you agree at the time with Mr. Holmstead's remarks, if so why? If not, why not?
 - c. Do you agree with Mr. Holmstead's remarks today that it is currently difficult, or impossible, to monetize the reduced risk of human health and ecological benefits from reducing mercury emissions from power plants? If so, please

¹⁹ <https://www.cadc.uscourts.gov/internet/opinions.nsf/284AC47088C07D0985257CBB004F0795/%24file/12-1100-1488346.pdf>

²⁰ <https://www.epw.senate.gov/public/cache/files/4/3/4324fd62-dc89-4820-bd93-ff3714fcb30/01AFD79733D77F24A71FEF9DAFCCB056.41712hearingwitness testimony paulson.pdf>

²¹ https://archive.epa.gov/ocir/hearings/testimony/108_2003_2004/web/pdf/2003_0708_jh.pdf

explain. If not, why not?

34. In 2005 GAO report that reviewed EPA's cost-benefit analysis for the Clean Air Mercury Rule, which you have testified you were heavily involved in writing, GAO identified, "four major shortcomings in the economic analysis underlying EPA's proposed mercury control options that limit its usefulness for informing decision makers about the economic trade-offs of the different policy options."²²
- a. Can you explain the cost-benefit analysis used for the proposed Clean Air Mercury Rule and why it was used?
 - b. Can you explain why the GAO found short-comings with this approach?
 - c. Do you agree that co-benefit pollution reductions should be considered when EPA is quantifying the benefits and costs of regulations? If not, why not?
 - d. While you were at EPA, did the agency ever use co-benefits to justify a clean air rule and has this approach ever been used in the past?
35. You were substantially involved in EPA's proposal and adoption of the Clean Air Mercury Rule and accompanying Delisting Rule. In 2005, for your EPW confirmation hearing you were asked the following question for the record: "With regard to trading of mercury, in your view, would it have been legally acceptable for EPA, taking into account the requirements of the Clean Air Act, to propose and adopt a facility specific mercury MACT that did not allow trading?" You answered, "After considering the utility unit emissions that would remain following imposition of the requirements of the Act, EPA determined that it was neither appropriate nor necessary to regulate utility units under section 112 of the Clean Air Act. Once EPA made that determination, it would not have been legally appropriate for EPA to issue a MACT standard." Three years later, the D.C. Circuit vacated the EPA's decision to delist power plants as a source under Section 112. Six years later under the Obama Administration, the EPA issued the Mercury and Air Toxics Rule to address mercury and air toxic emissions from power plants under the Section 112 of the Clean Air Act.
- a. Did you disagree with the court's ruling and legal reasoning against the EPA's actions while you were at the agency on mercury and air toxic power plant emissions? Do you continue to disagree today?
 - b. Do you still hold the position that it is not "appropriate nor necessary" for the EPA to regulate utility units under Section 112 of the Clean Air Act and therefore, still agree it is not legally appropriate for EPA to issue a MACT standard, as the EPA did through the Mercury and Air Toxics Standard? If so, please explain.
 - c. If you do not agree that EPA has met the "necessary and appropriate" criteria found in Section 112(n), what is your understanding of what that would mean for the Mercury and Air Toxics Rule?
36. The US Supreme Court has expressly declined to consider whether EPA should have chosen some other mechanism "under section 112" in regulating power plant mercury and all the other HAPs emitted by the industry. What is your position on that

²² <http://www.gao.gov/products/GAO-05-252>

precedent?

37. Do you agree that the EPA's recent consideration of the costs of the Mercury and Air Toxics Rule shows that the agency has met the "necessary and appropriate" criteria Congress provided under 112(n) to direct the EPA to regulate power plant mercury (and other air toxic) emissions under Section 112, and more specifically under Section 112(d)? If not, why not?
38. The Edison Electric Institute (EEI), the association that represents all U.S. investor-owned electric companies, has told my staff that, to their knowledge, about five facilities received an approval from the EPA to operate for up to an additional year, which was through April 2017. According to EEI, to their knowledge all of their member companies have fully implemented the Mercury and Air Toxics Standard Rule. EPA staff has reported to my staff something similar. The Mercury and Air Toxics Rule protects our children from harmful mercury and air toxics pollution; and by industry accounts is already being met with technology that is already bought, paid for and running on almost all our power plants.
- Do dispute reports that nearly all covered facilities are already in compliance with the Mercury and Air Toxics Standard? If so, please explain.
 - According to a recent report by Bloomberg New Energy Finance Report and the Business Council for Sustainable Energy, "consumers now pay 3% less per kilowatt-hour for electricity than in 2007."²³ This means the near universal compliance of the Mercury and Air Toxics Rule has been achieved without significant impacts to electricity reliability or affordability, in fact electricity prices have gone down. Do you agree? If not, why not?
 - Even though industry has achieved near universal compliance with the Mercury and Air Toxics Standards and electricity prices have gone down, not up, Administrator Pruitt is currently reviewing whether it is "appropriate and necessary" to issue the standards in the first place. Do you agree that the EPA should be conducting this review, if so, why?
 - If the EPA determines the agency has not met the "necessary and appropriate" criteria found in Section 112(n), and revokes the Mercury and Air Toxics Rule, what does that mean for all the pollution control technology that has been bought, paid for and running on our power plants helping the industry be in full compliance of the rule?
 - When you were last at the EPA, or after, do you know of any instances when a power plant bought and installed air control technology and decided not to run the technology? If so, please explain the instance. Please include in your explanation if there were any impacts to downwind states or to air pollution levels.
39. In a 2016 Law 360 article, you are quoted as saying, "The reason this [the Mercury and Air Toxics Standards Rule] was such a big issue for us is because by EPA's own analysis, if you look at the benefits generated by the hazardous air pollutant reductions this rule would achieve, the costs vastly outweigh the benefits. So from our perspective,

²³ <http://www.bcse.org/wp-content/uploads/2017-Sustainable-Energy-in-America-Factbook-Executive-Summary.pdf>

it's a regulation that made no sense and wasn't justified."²⁴ In April 2017, the EPA asked the D.C. Circuit Court of Appeals to delay oral arguments scheduled the Mercury and Air Toxics Standards (MATS) as it reviews the rule.

- a. It is clear from this statement you already have a formed view of the validity of the Mercury and Air Toxics Standard going into the agency. Will you commit to this Committee that you will recuse yourself from the review and any possible rewriting of the Mercury and Air Toxics Rule? If not, why not?
 - b. Do you continue to believe the Mercury and Air Toxics Standards is a regulation that made no sense and wasn't justified? If so, why?
40. Will you commit, that if confirmed, you will not act to weaken the Mercury and Air Toxics Standards, if not, why not?
41. This year, you represented the American Petroleum Institute as an intervenor in defense of Administrator Pruitt's 90-day stay of oil and gas pollution standards, which the D.C. Circuit found violated the Clean Air Act. In my office, you refused to recuse yourself from participating in this rule, is that still true and how do you justify that, if confirmed, you will come into the EPA as impartial regulator as it relates to this issue? Do you agree with the court's decision, and why not?
42. Section 109 of the Clean Air Act is very clear. It requires EPA to review the NAAQS for six common air pollutants including ground-level ozone, particulate matter, sulfur dioxide, nitrogen dioxide every 5 years. The Clean Air Act requires EPA to set these standards that "are requisite to protect the public health," with "an adequate margin of safety," and secondary standard necessary to protect public welfare.
- a. If confirmed, will you continue to hold to the five-year National Ambient Air Quality Standards review time period that the Clean Air Act requires of the EPA?
 - b. The science was clear that the 2008 ozone standard was not protecting public health, so EPA was required to Act. Is that not your understanding of the Clean Air Act?
 - c. If confirmed, will you commit to not further delay the implantation of the 2015 ozone NAAQS? If not, why not?
 - d. Do you agree with Justice Scalia's opinion in *Whitman v. American Trucking Associations* that it is "fairly clear that [the Clean Air Act] does not permit the EPA to consider costs in setting the standards" and if so, will you commit not to include consider costs when setting the National Ambient Air Quality Standards? If you do not agree, why not?
43. In 2006, while you served as Acting Assistant Administrator for Air, the EPA proposed to eliminate lead as a criteria pollutant under the Section 109 Clean Air Act National Ambient Air Quality Standard (NAAQS) process. Did you have any involvement in this proposal? If so, please explain.

²⁴ <https://www.law360.com/articles/742955/environmental-group-of-the-year-hunton-williams>

44. Like you, I am an avid runner. In Delaware during the summer, we often have code orange days warning about the high levels of ozone for that day. Much of Delaware's ozone pollution is coming across the state boundary from upwind states.
- Can you describe how high levels of ozone could damage my lungs if I were to take a long run during a code orange day?
 - Do you agree that ground-level ozone is a dangerous pollutant that causes respiratory and cardiovascular harm? If not, on what basis do you disagree?
 - If confirmed, how would you direct states to work together to reduce ozone pollution?
45. Clean Air Act section 110(a)(2)(D)(i)(I), also known as the "Good Neighbor" provision, requires that state implementation plans to address air pollution "contain adequate provisions prohibiting, consistent with the provisions of this subchapter, any source or other type of emissions activity within the State from emitting any air pollutant in amounts which will contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any such national primary or secondary ambient air quality standard." Under this provision of the Clean Air Act, "[w]henver the Administrator finds that the applicable implementation plan for any area is substantially inadequate . . . to mitigate adequately [] interstate pollutant transport . . . or to otherwise comply with any requirement of this chapter, the Administrator shall require the State to revise the plan as necessary to correct such inadequacies."
- Do you support the "Good Neighbor Provision" in the Clean Air Act and agree that this provision does not "encroach upon state sovereignty"? If not, why?
 - If confirmed, do you commit to fully apply and enforce the Good Neighbor provision?
46. Currently, under the Clean Air Act section 110(a)(2)(D)(i)(I), also known as the "Good Neighbor" provision, Delaware has sent four petitions to the EPA that identify facilities in other states that are emitting air pollution that are significantly contributing to Delaware's air quality and impacting Delaware's ability to maintain or be in attainment for the 2008 national ambient air quality standards (NAAQS) for ozone and the 2015 ozone NAAQS. The petitions are for: 1) Brunner Island facility's electric generating units located near York, Pennsylvania; 2) Homer City Generating Station's electric generating units located in Indiana County, Pennsylvania; 3) Harrison Power Station's electric generating units located near Haywood, Harrison County, West Virginia; and 4) Conemaugh Generating Station's electric generating units located in Indiana County, Pennsylvania. In addition, Maryland has filed a petition that requests EPA make a finding that 36 electric generating units located in the states of Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia are emitting air pollutants that significantly contribute to nonattainment or interfere with maintenance of the 2008 and the 2015 ozone NAAQS in Maryland. The EPA has granted itself six months extension on every petition and has done nothing after that. All of the extensions have long since expired.
- If confirmed, will you commit to promptly act on Good Neighbor petitions so states, like Delaware and Maryland, can protect their citizens from upwind pollution in neighboring and distant states? If not, why not?

- b. If confirmed, will you support, defend and enforce EPA’s Good Neighbor provisions to address air pollution that crosses state borders? If not, why not?
 - c. In some of these situations, like the Harrison Power Station near Haywood in West Virginia, the power plant in question has the needed technology on the facility to help reduce ozone pollution in downwind Delaware and West Virginia ratepayers are already paying for the technology, but the pollution control isn’t running. If confirmed, what will you do to ensure pollution control technology already on facilities runs to ensure downwind states have clean air?
 - d. If confirmed, will you fully implement the Cross State Air Pollution Rules?
 - e. If the Mercury and Air Toxics Rule is revoked, do you expect there will be an increase in upwind ozone and particulate pollution and have an impact on downwind states? If so, please explain. If not, why?
47. Just last month, you argued against an Obama Administration Occupational Safety and Health Administration indoor air rule that protects construction workers against silica dust, a type of dust that is linked to cancer and lung disease. During your arguments, you are quoted as saying, “People are designed to deal with dust — people are in dusty environments all the time, and it doesn’t kill them,”²⁵ The American Industrial Hygiene Association has stated that delaying the full enforcement of this rule will put – and this is their words, quote “2.3 million workers at greater risk to exposure, especially the construction industry — the backbone of our economy”
- a. Please provide the scientific studies that provided the basis for your argument in this case.
 - b. When you stated “people are designed to deal with dust,” what did you mean by that statement?
 - c. When you were last in the EPA, did you ever work on a rule was deemed later to ignore all of the science dealing with particle matter pollution?
 - d. Do you agree that there is robust science linking small particle pollution to negative health impacts, even death? If so, why is the science here different than for silica pollution?
48. Do you agree with President Trump’s decision to withdraw the United States from the International Paris Climate Accord? If so, please explain.
49. In part of his justifications for withdrawing from the Paris Climate Agreement, President Trump stated the Paris Accord could, “cost America as much as 2.7 million lost jobs by 2025 according to the National Economic Research Associates (NERA).”²⁶ This economic statistic and others linked to the NERA study were also distributed in White House materials as reasons the President was deciding to withdraw from the Paris Accord. Soon after the President’s speech, NERA stated, “In a set of talking points distributed by the White House in conjunction with its announcement of the US withdrawal from the Paris Agreement, the Trump Administration selectively used results

²⁵ <https://www.eenews.net/greenwire/stories/1060061731/search?keyword=silica>

²⁶ <https://www.whitehouse.gov/the-press-office/2017/06/01/statement-president-trump-paris-climate-accord>

from a NERA Economic Consulting study, “Impacts of Greenhouse Gas Regulations on the Industrial Sector.” ... Use of results from this analysis as estimates of the impact of the Paris Agreement alone mischaracterizes the purpose of NERA’s analysis, which was to explore the challenges of achieving reductions from US industrial sectors over a longer term. Selective use of results from a single implementation scenario and a single year compounds the mischaracterization.”²⁷

- a. In light of the NERA statement, do you think the President misspoke when he wrongly cited information from the NERA study in his Paris speech? If not, why not?
 - b. If confirmed, will you commit that you will not distort the NERA study – or any other economic study - to justify the U.S. withdrawing from the Paris Climate Accord or to justify the elimination or delay of climate policies?
 - c. After the President’s Paris Climate Accord speech, MIT’s Joint Program on the Science and Policy of Global Change issued a statement stating the President’s characterization of their analysis of the Paris Accord to be misleading.²⁸ If confirmed, will you commit that you will not distort the climate science studies to justify the U.S. withdrawing from the Paris Climate Accord or to justify the elimination or delay of climate policies?
50. In a Law360 interview, you were asked, “What is the most challenging case you have worked on and what made it challenging?” You responded, “Without a doubt, it would be Massachusetts v. EPA. I was at the EPA at the time, working as counsel to the assistant administrator for air, Jeff Holmstead.”²⁹ Please explain in detail, what your involvement was while in the EPA regarding regulations that led to, and the agency’s defense of the Massachusetts v. EPA case.

²⁷ <http://www.nera.com/news-events/press-releases/2017/nera-economic-consultings-study-of-us-emissions-reduction-policies.html>

²⁸ <http://news.mit.edu/2017/mit-issues-statement-research-paris-agreement-0602>

²⁹ <https://www.law360.com/articles/427231/q-a-with-hunton-williams-bill-wehrum>

Matthew Z. Leopold, nominee to be the General Counsel of the U.S. Environmental Protection Agency

1. For decades, both Republican and Democratic administrations alike have had written policies limiting White House contacts with agencies that have investigatory and enforcement responsibilities. These policies have recognized that even a simple phone call from the White House to an agency inquiring about or flagging a specific matter can upset the evenhanded application of the law. I recently learned that Devon Energy, a strong political supporter of Administrator Pruitt's, informed the EPA just 5 days after Mr. Pruitt was sworn in as Administrator that it was no longer willing to install air pollution technology or pay a high penalty to EPA for its illegal air emissions of cancer-causing benzene and other chemicals. We also know that Trump family casinos, hotels and golf courses have been the subject of EPA enforcement actions for violations of the Clean Air Act and Clean Water Act.
 - a. Do you agree that it is essential that in making decisions, EPA's Office of General Counsel (OGC) must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?
 - b. Will you commit to restricting communications between OGC and the White House staff regarding specific matters under the authority of OGC?
 - c. Will you commit to ensuring the staff of OGC is familiar with those restrictions?
 - d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OGC staff, including you, occur?

2. Recently, EPA conducted "anti-leaking" training for its employees³⁰. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.

5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of. ... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences- (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency

³⁰ https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089_story.html?utm_term=.e2bfc5e54d95

to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation... " In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

- a. If you are confirmed, will you commit to protect the rights of all career employees in OGC to make lawful disclosures, including their right to speak with Congress?
 - b. Will you commit to communicate employees' whistleblower rights via email to all OGC employees within a week of being sworn in?
3. In the wake of Hurricane Irma, at least 11 deaths and numerous injuries have been reported in Florida due to accidental carbon monoxide poisoning from gasoline-powered portable generators.³¹ One additional death has also been reported in North Carolina, along with other injuries throughout the Southeastern United States.³² Many of these deaths and injuries could have been prevented had stronger safety standards been in place for portable gasoline generators. In November 2016, the U.S. Consumer Product Safety Commission (CPSC), following years of work on the issue, voted to issue a Notice of Proposed Rulemaking (NPRM) to implement a mandatory safety standard for portable generators.³³ Since then, Administrator Pruitt and Acting CPSC Chairman Buerkle have separately said that section 213 of the Clean Air Act precludes CPSC action.
- a. Section 213 of the Clean Air Act is intended to regulate emissions from non-road engines or vehicles when the EPA determines that such emissions "are significant contributors to ozone or carbon monoxide concentrations in more than 1 area which has failed to attain the national ambient air quality standards for ozone or carbon monoxide." In your opinion, would the occasional indoor use of portable generators following a power outage be likely to be a significant contributor to ambient carbon monoxide concentrations in more than 1 area that has failed to attain the national ambient air quality standards for carbon monoxide? Why or why not?
 - b. There are currently no areas in the United States that have failed to attain the national ambient air quality standards for carbon monoxide, and this has been the case since 2010³⁴. As a matter of law, could section 213 of the Clean Air Act be used to regulate carbon monoxide emissions due to the indoor use of portable generators if there are no areas in the United States that fail to attain the national ambient air quality standards for carbon monoxide? Why or why not?

³¹ <http://www.miamiherald.com/news/weather/hurricane/article174097351.html> <http://www.sun-sentinel.com/news/weather/hurricane/sfl-carbon-monoxide-deaths-20170914-story.html>

³² <http://www.charlotteobserver.com/news/article173612361.html>

³³ <https://www.federalregister.gov/documents/2016/11/21/2016-26962/safety-standard-for-portable-generators>

³⁴ <https://www.epa.gov/green-book/green-book-carbon-monoxide-1971-area-information>

4. You spent more time – 6 years – as an attorney in the Environment and Natural Resources Division of the Department of Justice than in any other position. Based on your experience, to what extent do you believe that the work of the Environment and Natural Resources Division makes an important contribution to the protection of public health and the environment? Please explain and describe your views of the contributions the work of the Division makes.
5. Earlier this year, the fiscal year 2018 budget proposal³⁵ submitted to Congress sought to eliminate the \$20 million in funding the EPA provides for the Justice Department’s Environment and Natural Resources Division. EPA has historically provided about 27 percent of that office’s budget. Based on your experience as an attorney in the Environment and Natural Resources Division, please describe the potential impact on the work of the Division of such a reduction in funding. Do you support such a reduction in funding? Please provide your reasoning and any information you have supporting your answer. Since 2005, how much funding has been provided to ENRD by EPA? How much money has DOJ secured through fines, penalties, and commitments to remediate contamination and pollution during this same time period?
6. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:
 - i) When EPA first submitted the proposed repeal rule to OMB, the draft stated that the agency would undertake a new cost-benefit analysis as part of the second step of its process.
 - ii) OMB interpreted EPA’s first proposal to mean that the rule’s repeal would not avoid any costs to industry or have any economic impact at all. EPA’s political staff then directed the career staff to undertake a new economic analysis. In response to this direction, EPA career staff reportedly changed the table included in the 2015 rule to a) reflect 2016 dollars instead of 2014 dollars, b) convert “annual costs incurred” under the Clean Water Rule to “annual costs avoided” due to its repeal and c) convert “annual benefits gained” under the Clean Water Rule to “annual benefits forgone” due to its repeal. This new table was sent to OMB on June 8, 2017.
 - iii) OMB correctly concluded from EPA’s June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this ‘problem’

³⁵ <https://www.documentcloud.org/documents/4061910-EPA-Superfund-reimbursements-to-DOJ-documents.html#document/p7/a378119>

by simply deleting the majority of the benefits of the rule from the table and re-submitting it to OMB, which they did³⁶.

- a) If the events above occurred as described to my staff, do you agree that EPA's failure to even attempt to undertake a credible cost-benefit analysis of its proposal to repeal the Clean Water Rule would be vulnerable to assertions that the agency ran afoul of both the Clean Water Act and the Administrative Procedure Act? Why or why not?
 - b) The direction that was reportedly provided to the EPA career staff to make the various revisions to what was submitted to OMB was verbal, not written. If you are confirmed, do you commit to ensure that career staff in OGC will receive appropriately documented, rather than verbal, direction from political officials before they take action? If not, why not?
8. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by any Member of the Environment and Public Works Committee? If not, why not?
 9. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily³⁷. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?

³⁶ https://www.epa.gov/sites/production/files/2017-06/documents/economic_analysis_proposed_step1_rule.pdf
See Table 1

³⁷ <https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView>

David P. Ross, nominee to be Assistant Administrator for the Office of Water (OW) of the U.S. Environmental Protection Agency

1. For decades, both Republican and Democratic administrations alike have had written policies limiting White House contacts with agencies that have investigatory and enforcement responsibilities. These policies have recognized that even a simple phone call from the White House to an agency inquiring about or flagging a specific matter can upset the evenhanded application of the law. I recently learned that Devon Energy, a strong political supporter of Administrator Pruitt's, informed the EPA just 5 days after Mr. Pruitt was sworn in as Administrator that it was no longer willing to install air pollution technology or pay a high penalty to EPA for its illegal air emissions of cancer-causing benzene and other chemicals. We also know that Trump family casinos, hotels and golf courses have been the subject of EPA enforcement actions for violations of the Clean Air Act and Clean Water Act.
 - a. Do you agree that it is essential that in making decisions, EPA's OW must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?
 - b. Will you commit to restricting communications between OW and the White House staff regarding specific matters under the authority of OW?
 - c. Will you commit to ensuring the staff of OW is familiar with those restrictions?
 - d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OW staff, including you, occur?

2. Recently, EPA conducted "anti-leaking" training for its employees³⁸. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.

5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of. ... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences- (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency

³⁸ https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089_story.html?utm_term=.e2bfc5e54d95

to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation... " In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

- a. If you are confirmed, will you commit to protect the rights of all career employees in OW to make lawful disclosures, including their right to speak with Congress?
 - b. Will you commit to communicate employees' whistleblower rights via email to all OW employees within a week of being sworn in?
3. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:
 - i) When EPA first submitted the proposed repeal rule to OMB, the draft stated that the agency would undertake a new cost-benefit analysis as part of the second step of its process.
 - ii) OMB interpreted EPA's first proposal to mean that the rule's repeal would not avoid any costs to industry or have any economic impact at all. EPA's political staff then directed the career staff to undertake a new economic analysis. In response to this direction, EPA career staff reportedly changed the table included in the 2015 rule to a) reflect 2016 dollars instead of 2014 dollars, b) convert "annual costs incurred" under the Clean Water Rule to "annual costs avoided" due to its repeal and c) convert "annual benefits gained" under the Clean Water Rule to "annual benefits forgone" due to its repeal. This new table was sent to OMB on June 8, 2017.
 - iii) OMB correctly concluded from EPA's June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this 'problem' by simply deleting the majority of the benefits of the rule from the table and re-submitting it to OMB, which they did³⁹.
 - a. If the events above occurred as described to my staff, do you agree that EPA's failure to even attempt to undertake a credible cost-benefit analysis of its proposal to repeal the Clean Water Rule would be vulnerable to assertions that the agency

³⁹ https://www.epa.gov/sites/production/files/2017-06/documents/economic_analysis_proposed_step1_rule.pdf
See Table 1

7. The Farm Bureau has come out strongly against the Clean Water Rule (CWR). But the CWA section 404(f), which was enacted in 1977, specifically exempts normal farming activities including the construction of roads, ditches, and farm ponds. The CWR does not impinge on section 404(f) at all. Which specific farm activities does the CWR affect that are currently exempted under the 2008 guidance that is now in place?
8. Did EPA formulate a new, updated legal rationale for embracing the current waters of the United States definition through its proposed repeal and replacement of the Clean Water Rule? If so, please describe your understanding of the rationale.
9. Coal-fired power plants are by far the largest discharger of toxic water pollution in the US. In 2015, an effluent limitations guidelines (ELG) rule was finalized that would require power plants to eliminate the vast majority of this pollution using readily available, affordable wastewater treatment technology. In the last few months, however, EPA has postponed the compliance dates for two waste streams in the rule and begun a new rulemaking to reconsider the standards for these waste streams. EPA has argued that the 2015 rule was too cost-prohibitive to industry, yet the vast majority of power plants will incur zero costs to comply with the 2015 ELG rule. EPA had previously estimated that complying with this rule would prevent 1.4 billion pounds of toxic pollutants, including known carcinogens like arsenic and known neurotoxins like lead and mercury, from being discharged into waterways each year.
 - a. How will you ensure that any revised Steam ELG standards and/or limits do not negatively impact drinking water systems?
 - b. In its proposed revisions to the 2015 power plant ELG, should EPA consider technology options for treating flue gas desulfurization waste that would limit bromide discharges from power plants? Why or why not?
10. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by any Member of the Environment and Public Works Committee? If not, why not?
11. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily⁴⁰. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?
12. You are currently the Wisconsin Department of Justice's Environmental Protection Unit Director. It is your responsibility to manage environmental litigation and prosecute violations of state environmental law.
 - a. Under the cooperative federalism structure of many of our environmental statutes, do you believe the federal government, and EPA in particular, is an important partner to state environmental work?

⁴⁰ <https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView>

- b. The Trump Administration has proposed reducing funding for the Office of Enforcement and Compliance Assurance by 24 percent. In your opinion, how would a funding cut of this size affect the partnership between Wisconsin and EPA?
 - c. If the Wisconsin Department of Justice's Environmental Protection Unit was cut by 24 percent, how would that affect the ability of your unit to perform its statutory responsibilities?
13. The Trump Administration has proposed eliminating the Great Lakes Restoration Initiative. This would cut \$300 million dollars in funding to states like Wisconsin for environmental restoration activities designed to improve the health of the Great Lakes. You have been nominated to head the Office of Water. Do you support the proposed elimination of EPA's Geographic Programs funding? What impact will this have on the Great Lakes? If this program is eliminated, how would you, if confirmed, accomplish your statutorily required objective to improve the health of the nation's waters, including the Great Lakes? In particular, how would the elimination of this program affect multistate and binational commitments and initiatives to deal with non-point source pollution issues and resulting algal blooms, as described in an October 3, 2017 New York Times article⁴¹? Do you support designation of the Western portions of Lake Erie as impaired and development of a TMDL to identify and reduce the loadings of nutrients, especially phosphorus, that contribute to the problem?

⁴¹ <https://www.nytimes.com/interactive/2017/10/03/science/earth/lake-erie.html?smid=tw-share& r=0>

Attachments – Michael Dourson

From: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Sent: Thursday, March 17, 2016 2:10 PM
To: Freedhoff, Michal (Markey)
Subject: TSCA TA - Section 6 Issue

Attachment 1

Michal,

In reviewing bill text (house and senate passed bills), EPA just discovered a technical issue that will have significant policy implications for EPA's ongoing work under Section 6. As currently drafted, both Senate and House bills could frustrate EPA's ability to timely manage risks that have been (or may be) identified in our current Work Plan risk assessments.

As you know, EPA has been working on risk assessments (draft and final) for a number of chemical substances - TCE, NMP, MC, and 1-BP. These risk assessments have been scoped relatively narrowly, so as to focus the Agency's resources on uses most likely to present risk. EPA is *not* looking at all the conditions of use for these chemicals.

This approach, which might be characterized as a *partial* risk evaluation or *partial* safety determination, we see as simply not contemplated under the Senate and House bills. The section 6 structure in both bills would require EPA to assess a chemical in its entirety, based on all conditions of use – not just a subset of those uses.

Should the House/Senate construct become law, the Agency would be left with a difficult choice in moving forward with our ongoing Work Plan assessment and rules.

One option might be to move forward with finalizing the risk evaluation and regulating a subset of chemical uses. There's some risk that the new law would not support such an interpretation. Even if it would, the risk management deadline for the chemical would start ticking immediately. That means that EPA would be on the clock to expand the risk evaluation to cover remaining non-scoped uses, finalize those determinations, AND complete a rulemaking to manage any associated risks. For risk assessments that are draft or final, this appears to be the public policy preferred option. It's highly unlikely that EPA would be able to complete this work for non-scoped uses within the statutory timeframes.

Alternatively, EPA could hold off on moving to risk management finalizing and spend additional time evaluating the full suite of uses. This would have the practical effect of allowing known risks to health or the environment (i.e., those identified in the narrowly-scoped assessment) to continue unregulated during this period.

We'd welcome an opportunity to work with you on a drafting solution to this issue, but wanted to bring to your attention as soon as possible.

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 <Kaiser.Sven-Erik@epa.gov>
Sent: Saturday, April 2, 2016 9:38 PM
To: Freedhoff, Michal (Markey)
Subject: Fwd: Revised partial risk evaluation and management language
Attachments: Markey.TSCA TA.Proceeding in phases pared down.docx; ATT00001.htm

Resend, please confirm attachment went through. Thanks,
Sven

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use 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.

Re-title Section 26(j) as follows:

(j) POLICIES, PROCEDURES, ~~AND GUIDANCE~~, AND CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS

Renumber 26(j)(5) as 26(j)(6), and add the following after 26(j)(4):

(5) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS

(A) With respect to chemical substances listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which EPA has completed risk assessments on or after XXX but prior to the date of enactment of the TSCA Modernization Act of 2015, the Administrator may ~~conduct risk evaluations under section 6(b)(4) and~~ publish proposed and final rules under section 6(a) for the uses assessed, as appropriate, based on the results of those risk assessments, notwithstanding the fact that the risk assessments the Administrator has completed for such chemical substances did not evaluate all conditions of use. ~~Any such risk evaluations shall evaluate the risks from the uses of the chemical substances that the Administrator assessed in the completed TSCA Work Plan risk assessments, to determine whether the chemical substances present an unreasonable risk of injury to health or the environment under those uses in accordance with section 6(b)(4), and any such rules shall ensure that the chemical substances do not present an unreasonable risk of injury to health or the environment, as that term is used in section 6(b)(4)(A), under those uses. In conducting such risk evaluations and proposing and promulgating such rules, the Administrator shall follow the deadlines and other requirements of sections 6(b)(4) and 6(c), as applied to the uses addressed in the rulemakings, with the deadlines running from the date of enactment of the TSCA Modernization Act of 2015.~~

~~(B) The Administrator shall subject any conditions of use that had not been considered in the completed risk assessments of these chemical substances to the processes and requirements of section 6(a), 6(b), and 6(c), as applied to those conditions of use.~~

Attachment 2 - TA on an April 7, 2016 draft of Section 5

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

~~Internal x-refs where existing TSCA lettering/numbering changed have not been confirmed 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 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).~~

(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~~

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

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).

(B) determining 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 (c) 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 (54), 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).~~

~~(343) 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.~~

(454)(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.

(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.

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.

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), ~~with:~~—

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.

(2B) 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.

(3C) 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 inline 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.

From: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Sent: Saturday, April 9, 2016 4:47 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on Section 5 - SNUR

Attachment 3

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)

From: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Sent: Monday, December 12, 2016 11:43 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey Request on TSCA risk assessments and conditions of use

Attachment 4

Michal,

This responds to the questions on TSCA risk assessments and conditions of use.

In interpreting the passages from TSCA that cited in the request, EPA views Section 6(b)(4)(A) as a key starting point: a risk evaluation is a process for determining whether a chemical substance presents an unreasonable risk. More specifically, the question is whether the chemical substance presents an unreasonable risk, under the conditions of use. We agree that “conditions of use” is broadly defined in Section 3. Accordingly, some chemical substances may have a great many particular uses. Nonetheless, EPA could consider similar uses together, for purposes of risk assessment, and it would not necessarily prepare detailed risk assessments addressing each individual uses. Note that EPA would not be conducting multiple risk evaluations for the multiple uses of a chemical: since there is only one chemical substance under review, there is only one risk evaluation, and there is only one conclusion for that chemical substance (either unreasonable risk or not unreasonable risk).

Similarly, EPA is directed to designate “a chemical substance” as either being a high priority or a low priority under Section 6(b)(1)(B). Concern about a single use could suffice to justify making a “may present” finding for the entire chemical substance, but EPA would **still** make a determination that **the chemical substance** “may present” an unreasonable risk. Nor would EPA determine that particular uses are “low-priority.” A low-priority use is not a defined concept under TSCA. The low-priority designation applies to the whole chemical substance. Consistent with 6(b)(1)(A), EPA would certainly *consider* the various conditions of use, but the results from such consideration would be weighed together to reach a conclusion about whether the substance as a whole is a high-priority substance or a low-priority substance.

When EPA proceeds to a risk evaluation, consistent with the direction in 6(b)(4)(A), EPA would consider all the conditions of use. But here again, EPA is doing a risk evaluation of the chemical substance. A full risk evaluation of the chemical substance may involve conducting a more detailed assessment of some uses and a less detailed assessment of other uses. **And under certain circumstances EPA may choose to expedite the part of a risk evaluation that deals with a particular condition of use, so as to move a chemical substance more rapidly to risk management under TSCA section 6(a). But in any case, the Agency would still complete a full risk evaluation on the chemical substance under all identified conditions of use within the statutory 3-year deadline.** Similarly, the requirements of 6(b)(4)(F) need to be satisfied for the overall chemical substance. EPA need not demonstrate that it has satisfied these requirements individually, with respect to each individual use of the chemical substance. This is because EPA is not conducting risk evaluations of individual uses of the chemical substance.

EPA does not interpret 6(b)(4)(D) as conferring discretion to exclude hazards, exposures, or conditions of use from the scope of the risk evaluation, or to exclude vulnerable subpopulations from the scope of the risk evaluation if the Administrator has previously identified them as relevant to the risk evaluation. The phrase “the Administrator expects to consider,” simply acknowledges that not all hazards, exposures, uses or populations will be relevant to every risk evaluation.

Respecting your particular questions:

1) Does EPA believe it has to do a full risk evaluation on all conditions of use? In that case, would any use that EPA did not find posed an unreasonable risk be part of a “no unreasonable risk determination” for that chemical, and would those also be subject to 18a preemption?

Response: EPA believes it has to do a full risk evaluation of the chemical substance, taking into account all circumstances that EPA determines qualify as "conditions of use" within the meaning TSCA section 3. But EPA would not make a “no unreasonable risk determination” with respect to individual uses. Although EPA may identify particular uses that present greater or lesser risks during the assessment, the unreasonable risk determination in section 6(i)(1) will ultimately be based on the chemical substance as a whole. Section 18(a) preemption would only apply to those uses “included in any final action...taken pursuant to 6(a) or 6(i)(1).” Irrespective of whether EPA ultimately concludes that the chemical substance presents an unreasonable risk or does not present an unreasonable risk, there would be no 18a preemption with respect to any “hazards, exposures, risks, [or] uses or conditions of use,” that EPA omits from the scope of the risk evaluation. See Section 18(c)(3).

2) Does EPA believe it has to CONSIDER all conditions of use, decide when it is prioritizing the chemical which uses meet the threshold for an RE and which do not, and document that as part of prioritization? In that case, would the uses that did not meet the threshold for an RE need to be deemed “low priority chemical conditions of use” or otherwise just not be in the RE, not subject to any final agency action (and thus not subject to any preemption)?

Response: There is no threshold for a condition of use to be included in the risk evaluation. A risk evaluation is based on “the conditions of use,” 6(b)(4)(A), which EPA interprets to mean all the circumstances that EPA determines qualify as "conditions of use" within the meaning TSCA section 3. The statute does not provide for EPA to designate “low priority” conditions of use. Only chemical substances can be “low priority.”

3) Does EPA believe it has to CONSIDER all conditions of use as part of scoping the RE, and that it also has to note which ones are getting a full RE in the scope and describe the reasons why it is not giving a full RE to some uses? In that case, for the uses that are not getting a full RE, would EPA be able to make a “no unreasonable risk” determination (and thus subject these uses to 18a preemption) even though EPA chose not to fully review them, or could these uses just receive no final agency action regulatory treatment and thus not be subject to 18a preemption?

Response: As noted above, EPA would not prepare a risk evaluation for any individual use. Where a risk evaluation involves evaluating uses with varying degrees of detail, the risk evaluation will explain why such variation was warranted. A use is “fully reviewed,” when it is reviewed in sufficient detail to be weighed, along with all the other uses, in making the overall determination whether the chemical substance presents an unreasonable risk or not. Thus, different uses could all be fully reviewed, **even though EPA may have conducted less refined analyses on some.** EPA can make a determination on a chemical substance (whether unreasonable risk or not unreasonable risk) notwithstanding the fact that **EPA's conclusions for some uses may be based on less refined analyses.** As noted above, if EPA simply omitted a use from consideration, there would be no 18a preemption with respect to that use. If particular parties believed that the level of detail with which a use was evaluated in a risk evaluation was so low as to constitute a *de facto* omission of that use from consideration, such claims would have to be adjudicated on a case-by-case basis.

4) Are there other alternatives that I haven't considered that better describe EPA's interpretation of the language?

Response: See discussion above.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, July 26, 2016 4:37 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: question on conditions of use and preemption

Sven

Something that I've been talking to a bunch of people about relates to the nature of EPA's obligation to assess all conditions of use associated with a chemical substance as part of a risk evaluation. It was this perceived obligation that led to the development of the partial RE language, so I understand EPA's general take – but I have some questions about how EPA interprets the final bill language, and how EPA would expect this to intersect with 18a preemption. While this isn't a time-sensitive request, it does bear directly on the RE and prioritization rulemakings, and I'm guessing your team is also asking itself these same questions. Thanks.

I'm pasting below some of the key references to conditions of use in the bill and in caps, my read on these – first question – is EPA's read consistent with mine (and if not, what am I missing)?:

(4) The term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. **IMPLIED – EPA SHOULD SURVEY/COLLECT THE KNOWN UNIVERSE OF USES FOR A SUBSTANCE**

(i) **HIGH-PRIORITY SUBSTANCES.**—The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. **MY READ – EPA CAN DEEM SOMETHING TO BE A HIGH PRIORITY CHEMICAL IF ANY USE MEETS THE “MAY PRESENT” THRESHOLD. LESS CLEAR TO ME - EPA COULD ALSO DETERMINE, AT THIS STAGE IN THE PROCESS, THAT SOME USES DO NOT MEET THIS THRESHOLD, BECAUSE OF THE HIGHLIGHTED LANGUAGE BELOW**

(A) **ESTABLISHMENT OF PROCESS.**—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

(4) **RISK EVALUATION PROCESS AND DEADLINES.**—

(i) (A) **IN GENERAL.**—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk

factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use. IMPLIED – EPA HAS TO DO A RISK EVALUATION ON ALL USES OF THE CHEMICAL. LESS CLEAR – COULD EPA ARGUE THAT IT ONLY HAS TO DO A FULL RISK EVALUATION ON ANY USE THAT MET THE “MAY PRESENT” THRESHOLD WHEN THE CHEMICAL WAS DESIGNATED A HIGH PRIORITY CHEMICAL?

(F) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

(v) describe the weight of the scientific evidence for the identified hazard and exposure. - IMPLIED – THIS LIST OF REQUIREMENTS APPLIES TO ALL USES OF THE CHEMICAL. LESS CLEAR – COULD EPA ARGUE THAT IT ONLY HAS TO DO A FULL RISK EVALUATION TO WHICH THESE REQUIREMENTS APPLY ON ANY USE THAT MET THE “MAY PRESENT” THRESHOLD WHEN THE CHEMICAL WAS DESIGNATED A HIGH PRIORITY CHEMICAL?

“(D) SCOPE.—The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider ...” THIS LANGUAGE SEEMS TO STATE THAT EPA DOES HAVE THE DISCRETION TO ONLY LOOK AT SOME OF THESE CONSIDERATIONS, INCLUDING CONDITIONS OF USE, AS PART OF A FULL RISK EVALUATION.

So the rest of my questions are as follows:

- 1) Does EPA believe it has to do a full risk evaluation on all conditions of use? In that case, would any use that EPA did not find posed an unreasonable risk be part of a “no unreasonable risk determination” for that chemical, and would those also be subject to 18a preemption?
- 2) Does EPA believe it has to CONSIDER all conditions of use, decide when it is prioritizing the chemical which uses meet the threshold for an RE and which do not, and document that as part of prioritization? In that case, would the uses that did not meet the threshold for an RE need to be deemed “low priority chemical conditions of use” or otherwise just not be in the RE, not subject to any final agency action (and thus not subject to any preemption)?
- 3) Does EPA believe it has to CONSIDER all conditions of use as part of scoping the RE, and that it also has to note which ones are getting a full RE in the scope and describe the reasons why it is not giving a full RE to some uses? In that case, for the uses that are not getting a full RE, would EPA be able to make a “no unreasonable risk” determination (and thus subject these uses to 18a preemption) even though EPA chose not to fully review them, or could these uses just receive no final agency action regulatory treatment and thus not be subject to 18a preemption?
- 4) Are there other alternatives that I haven’t considered that better describe EPA’s interpretation of the language?

18(a)(1) (B) CHEMICAL SUBSTANCES FOUND NOT TO PRESENT AN UNREASONABLE RISK OR RESTRICTED.—A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) for which the determination described in section 6(i)(1) is made, consistent with the scope of the risk evaluation under section (6)(b)(4)(D); or

(ii) for which a final rule is promulgated under section 6(a), after the effective date of the rule issued under section 6(a) for the chemical substance, consistent with the scope of the risk evaluation under section (6)(b)(4)(D).

c) SCOPE OF PREEMPTION.—Federal preemption under subsections (a) and (b) of statutes, criminal penalties, and administrative actions applicable to specific chemical substances shall apply only to—

(1) with respect to subsection (a)(1)(A), the chemical substances or category of chemical substances subject to a rule, order, or consent agreement under section 4, 5, or 6;

(2) with respect to subsection (b), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D);

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

(4) with respect to subsection (a)(1)(C), the uses of such chemical substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

Thanks
Michal

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****This is a RLSO of Section 5, comparing HLC version timestamped April 12, 2016 at 1:50pm to HLC version timestamped April, 18, 2016 at 3:38pm.**

[DISCUSSION DRAFT]

1 SEC. II. MANUFACTURING AND PROCESSING NOTICES.

2 Section 5 of the Toxic Substances Control Act (15
3 U.S.C. 2604) is amended—

4 (1) in subsection (a)—

5 (A) in paragraph (1)—

6 (i) by striking “Except as provided
7 in” and inserting “(A) Except as provided
8 in subparagraph (B) of this paragraph
9 and”;

10 (ii) by redesignating subparagraphs
11 (A) and (B) as clauses (i) and (ii), respec-
12 tively;

13 (iii) by striking all that follows “sig-
14 nificant new use” and inserting a period;
15 and

16 (iv) by adding at the end the fol-
17 lowing:

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

20 “(i) such person submits to the Adminis-
21 trator, at least 90 days before such manufac-
22 ture or processing, a notice, in accordance with

1 subsection (d), of such person's intention to
2 manufacture or process such substance and
3 such person complies with any applicable re-
4 quirement of or imposed under subsection (b),
5 (e), or (f); and

6 "(ii) the Administrator conducts a review
7 of the notice and either—

8 "(I) makes a determination under
9 paragraph (3)(A) and, as necessary, issues
10 an order under subsection (f)(1); or

11 "(II) makes a determination under
12 paragraph (3)(B) and issues an order
13 under subsection (e)(1)(B)."; and

14 (B) by adding at the end the following new
15 paragraphs:

16
17 "(3) REVIEW AND DETERMINATION.—

18 ~~"Before the end of the applicable review period,
which shall be the 90-day period for review under
paragraph (1), subject to any extensions made pursuant to
subsection (b), (c) or (e), and subject to section 18, the
Administrator shall review a notice received under
paragraph (1), and—"~~

19 Not later than 90 days after receipt of a notice under para-
20 graph (1), subject to section 18, the Administrator
21 shall review such notice and—

22 "(A) determine whether the relevant chem-
23 ical substance or significant new use may

Commented [GB1]: Seems like this should refer to the applicable review period, not the 90-day period, like SLC did. Isn't that the period in which the Administrator must do one of these things?

24 present an unreasonable risk of injury to health
25 or the environment, without consideration of
26 costs or other nonrisk factors, including an un-
27 reasonable risk to a potentially exposed or sus-

1 ceptible subpopulation identified as relevant by
2 the Administrator under the conditions of use,
3 and take applicable action under subsection (f)
4 or (g); or

5 “(B) determine that additional information
6 is necessary to make the determination under
7 subparagraph (A), and take applicable action
8 under subsection (e).

9 “(4) FAILURE TO RENDER DETERMINATION.—

10 ~~“(A) IN GENERAL.—The Administrator~~
11 ~~shall complete a review of a notice required by~~
 ~~this section within the applicable review period~~

12 “(BA) FAILURE TO RENDER DETERMINA-
13 TION.—If the Administrator fails to make a de-
14 termination on a notice under paragraph (3) by
15 the end of the applicable review period and the
16 notice has not been withdrawn by the sub-
17 mitter, the Administrator shall refund to the
18 submitter all applicable fees charged to the sub-
19 mitter for review of the notice pursuant to sec-
20 tion 26(b)(1), and the Administrator shall not
21 be relieved of any requirement to make such de-
22 termination.

23 “(CB) LIMITATIONS.—(i) A refund of appli-
24 cable fees under subparagraph (A) shall not be
25 made if the Administrator certifies that the

submitter has not provided information required

under subsections (b) or (e) or has otherwise

1 unduly delayed the process such that the Ad-
2 ministrator is unable to render a determination
3 within the applicable period of review.

4 “(ii) A failure of the Administrator to
5 render a decision shall not be deemed to con-
6 stitute a withdrawal of the notice.

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

11 “(5) ARTICLE CONSIDERATION.—The Adminis-
12 trator may require notification under this section for
13 the import or processing of a chemical substance as
14 part of an article or category of articles under para-
15 graph (1)(B) if the Administrator makes an affirma-
16 tive finding in a rule under paragraph (2) that the
17 reasonable potential for exposure to the chemical
18 substance through the article or category of articles
19 subject to the rule justifies notification.”;

20 (2) in subsection (b)—

21 (A) in the subsection heading, by striking
22 “TEST DATA” and inserting “INFORMATION”;

23 (B) in paragraph (1)—

24 (i) in subparagraph (A)—

- 1 (I) by striking “test data” and
- 2 inserting “information”; and
- 3 (II) by striking “such data” and
- 4 inserting “such information”; and
- 5 (ii) in subparagraph (B), by striking
- 6 “test data” and inserting “information”;
- 7 (C) in paragraph (2)—
- 8 (i) in subparagraph (A)—
- 9 (I) by striking “test data” and
- 10 inserting “information”;
- 11 (II) by striking “shall” and in-
- 12 sserting “may”; and
- 13 (III) by striking “data pre-
- 14 scribed” and inserting “information
- 15 prescribed”; and
- 16 (ii) in subparagraph (B)—
- 17 (I) by striking “Data” and in-
- 18 sserting “Information”;
- 19 (II) by striking “data” both
- 20 places it appears and inserting “infor-
- 21 mation”; and
- 22 (III) by striking “show” and in-
- 23 sserting “shows”;
- 24 (D) in paragraph (3)—

- 1 (i) by striking “Data” and inserting
- 2 “Information”; and
- 3 (ii) by striking “paragraph (1) or (2)”
- 4 and inserting “paragraph (1) or (2) of this
- 5 subsection or under subsection (e)”; and
- 6 (E) in paragraph (4)—
- 7 (i) in subparagraph (A)(i), by insert-
- 8 ing “, without consideration of costs or
- 9 other nonrisk factors” after “health or the
- 10 environment”; and
- 11 (ii) in subparagraph (C), by striking
- 12 “, except that” and all that follows
- 13 through “subparagraph (A)”;
14 (3) in subsection (c)—
- 15 (A) in the subsection heading, by inserting
- 16 “AND REVIEW” after “NOTICE”; and
- 17 (B) by striking “before which” and all that
- 18 follows through “subsection may begin”;
- 19 (4) in subsection (d)—
- 20 (A) by striking “test data” in paragraph
- 21 (1)(B) and inserting “information”;
- 22 (B) by striking “data” each place it ap-
- 23 pears in paragraph (1)(C) and paragraph (2)
- 24 and inserting “information”;

1 (C) in paragraph (2)(B), by striking “uses
2 or intended uses of such substance” and insert-
3 ing “uses of such substance identified in the no-
4 tice and any additional uses of such substance
5 that are reasonably foreseeable by the Adminis-
6 trator”; and

7 (D) in paragraph (3)—

8 (i) by striking “for which the notifica-
9 tion period prescribed in subsection (a),
10 (b), or (c)” and inserting “for which the
11 applicable review period”; and

12 (ii) by striking “such notification pe-
13 riod” and inserting “such period”;

14 (5) by amending subsection (e) to read as fol-
15 lows:

16 “(e) REGULATION WHEN AVAILABLE INFORMATION
17 IS INSUFFICIENT.—(1) If the Administrator determines
18 that the information available to the Administrator is in-
19 sufficient to permit the Administrator to make a deter-
20 mination in accordance with subsection (a)(3)(A) for a
21 chemical substance or significant new use with respect to
22 which notice is required by subsection (a)—

23 “(A) the Administrator—

1 (i) shall provide an opportunity for the
 2 submitter of the notice to submit the additional
 3 information within the applicable review period;

4 (ii) may, by agreement with the sub-
 5 mitter, extend the applicable review period for
 6 a reasonable time to allow the development and
 7 submission of the additional information under
 8 section 4; and

24 ~~“(iii) may extend the applicable review period as
 necessary and promulgate a rule, enter into a
 25 consent agreement, or issue an order under sec-
 26 tion 4 to require the development of the infor-
 27 mation; and~~

1 ~~“(iv) on receipt of the additional informa-
 2 tion the Administrator finds supports the deter-
 3 mination under subsection (a)(3)(A), which shall
 automatically extend the review period for 90 days,
 shall
 4 make the determination within 90 days of re-
 5 ceipt of the information; and~~

1 (iii) on receipt of the additional informa-
 2 tion complying with a rule, testing consent
 3 agreement, or order issued under section 4,
 4 may extend the review period not more than 90
 5 days to make a decision; and

6 “(B) the Administrator may issue an order to
 7 take effect on the expiration of the applicable review

Commented [GB2]: Not sure this is needed, since section 4 already provides for testing for this purpose, and this suggests that EPA and the applicant cannot by agreement extend the period to allow for the submitter to voluntarily develop information. But maybe that's intended, in which case this is fine.

Commented [GB3]: (ii) refers to “applicable” review period. Either formulation seems acceptable in this context, but should be consistent.

Commented [GB4]: (iii) is different from SLC in several ways. 1. It does not require EPA to make an (a)(3)(A) determination upon receipt of information, both because it merely allows EPA to extend upon receipt of info, and if EPA does extend, merely specifies that EPA “make a decision”, not “make the determination under subsection (a)(3)(A)” as SLC specified. 2. The section 4 reference seems too limiting. Even if (ii) is limited to info development under sec 4, (i) seems to contemplate voluntary submission of additional information. 3. This refers to EPA acting once information compliant with a rule, etc., is submitted, whereas SLC required action only upon receipt of information that supports the (a)(3)(A) determination.

8 period to prohibit or otherwise restrict the manufac-
9 ture, processing, distribution in commerce, use, or
10 disposal of the chemical substance, or manufacture
11 or processing of the chemical substance for a signifi-
12 cant new use, or any combination of such activities,
13 sufficient to allay the Administrator's initial concern
14 that, in the absence of sufficient information, the
15 substance or significant new use may present an un-
16 reasonable risk of injury to health or the environ-
17 ment.

1 “(2) In selecting among prohibitions and other re-
2 strictions to include in an order to be issued by the Admin-
3 istrator to meet the standard under paragraph (1), the
4 Administrator shall consider, to the extent practicable
5 based on reasonably available information, costs and other
6 nonrisk factors.

7 “(3) If the Administrator issues an order under para-
8 graph (1), the submitter of the notice under subsection
9 (a) may commence manufacture of the chemical sub-
10 stance, or manufacture or processing of the chemical sub-
11 stance for a significant new use, pursuant to this sub-
12 section only in compliance with the restrictions specified
13 in the order.

14 “(4) Not later than 90 days after issuing an order
15 under paragraph (1), the Administrator shall consider
16 whether to promulgate a rule pursuant to subsection
17 (a)(2) that identifies as a significant new use any manu-
18 facturing, processing, use, distribution in commerce, or
19 disposal of the chemical substance that does not conform
20 to the restrictions imposed by the order, and, as applica-
21 ble, initiate such a rulemaking or publish a statement de-
22 scribing the reasons of the Administrator for not initiating
23 such a rulemaking.

24 “(5) An order may not be issued under paragraph
25 (1) respecting a chemical substance—

1 “(A) later than 45 days before the expiration of
2 the notification period applicable to the manufacture
3 or processing of such substance under subsection
4 (a), (b), or (c); and

5 “(B) unless the Administrator has, on or before
6 the issuance of the order, notified, in writing, each
7 manufacturer or processor, as the case may be, of
8 such substance of the determination which underlies
9 such order.”;

10 (6) by amending subsection (f) to read as fol-
11 lows:

12 “(f) PROTECTION AGAINST POTENTIAL UNREASON-
13 ABLE RISKS.—

14 “(1) ORDERS.—If the Administrator determines
15 that the manufacture, processing, distribution in
16 commerce, use, or disposal of a chemical substance
17 or a significant new use with respect to which notice
18 is required by subsection (a), or that any combina-
19 tion of such activities, may present an unreasonable
20 risk of injury to health or the environment in ac-
21 cordance with subsection (a)(3)(A)—

22 “(A) the Administrator shall issue an
23 order, to take effect on or before the expiration
24 of the applicable review period to prohibit or
25 otherwise restrict the manufacture, processing,

1 distribution in commerce, use, or disposal of the
2 chemical substance, or of the chemical sub-
3 stance for a significant new use, sufficient to
4 allay the Administrator's initial concern that
5 the substance or significant new use may
6 present an unreasonable risk of injury to health
7 or the environment;

8 “(B) no person may commence manufac-
9 ture of the chemical substance, or manufacture
10 or processing of the chemical substance for a
11 significant new use, pursuant to this subsection
12 except in compliance with the restrictions speci-
13 fied in the order; and

14 “(C) not later than 90 days after issuing
15 an order under subparagraph (A), the Adminis-
16 trator shall consider whether to promulgate a
17 rule pursuant to subsection (a)(2) that identi-
18 fies as a significant new use any manufac-
19 turing, processing, use, distribution in com-
20 merce, or disposal of the chemical substance
21 that does not conform to the restrictions im-
22 posed by the order, and, as applicable, initiate
23 such a rulemaking or publish a statement de-
24 scribing the reasons of the Administrator for
25 not initiating such a rulemaking.

1 “(2) SELECTING PROHIBITIONS AND RESTRIC-
2 TIONS.—In selecting among prohibitions and other
3 restrictions to include in an order to be issued by
4 the Administrator to meet the standard under para-
5 graph (1), the Administrator shall consider, to the
6 extent practicable based on reasonably available in-
7 formation, ~~consider~~ costs and other nonrisk factors, and
8 such an order shall include a requirement described in
9 section 6(a).

10 “(3) PERSISTENT AND BIOACCUMULATIVE SUB-
11 STANCES.—For a chemical substance that is subject
12 to the requirements of this subsection and that the
13 Administrator determines, with respect to persist-
14 ence and bioaccumulation, scores high for 1 and ei-
15 ther high or moderate for the other, pursuant to the
16 TSCA Work Plan Chemicals Methods Document
17 published by the Administrator in February 2012
18 (or a successor scoring system), the Administrator
19 shall, in selecting among prohibitions and other re-
20 strictions to include in an order to be issued by the
21 Administrator to meet the standard under para-
22 graph (1), reduce the potential for exposure to the
23 substance to the ~~maximum~~ extent practicable.

24 “(4) WORKPLACE EXPOSURES.—To the extent
25 practicable, the Administrator shall consult with the

Commented [GB5]: Any requirement? Note this this doesn't limit EPA to imposing (a) requirements, it simply seems to require that the requirements we impose have to include a 6(a) requirement. Seems kind of arbitrary.

Commented [GB6]: Note deletion of “maximum” from required exposure reduction for PBTs.

1 Assistant Secretary of Labor for Occupational Safe-
2 ty and Health prior to adopting any prohibition or
3 other restriction under this subsection to address
4 workplace exposures.”;

5 (7) by amending subsection (g) to read as fol-
6 lows:

7 “(g) STATEMENT ON ADMINISTRATOR FINDING.—If
8 the Administrator finds, in accordance with subsection
9 (a)(3)(A), that a determination that the relevant chemical
10 substance or significant new use may present an unreason-
11 able risk of injury to health or the environment is not war-
12 ranted, then notwithstanding any remaining portion of the
13 applicable review period, the submitter of the notice may
14 commence manufacture for commercial purposes of the
15 chemical substance or manufacture or processing for a
16 commercial purposes for a significant new use, and the Ad-
17 ministrator shall make public a statement of the Adminis-
18 trator’s finding. Such a statement shall be submitted for
19 publication in the Federal Register as soon as is prac-
20 ticable before the expiration of such period. Publication
21 of such statement in accordance with the preceding sen-
22 tence is not a prerequisite to the manufacturing or proc-
23 essing of the substance with respect to which the state-
24 ment is to be published.”;

25 (8) in subsection (h)—

Commented [GB7]: Why is this “a commercial purpose” but line 14 says “commercial purposes”? Actually, both should probably be dropped, since 5(i) defines manufacture and processing for purposes of the section to refer only to mfr and processing for commercial purposes.

1 (A) in paragraph (1)(A), by inserting “,
2 including an unreasonable risk to a potentially
3 exposed or susceptible subpopulation identified
4 by the Administrator for the specific uses iden-
5 tified in the application” after “health or the
6 environment”;

7 (B) in paragraph (2), by striking “data”
8 each place it appears and inserting “informa-
9 tion”; and

10 (C) in paragraph (4), by striking “. A rule
11 promulgated” and all that follows through “sec-
12 tion 6(c)” and inserting “, ~~without consideration of costs or
13 other nonrisk factors,~~ includ-

14 ing an unreasonable risk to a potentially ex-
15 posed or susceptible subpopulation identified by
16 the Administrator under the conditions of use” ; and
17 (9) by amending subsection (i) to read as fol-
18 lows:

19 “(i) DEFINITIONS.—(1) For purposes of this section,
20 the terms ‘manufacture’ and ‘process’ mean manufac-
21 turing or processing for commercial purposes.

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

“(3) For purposes of this section, the term ‘applicable
review period’ means the period starting on the date the

Commented [GB8]: The striking of this language changes the relationship between 5(a) and 5(h) in current TSCA. Under current TSCA, this exemption (5h4) applies the same standard as the standard of review under (a), the logic being that EPA can exempt from new chemical review chemicals that it can determine upfront will meet the applicable standard. Since the review standard under the amended section 5(a) would be without consideration of cost or other nonrisk factors, it’s not clear why the standard to be excused from review would not include the same language about cost and nonrisk factors. (We had made a similar comment on SLC about the absence of the “cost and other nonrisk” language in (h)(1)(A), lines 1-6 at the top of this page).

1 Administrator receives a notice under subsection (a)(1)
2 and ending on the date the Administrator makes a deter-
3 mination under subsection (a)(3)(A), as extended pursu-
4 ant to subsection (c) or (e)(1)(A).”

Commented [GB9]: This formulation seems to change (or at least confuses) the operation of the applicable review period from SLC. Under SLC, the period was a defined period of time: the 90 days given under (a), plus any extensions under b, c, or e. This HLC formulation appears to say that the period doesn't end until EPA makes the a3A determination. Note that neither this draft nor the SLC draft actually requires EPA ever to make the a3A determination (and this draft makes it seem even more discretionary, per the comment above). Maybe the intent is that the applicable period end following any extensions under c or e1A with or without a determination, but it doesn't really say that.

Attachment 6
April 12, 2016

Senate Legislative Counsel
Draft Copy of O:\MCC\MCC16324.XML

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.

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SEC. __. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

- (1) by striking “test data” each place it appears and inserting “information”;
- (2) by striking “data” each place it appears and inserting “information”;
- (3) in subsection (a)—

- (A) in paragraph (1), by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and indenting accordingly;

- (B) by striking “(a) In General.—(1) Except” and inserting the following:

“(a) Notices.—

“(1) PROHIBITION AND REQUIREMENT.—

“(A) PROHIBITION.—Except”;

(C) in subparagraph (A) (as so designated)—

- (i) in the undesignated matter at the end, by striking “unless such person” and inserting the following: “unless the requirements of subparagraph (B) are fulfilled.

“(B) REQUIREMENTS.—~~Subparagraph (A) does not apply if—~~

- “(i) a person described in that subparagraph”;

- (ii) by striking “requirement of subsection (b).” and inserting the following: “requirement of or imposed under subsections (b), (e), or (f); and

- “(ii) the Administrator conducts a review of the notice; and

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

- “(bb) makes a determination under paragraph (3)(B) and issues an order under subsection (e)(1)(B).”; and

(D) by adding at the end the following:

“(3) REVIEW.—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

Commented [A1]: “Requirement” should probably be plural.

Commented [A2]: This is a new structure, which seems problematic. (A) provides that no one can commence manufacturing or processing of new a new chem or for new use except in compliance with (B), then (B) says that (A) doesn't apply if B is satisfied. That doesn't really make sense. Why re-word from current law? If it must be reworded, it would make more sense to start (B) by saying “The requirements of subparagraph (B) are fulfilled if” instead of “Subparagraph (A) does not apply if”.

Commented [A3]: Is there a reason this language is included here re the (f) order but not included in (bb) re the (e) order?

Commented [A4]: EPA TA: Why designate the first clause as (I)(aa) and the second clause as (bb)? Shouldn't this just be (I) and (II)?

Commented [A5]: TA request: Would it would to replace this with: “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)”

Commented [A6R5]: EPA TA: On further review, we now see better the issue you were trying to address with respect to (b) and (e). Our recommendation, consistent with past TA, is to develop one formulation that describes the period, including extensions, and use it consistently throughout the section, except where you mean something different. You could say: “Before the end of the applicable review period [or notification and review period] under (1), (b), (c) or (e). . .” In adapting this phrase for other subsections, you would need to change the reference to “(1)” to “(a)” or “(a)(1)”.

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1 consideration of costs or other nonrisk factors, including an unreasonable risk to a
2 potentially exposed or susceptible subpopulation identified as relevant by the
3 Administrator under the conditions of use, and take applicable action under subsection
4 (f) or (g); or

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

7 “(4) FAILURE TO RENDER DETERMINATION.—

8 “(A) IN GENERAL.—The Administrator shall complete a review of a notice required
9 by this section within the review period provided in this subsection and subsection (c).

10 “(B) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a
11 determination on a notice under paragraph (3) by the end of the applicable review
12 period, including an extension pursuant to subsection (d), and the notice has not been
13 withdrawn by the submitter, the Administrator shall refund to the submitter all
14 applicable fees charged to the submitter for review of the notice pursuant to section
15 26(b)(1), and the Administrator shall not be relieved of any requirement to make the
16 determination.

17 “(C) LIMITATIONS.—

18 “(i) IN GENERAL.—A refund of applicable fees under subparagraph (B) shall not
19 be made if the Administrator certifies that the submitter has not provided
20 information required under subsection (b) or (e) or has otherwise unduly delayed
21 the process so that the Administrator is unable to render a determination within
22 the applicable period of review.

23 “(ii) NO DECISION.—A failure of the Administrator to render a decision shall
24 not be considered a withdrawal of the notice.

25 “(iii) RELATIONSHIP TO OTHER LAW.—Nothing in this paragraph relieves the
26 Administrator or the submitter of the notice from any requirement of this section.

27 “(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this
28 section for the import or processing of a chemical substance as part of an article or category
29 of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a
30 rule under paragraph (2) that the reasonable potential for exposure to the chemical
31 substance through the article or category of articles subject to the rule justifies
32 notification.”;

33 (4) in subsection (b)—

34 (A) in the subsection heading, by striking “Test Data” and inserting “Information”;

35 (B) in paragraph (1)—

36 (i) in subparagraph (A)—

37 (I) by striking “rule promulgated” and inserting “rule, order, or consent

Commented [A7]: Note: if there are concerns about whether (3) above adequately accounts for (b) and (e), doesn't this raise the same concerns? Seems best to stick with one formulation.

Commented [A8]: (b) and (e)? This is really important – otherwise EPA will have to refund money despite an extension (including an agreed extension) under (e).

Commented [A9]: This seems redundant of (C)(iii) below

Commented [A10]: Doesn't really seem like the right title. The rest of section 5 doesn't seem like “other law”

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- 1 agreement"; and
- 2 (II) by inserting ", order, or consent agreement" after "such rule";
- 3 (ii) in subparagraph (B)(ii), by striking "promulgated" and inserting "or order";
- 4 and
- 5 (iii) in the undesignated matter at the end—
- 6 (I) by inserting "or order" after "such rule";
- 7 (II) by striking "subsection (a)(1)(A)" and inserting "subsection
- 8 (a)(1)(A)(i)"; and
- 9 (III) by striking "subsection (a)(1)(B)" and inserting "subsection
- 10 (a)(1)(A)(ii)";
- 11 (C) in paragraph (2)—
- 12 (i) in subparagraph (A)—
- 13 (I) in clause (ii), by striking "rule promulgated" and inserting "rule, order,
- 14 or consent agreement"; and
- 15 (II) in the undesignated matter at the end, by striking "shall" and inserting
- 16 "may"; and
- 17 (ii) in subparagraph (B)—
- 18 (I) in the matter preceding clause (i), by striking "Data" and inserting
- 19 "Information";
- 20 (II) in clause (i), by striking "subsection (a)(1)(A)" and inserting
- 21 "subsection (a)(1)(A)(i)"; and
- 22 (III) in clause (ii), by striking "subsection (a)(1)(B)" and inserting
- 23 "subsection (a)(1)(A)(ii)";
- 24 (D) in paragraph (3)—
- 25 (i) by striking "Data" and inserting "Information"; and
- 26 (ii) by inserting "of this subsection or under subsection (e)" after "(2)"; and
- 27 (E) in paragraph (4)—
- 28 (i) in subparagraph (A)(i), by inserting ", without consideration of costs or
- 29 other nonrisk factors" before the period at the end; and
- 30 (ii) in subparagraph (C), by striking ", except that" and all that follows through
- 31 "subparagraph (A)";
- 32 (5) in subsection (c)—
- 33 (A) in the subsection heading, by inserting "and Review" after "Notice"; and

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1 (B) in the first sentence, by striking “, prescribed by” and all that follows through
2 “begin.” and inserting “prescribed by subsection (a) or (b).”;
3 (6) in subsection (d)—
4 (A) in paragraph (2)—
5 (i) in subparagraph (B), by striking “uses or intended uses of such substance”
6 and inserting “uses of the substance identified in the notice and any additional
7 uses of the substance that are reasonably foreseeable by the Administrator”; and
8 (ii) in subparagraph (C), by inserting “, order, or consent agreement” after
9 “rule”; and
10 (B) in paragraph (3), by striking “notification” both places it appears;
11 (7) by striking subsections (e) through (g) and inserting the following:
12 “(e) Regulation When Available Information Is Insufficient.—
13 “(1) IN GENERAL.—If the Administrator determines that the information available to the
14 Administrator is insufficient to permit the Administrator to make a determination in
15 accordance with subsection (a)(3)(A) for a chemical substance or significant new use with
16 respect to which notice is required by subsection (a)—
17 “(A) the Administrator—
18 “(i) shall provide an opportunity for the submitter of the notice to submit the
19 additional information within the applicable notification and review period under
20 subsection (a), (b), or (c);
21 “(ii) may, by agreement with the submitter, extend the review period for a
22 reasonable time to allow the development and submission of the additional
23 information;
24 “(iii) may extend the notification and review period and promulgate a rule,
25 enter into a consent agreement, or issue an order under section 4 to require the
26 development of the information; and
27 “(iv) on receipt of additional information within the time prescribed pursuant to
28 (i), (ii), or (iii) that the Administrator finds supports the determination under
29 subsection (a)(3)(A), which shall automatically extend the notification and review
30 period for 90 days, shall make the determination not later than 90 days after
31 receipt of the information; and
32 “(B) the Administrator may issue an order to take effect on the expiration of the
33 applicable notification and review period under subsection (a), (b), or (c) to prohibit, or
34 otherwise restrict, the manufacture, processing, distribution in commerce, use, or
35 disposal of the chemical substance, or manufacture or processing of the chemical
36 substance for a significant new use, or any combination of such activities, sufficient to
37 allay the initial concern of the Administrator that, in the absence of sufficient

Commented [A11]: Note that (d)(3) still refers to the expiration of the period under a, b, or c and does not account for extensions under e.

Commented [A12]: Related to the TA above as to the review period: the structure of (e)(1)(A) contributes to the problem by merely allowing EPA to extend the period but then providing that EPA must act under a3A, despite the fact that the review period may not have been extended. We suggest the edits in the text to resolve this issue. We don't perceive that these change the intended effect but rather effectuate what we understand to be the intent.

Commented [A13]: Presumably it would be impossible (or nearly so) to get a test rule or order out, and get the info back, within the review period.

Commented [A14]: This is needed because, without it, this 90 days of review would be occurring outside the review period, which we don't appear to have authority to do under (a)(3).

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1 information, the substance or significant new use may present an unreasonable risk.

Commented [A15]: Should add "of injury to health or the environment". That should always follow "unreasonable risk".

2 "(2) CONSIDERATIONS.—In selecting among prohibitions and other restrictions to include
3 in an order to be issued by the Administrator to meet the standard under paragraph (1), the
4 Administrator shall consider, to the extent practicable based on reasonably available
5 information, costs and other nonrisk factors.

6 "(3) COMPLIANCE WITH ORDER.—If the Administrator issues an order under paragraph
7 (1), the submitter of the notice under subsection (a) may commence manufacture of the
8 chemical substance, or manufacture or processing of the chemical substance for a
9 significant new use pursuant to this paragraph only in compliance with the restrictions
10 specified in the order.

Commented [A16]: Should have comma after "use".

11 "(4) SIGNIFICANT NEW USE.—Not later than 90 days after issuing an order under
12 paragraph (1), the Administrator shall consider whether to promulgate a rule pursuant to
13 subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use,
14 distribution in commerce, or disposal of the chemical substance that does not conform to the
15 restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a
16 statement describing the reasons of the Administrator for not initiating such a rulemaking.

17 "(5) NOTIFICATION.—An order may not be issued under paragraph (1) respecting a
18 chemical substance—

19 "(A) later than 45 days before the expiration of the notification period applicable to
20 the manufacture or processing of the substance under subsection (a), (b), or (c); and

21 "(B) unless the Administrator has, on or before the issuance of the order, notified, in
22 writing, each manufacturer or processor, as the case may be, of the substance of the
23 determination which underlies the order.

24 "(f) Protection Against Potential Unreasonable Risks.—

25 "(1) IN GENERAL.—If the Administrator determines that the manufacture, processing,
26 distribution in commerce, use, or disposal of a chemical substance or a significant new use
27 with respect to which notice is required by subsection (a), or that any combination of such
28 activities, may present an unreasonable risk of injury to health or environment in
29 accordance with subsection (a)(3)(A)—

30 "(A) the Administrator shall issue an order, to take effect on or before the expiration
31 of the applicable notification and review period under subsection (a), (b), or (c), to
32 prohibit or otherwise restrict the manufacture, processing, distribution in commerce,
33 use, or disposal of the chemical substance, or of the chemical substance for a
34 significant new use, sufficient to allay the initial concern of the Administrator that the
35 substance or significant new use may present an unreasonable risk;

Commented [A17]: Need to add (e), to account for (f) orders EPA issues following review of info obtained under an (e) extension.

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

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1 “(C) not later than 90 days after issuing an order under subparagraph (A), the
2 Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2)
3 that identifies as a significant new use any manufacturing, processing, use, distribution
4 in commerce, or disposal of the chemical substance that does not conform to the
5 restrictions imposed by the order, and, as applicable, initiate such a rulemaking or
6 publish a statement describing the reasons of the Administrator for not initiating such a
7 rulemaking.

8 “(2) CONSIDERATIONS.—In selecting among prohibitions and other restrictions to include
9 in an order to be issued by the Administrator to meet the standard under paragraph (1), the
10 Administrator shall, to the extent practicable based on reasonably available information,
11 consider costs and other nonrisk factors.

12 “(3) INCLUSIONS.—An order issued by the Administrator to meet the standard under
13 paragraph (1) may include—

14 “(A) a requirement limiting the amount of the chemical substance which may be
15 manufactured, processed, or distributed in commerce;

16 “(B) a requirement described in paragraph [(2), (3), (4), (5), (6), or (7) of section
17 6(a)]; or

18 “(C) any combination of the requirements referred to in subparagraph (B).

19 “(4) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance that is
20 subject to the requirements of this subsection and that the Administrator determines, with
21 respect to persistence and bioaccumulation, scores high for 1 and either high or moderate
22 for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by
23 the Administrator in February 2012 (or a successor scoring system), the Administrator shall,
24 in selecting among prohibitions and other restrictions to include in an order to be issued by
25 the Administrator to meet the standard under paragraph (1), reduce the potential for
26 exposure to the substance, to the maximum extent practicable.

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

30 “(g) Statement of Administrator Findings.—

31 “(1) IN GENERAL.—If the Administrator finds, in accordance with subsection (a)(3)(A),
32 that a determination that the relevant chemical substance or significant new use may present
33 an unreasonable risk of injury to health or the environment is not warranted, then
34 notwithstanding any remaining portion of the period for review under subsection (a), (b), or
35 (c) applicable to the manufacturing or processing of the substance or of the substance for a
36 significant new use—

37 “(A) the submitter of the notice may commence manufacture for commercial
38 purposes of the chemical substance or manufacture or processing of the chemical
39 substance for a significant new use;

Commented [A18]: Per earlier TA, we continue to wonder why (A) and (B) aren't merged into a single provision authorizing EPA to issue any restrictions allowed under 6(a). If a reference to "all uses" is added to TSCA 6(a)(2) per the Senate offer, this is probably harmless, but on its face (A) omits the portion of 6(a)(1) allowing EPA to prohibit manufacture, processing and distribution in commerce, and EPA will not be able to issue such a prohibition if the senate offer language does not stick. We also continue to wonder why the allowable order conditions are constrained for (f) orders – issued upon a "may present" finding – but not for (e) orders – issued based only on lack of information.

Commented [A19]: Or (e)?

Commented [A20]: This highlighted phrase should be dropped. Be consistent in reference to the period – you haven't used this elsewhere in referring to the period.

Commented [A21]: Any reason this modifies mfr of a new chemical but not mfr and processing for a SNU later in the subparagraph?

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- 1 “(B) the Administrator shall make public a statement of the finding of the
2 Administrator; and
- 3 “(C) the Administrator shall submit the statement described in subparagraph (B) for
4 publication in the Federal Register as soon as is practicable before the expiration of the
5 period for review.
- 6 “(2) PUBLICATION.—Publication of a statement in accordance with paragraph (1)(C) is
7 not a prerequisite to the manufacturing or processing of the substance with respect to which
8 the statement is to be published.”;
- 9 (8) in subsection (h)—
- 10 (A) in paragraph (1)—
- 11 (i) in subparagraph (A), by striking “environment,” and inserting “environment,
12 including an unreasonable risk to a potentially exposed or susceptible
13 subpopulation identified by the Administrator for the specific uses identified in
14 the application;” and
- 15 (ii) in subparagraph (B), by striking “appropriate” and inserting “warranted”;
16 and
- 17 (B) beginning in the first sentence of paragraph (4), by striking “environment.” and
18 all that follows through the “section 6(c).” and inserting “environment, without
19 consideration of costs or other nonrisk factors, including an unreasonable risk to a
20 potentially exposed or susceptible subpopulation identified by the Administrator under
21 the conditions of use.”; and
- 22 (9) by striking subsection (i) and inserting the following:
- 23 “(i) Definitions.—
- 24 “(1) MANUFACTURE; PROCESS.—In this section, the terms ‘manufacture’ and ‘process’
25 mean manufacturing or processing for commercial purposes.
- 26 “(2) REQUIREMENT.—For purposes of this Act, the term ‘requirement’ as used in this
27 section shall not displace any statutory or common law.”.
- 28

Commented [A22]: EPA TA: Did you intend to drop the proviso that this would be without consideration of costs or other nonrisk factors? You included the proviso in the exemption under (h)(4), so there will be a very definite implication here that you intend to have EPA consider cost and non-risk factors when weighing a test marketing exemption application.

Attachment 7

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.

(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 a 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

(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

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 4.

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.

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.

(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.

(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

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 **issued** 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.

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 mandatory (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.

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)."

(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—

Commented [A48]: Leg counsel to conform x-refs as needed in para (3)

(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

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.

(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.

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.

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.

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.

(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

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 **justified**" 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 "finding"? 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 information on 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 information 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, 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 information 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

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.

(4) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the

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.

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]