

Detailed Analysis and Additional Views of Democratic Members on the Motion to Concur in the House Amendment to the Senate Amendment to the Bill H.R. 2576 Entitled “An Act to Modernize the Toxic Substances Control Act, and for Other Purposes”

June 7, 2016

As the lead Senate Democratic negotiators on H.R. 2576, (hereinafter referred to as the Frank R. Lautenberg Chemical Safety for the 21st Century Act), we submit the following additional views that describe the intent of the negotiators on elements of the final bill text.

1. “Will Present”

Existing TSCA as in effect before the date of enactment of Frank R Lautenberg Chemical Safety for the 21st Century Act includes the authority, contained in several sections (see, for example, section 6(a)), for EPA to take regulatory actions related to chemical substances or mixtures if it determines that the chemical substance or mixture “presents or will present” an unreasonable risk to health or the environment.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act includes language that removes all instances of “will present” from existing TSCA and the amendments thereto. This does not reflect an intent on the part of Congressional negotiators to remove EPA's authority to consider future or reasonably anticipated risks in evaluating whether a chemical substance or mixture presents an unreasonable risk to health or the environment. In fact, a new definition added to TSCA explicitly provides such authority and a mandate for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur:

“(4) The term ‘conditions of use’ means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of”;

2. Mixtures

In section 6(b) of TSCA, as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, EPA is directed to undertake risk evaluations on chemical substances

in order to determine whether they pose an unreasonable risk to health or the environment. Some have questioned whether the failure to explicitly authorize risk evaluations on mixtures calls into question EPA's authority to evaluate the risks from chemical substances in mixtures.

The definition of 'conditions of use' described above plainly covers all uses of a chemical substance, including its incorporation in a mixture, and thus would clearly enable and require, where relevant, EPA to evaluate the risks of the chemical substance as a component of a mixture.

3. New Chemicals

While existing TSCA does not preclude EPA from reviewing new chemicals and significant new uses following notification by the manufacturer or processor, it does not require EPA to do so or to reach conclusions on the potential risks of all such chemicals before they enter the marketplace. EPA has authority to issue orders blocking or limiting production or other activities if it finds that available information is inadequate and the chemical may present an unreasonable risk, but the burden is on EPA to invoke this authority; if it fails to do so within the 90-180 day review period, manufacture of the new chemical can automatically commence. This bill makes significant changes to this passive approach under current law: For the first time, EPA will be required to review all new chemicals and significant new uses and make an affirmative finding regarding the chemical's or significant new use's potential risks as a condition for commencement of manufacture for commercial purposes and, in the absence of a finding that the chemical or significant new use is not likely to present an unreasonable risk, manufacture will not be allowed to occur. If EPA finds that it lacks sufficient information to evaluate the chemical's or significant new use's risks or that the chemical or significant new use does or may present an unreasonable risk, it is obligated to issue an order or rule that precludes market entry or imposes conditions sufficient to prevent an unreasonable risk. EPA can also require additional testing. Only chemicals and significant new uses that EPA finds are not likely to present an unreasonable risk can enter production without restriction. This affirmative approach to better ensuring the safety of new chemicals entering the market is essential to restoring the public's confidence in our chemical safety system.

4. Unreasonable Risk

TSCA as in effect before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act authorized EPA to regulate chemical substances if it determined that the chemical substance "presents or will present an unreasonable risk of injury to health or the environment." In its decision in *Corrosion Proof Fittings vs EPA*, the U.S. Court of Appeals, 5th Circuit overturned EPA's proposed ban on asbestos, in part because it believed that "In evaluating what is 'unreasonable,' the EPA is required to consider the costs of any proposed actions and to 'carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.'" 15 U.S.C. Sec. 2601(c).

As the District of Columbia Circuit stated when evaluating similar language governing the Federal Hazardous Substances Act, "[t]he requirement that the risk be 'unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." *Forester v. CPSC*, 559 F.2d 774 789 (D.C.Cir.1977). We have quoted this language approvingly when evaluating other statutes using similar language. See, e.g., *Aqua Slide*, 569 F.2d at 839."

The Frank R Lautenberg Chemical Safety for the 21st Century Act clearly rejects that approach to determining what "unreasonable risk of injury to health or the environment" means, by adding text that directs EPA to determine whether such risks exist "without consideration of costs or other nonrisk factors" and, if they do, to promulgate a rule that ensures "that the chemical substance no longer presents such risk." In this manner, Congress has ensured that when EPA evaluates a chemical to determine whether it poses an unreasonable risk to health or the environment and regulates the chemical if it does, the Agency may not apply the sort of "balancing test" described above.

5. Prioritization

Section 6(b) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, defines high-

priority chemical substances and low-priority chemical substances as follows:

“(i) 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 environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

“(ii) LOW-PRIORITY SUBSTANCES.--The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.”

The direction to EPA for the designation of low-priority substances is of note in that it requires such designations to be made only when there is “information sufficient to establish” that the standard for designating a substance as a high-priority substance is not met. Clear authority is provided under section 4(a)(2)(B), as created in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to enable EPA to obtain the information needed to prioritize chemicals for which information is initially insufficient. The bill text also goes on to state that if “the information available to the Administrator at the end of such an extension [for testing of a chemical substance in order to determine its priority designation] remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.”

These provisions are intended to ensure that the only chemicals to be designated low-priority are those for which EPA both has sufficient information and, based on that information, affirmatively concludes that the substance does not warrant a finding that it may present an unreasonable risk.

6. Industry Requested Chemicals

Sec. 6(b)(4)(E) sets the percentage of risk evaluations that the Administrator shall conduct at industry's request at

between 25 percent (if enough requests are submitted) and 50 percent. The Administrator should set up a system to ensure that those percentages are met and not exceeded in each fiscal year. An informal effort that simply takes requests as they come in and hopes that the percentages will work out does not meet the requirement that the Administrator "ensure" that the percentages be met. Also, clause (E)(ii) makes clear that industry requests for risk evaluations "shall be" subject to fees. Therefore, if at any point the fees imposed by the Frank Lautenberg Act (which are subject to a termination in section 26(b)(6)) are allowed to lapse, industry's opportunity to seek risk evaluations will also lapse and the minimum 25 percent requirement will not apply.

7. Pace of and long-term goal for EPA safety reviews of existing chemicals

Existing TSCA grandfathered in tens of thousands of chemicals to the inventory without requiring any review of their safety. The Frank R. Lautenberg Chemical Safety for the 21st Century Act sets in motion a process under which EPA will for the first time systematically review the safety of chemicals in active commerce. While this will take many years, the goal of the legislation is to ensure that all chemicals on the market get such a review. The initial targets for numbers of reviews are relatively low, reflecting current EPA capacity and resources. These targets represent floors, not ceilings, and Senate Democratic negotiators expect that as EPA begins to collect fees, gets procedures established and gains experience, these targets can be exceeded in furtherance of the legislation's goals.

8. "Maximum" extent practicable

Several sections of the Frank R. Lautenberg Chemical Safety for the 21st Century Act include direction to EPA to take certain actions to "the extent practicable", in contrast to language in [S 697](#) as reported by the Senate that actions be taken to "the maximum extent practicable." During House-Senate negotiations on the bill, Senate negotiators were informed that House Legislative Counsel believed the terms "extent practicable" and "maximum extent practicable" are synonymous, and ultimately Congress agreed to include "extent practicable" in the Frank R. Lautenberg Chemical

Safety for the 21st Century Act with the expectation that no change in meaning from S. 697 as reported by the Senate be inferred from that agreement.

9. Cost considerations in rulemaking

Section 6(c)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act lists what is required in analysis intended to support an EPA rule for a chemical substance or mixture:

“(2) REQUIREMENTS FOR RULE.--“(A) STATEMENT OF EFFECTS.--

In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to--

“(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

“(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

“(iii) the benefits of the chemical substance or mixture for various uses; and

“(iv) the reasonably ascertainable economic consequences of the rule, including consideration of--

“(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

“(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

“(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

The language above specifies the information on effects, exposures and costs that EPA is to consider in determining how to regulate a chemical substance that presents an unreasonable risk as determined in EPA's risk evaluation.

Senate Democratic negotiators clarify that sections 6(c)(2)(A)(i) and (ii) do not require EPA to conduct a second risk evaluation-like analysis to identify the specified information, but rather, can satisfy these requirements on the basis of the conclusions regarding the chemical's health and environmental effects and exposures in the risk evaluation itself.

The scope of the statement EPA is required to prepare under clauses (i)-(iv) is bounded in two important respects. First, it is to be based on information reasonably available to EPA, and hence does not require new information collection or development. Second, EPA's consideration of costs and benefits and cost-effectiveness is limited to the requirements of the rule itself and the 1 or more "primary" alternatives it considered, not every possible alternative. The role of the statement required under subparagraph (c)(2)(A) in selecting the restrictions to include in its rule is delineated in subparagraph (c)(2)(B). Under this provision, EPA must "factor in" the considerations described in the statement "to the extent practicable" and "in accordance with subsection (a)." As revised, subsection (a) deletes the paralyzing "least burdensome" requirement in the existing law and instructs that EPA's rule must ensure that the chemical substance or mixture "no longer presents" the unreasonable risk identified in the risk evaluation. Thus, it is clear that the considerations in the statement required under subparagraph (c)(2)(A) do not require EPA to demonstrate benefits outweigh costs, to definitively determine or select the least-cost alternative, or to select an option that is demonstrably cost-effective or is the least burdensome adequately protective option. Rather, it requires only that EPA take into account the specified considerations in deciding among restrictions to impose, which must be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified. The Frank R. Lautenberg Chemical Safety for the 21st Century Act clearly rejects the regulatory approach and framework that led to the failed asbestos ban and phase-out rule of 1989 in *Corrosion Proof Fittings v. EPA* 947 F.2d 1201 (5th Cir. 1991).

10. "Minimum" labeling requirements

Section 6(a) of TSCA, as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, ensures that the requirements EPA can impose to address an unreasonable risk to health or the environment include requiring "clear and adequate minimum" warnings. The addition of the word "minimum" was intended to avoid the sort of litigation that was undertaken in *Wyeth v. Levine*, 555 U.S. 555 (2009), when a plaintiff won a Supreme Court decision after alleging that the harm she suffered from a drug that had been labeled in

accordance with FDA requirements had nevertheless been inadequately labeled under Vermont law. This ensures that manufacturers or processors of chemical substances and mixtures can always take additional measures, if in the interest of protecting health and the environment, it would be reasonable to do so.

11. Critical Use Exemptions

Section 6(g) of TSCA, as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, authorizes EPA to exempt specific conditions of use from otherwise applicable section 6(a) rule requirements, if EPA makes specified findings. Section 6(g)(4) in turn requires EPA to include in such an exemption conditions that are "necessary to protect health and the environment while achieving the purposes of the exemption." It is Congress' intent that the conditions EPA imposes will protect health and the environment to the extent feasible, recognizing that, by its nature, an exemption will allow for activities that present some degree of unreasonable risk.

12. Regulatory Compliance

Several sections of the Frank R. Lautenberg Chemical Safety for the 21st Century Act clarify the Congressional intent that compliance with federal EPA standards, rules or other requirements shall not preclude liability in circumstances where a reasonable manufacturer or processor or distributor of a chemical substance or mixture could or should have taken additional measures or precautions in the interest of protecting public health and the environment.

13. TSCA as the Primary Statute for the Regulation of Toxic Substances

EPA's authorities and duties under section 6 of TSCA have been significantly expanded under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, now including comprehensive deadlines and throughput expectations for chemical prioritization, risk evaluation, and risk management. The interagency referral process and the intra-agency consideration process established under Section 9 of existing TSCA must now be regarded in a different light since

TSCA can no longer be construed as a "gap-filler" statutory authority of last resort. The changes in section 9 are consistent with this recognition and do not conflict with the fundamental expectation that, where EPA concludes that a chemical presents an unreasonable risk, the Agency should act in a timely manner to ensure that the chemical substance no longer presents such risk. Thus, once EPA has reached this conclusion, Section 9(a) is not intended to supersede or modify the Agency's obligations under Sections 6(a) or 7 to address risks from activities involving the chemical substance, except as expressly identified in a section 9(a) referral for regulation by another agency which EPA believes has sufficient authority to eliminate the risk and where the agency acts in a timely and effective manner to do so.

Regarding EPA's consideration of whether to use non-TSCA EPA authorities in order to address unreasonable chemical risks identified under TSCA, the new section 9(b)(2) merely consolidates existing language which was previously split between section 6(c) and section 9(b). It only applies where the Administrator has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities. It allows the Administrator substantial discretion to use TSCA nonetheless, and it certainly does not reflect that TSCA is an authority of last resort in such cases. Importantly, the provision adds a new qualification, not in original TSCA, that the required considerations are to be "based on information reasonably available to the Administrator" to ensure that such considerations do not require additional information to be collected or developed. Furthermore, none of these revisions were intended to alter the clear intent of Congress, reflected in the original legislative history of TSCA, that these decisions would be completely discretionary with the Administrator and not subject to judicial review in any manner.

14. Disclosure of Confidential Business Information

S. 697 as passed by the Senate included several requirements as amendments to sections 8 and 14 of existing TSCA that direct EPA to "promptly" make confidential business information public when it determines that protections against disclosure of such information should no longer apply. The Frank R. Lautenberg Chemical Safety for the

21st Century Act instead directs EPA to remove the protections against disclosure when it determines that they should no longer apply. Because EPA informed Senate negotiators that its practice is to promptly make public information that is no longer protected against disclosure, we see no difference or distinction in meaning between the language in S. 697 as passed and the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and expect EPA to continue its current practice of affirmatively making public information that is not or no longer protected from disclosure as expeditiously as possible.

Subsection 14(d)(9) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, further clarifies the Congressional intent that any information required pursuant to discovery, subpoena, court order, or any other judicial process is always allowable and discoverable under State and Federal law, and not protected from disclosure.

15. Chemical Identity

Section 14(b)(2) of the bill retains TSCA's provision making clear that information from health and safety studies is not protected from disclosure. It also retains TSCA's two existing exceptions from disclosure of information from health and safety studies: for information where disclosure would disclose either how a chemical is manufactured or processed or the portion a chemical comprises in a mixture. A clarification has been added to the provision to note explicitly that the specific identity of a chemical is among the types of information that need not be disclosed, when disclosing health and safety information, if doing so would also disclose how a chemical is made or the portion a chemical comprises in a mixture. This clarification does not signal any Congressional intent to alter the meaning of the provision, only to clarify its intent.

16. "Requirements"

Subsection 5(i)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA

action or inaction on a chemical substance.

Subsection 6(j) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA action or inaction on a chemical substance.

17. State-Federal Relationship

Sections 18(a)(1)(B) and 18(b)(1) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, refer to circumstances under which a state may not establish or continue to enforce a "statute, criminal penalty, or administrative action" on a chemical substance. Section 18(b)(2) states that "this subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any statute enacted, criminal penalty assessed, or administrative action taken". In an email transmitted by Senate Republican negotiators at 11:45 AM on May 23, 2016, the Senate requested that House Legislative Counsel delete the word "assessed," but this change was not made in advance of the 12 PM deadline to file the bill text with the House Rules Committee. The Senate's clear intent was not to change or in any way limit the meaning of the phrase "criminal penalty" in section 18(b)(2).

Section 18(d)(I) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, references "risk evaluations" on chemical substances that may be conducted by states or political subdivisions of states with the clear intent to describe the circumstances in which such efforts would not be preempted by federal action. The term "Risk Evaluation" may not be universally utilized in every state or political subdivision of a state, but researching each analogous term used in each state or political subdivision of a state in order to explicitly list it was neither realistic nor possible. The use of this term is not intended to be in any way limiting.

Section 18(d)(1)(A)(ii) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, fully preserves the authority of states or political subdivisions of states to impose "information obligation" requirements on manufacturers or processors with respect to chemicals they produce or use. The provision cites examples of such

obligations: reporting and monitoring or ``other information obligations." These may include, but are not limited to, state requirements related to information, such as companies' obligations to disclose use information, to provide warnings or to label products or chemicals with certain information regarding risks and recommended actions to reduce exposure or environmental release.

Section 18(d)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, specifies that nothing in this section shall modify the preemptive effect of any prior rule or order by the Administrator prior to the effective date, responding to concerns that prior EPA action on substances such as polychlorinated biphenyls would be potentially immunized from liability for injury or harm.

Section 18(e) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, grandfather existing and enacted state laws and regulatory actions, and requirements imposed now or in the future under the authority of state laws that were in effect on August 31, 2003.

Section 18(f) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, provides discretionary and mandatory waivers which exempt regulatory action by states and their political subdivisions from any federal preemptive effect. In particular, Subsection 18(f)(2)(B) specifies that, where requested, EPA shall grant a waiver from preemption under subsection (b) upon the enactment of any statute, or the proposal or completion of a preliminary administrative action, with the intent of prohibiting or otherwise restricting a chemical substance or mixture, provided these actions occur during the 18-month period after EPA initiates the prioritization process and before EPA publishes the scope of the risk evaluation for the chemical substance (which cannot be less than 12 months after EPA initiates the prioritization process).

Section 18(g) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, specifies that no preemption of any common law or statutory causes of action for civil relief or criminal conduct shall occur, and that nothing in this Act shall be interpreted as dispositive or otherwise limiting any civil action or other claim for relief. This section also clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA action or inaction on

a chemical substance. This section further clarifies Congress' intent that no express, implied, or actual conflict exists between any federal regulatory action and any state, federal, or maritime tort action, responding to the perceived conflict contemplated in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) and its progeny.

18. Fees

Fees under section 26(b), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, are authorized to be collected so that 25% of EPA's overall costs to carry out section 4, 5, and 6, and to collect, process, review, provide access to and protect from disclosure information, are defrayed, subject to a \$25,000,000 cap (that itself can be adjusted for inflation or if it no longer provides 25% of EPA's costs listed above). While the collection of fees is tied to the submission of particular information under sections 4 and 5 or the manufacturing or processing of a particular chemical substance undergoing a risk evaluation under section 6, in general the use of these fees is not limited to defraying the cost of the action that was the basis for payment of the fee. The exception to this general principle is for fees to defray the cost of conducting manufacturer requested risk evaluations, which are independent of the \$25 million cap or 25% limit. These must be spent on the particular risk evaluation that was the basis for payment of the fee. This limitation applies only to the fee collected for the purpose of conducting the risk evaluation and does not prevent EPA from collecting further fees from such persons for other purposes for which payment of fees are authorized under the section. For example, if a manufacturer-requested risk evaluation later leads to risk management action, EPA may assign further fees to manufacturers and processors of that substance, subject to the \$25,000,000 cap and the requirement to not exceed 25% of overall program costs for carrying out sections 4, 5, and 6, and to collect, process, review, provide access to and protect from disclosure information.

We also note that some have raised the possibility that section 26(b)(4)(B)(i)(I), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, could be read to exclude the cost of risk evaluations, other than industry-requested risk evaluations, from the costs that can be covered by fees. This was not the intent and is not

consistent with the statutory language. As clearly indicated in section 26(b)(1), the amended law provides that manufacturers and processors of chemicals subject to risk evaluations be subject to fees, and that fees be collected to defray the cost of administering sections 4, 5, and 6, and of collecting, processing, reviewing and providing access to and protecting from disclosure information. Risk evaluations are a central element of section 6. And as demonstrated by section 6(b)(4)(F)(i), the intent of the bill is that the EPA-initiated risk evaluations be defrayed at the 25% level (subject to the \$25,000,000 cap), in contrast to the industry-initiated evaluations, which are funded at the 50% or 100% level. The final citation in section 26(b)(4)(B)(i) should be read as section 6(b)(4)(C)(ii), as it is in section 6(b)(4)(F)(i), not to section 6(b) generally.

19. Scientific Standards

The term "weight of evidence" refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

This requirement is not intended to prevent the Agency from considering academic studies, or any other category of study. We expect that when EPA makes a weight of the evidence decision it will fully describe its use and methods.

20. Partial Risk Evaluations

Section 26(1)(4) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, states "(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.--With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."

EPA has completed risk assessments on TCE, NMP, and MC, but has not yet proposed or finalized section 6(a) rules to address the risks that were identified. The risk assessments for these chemicals were not conducted across all conditions of use. During the bi-cameral negotiations, EPA expressed the view that, rather than reexamine and perhaps broaden the scope of these assessments, it is better to proceed with proposed and final rules on the covered chemicals to avoid any delay in the imposition of important public health protections that are known to be needed. Congress shared these concerns. The language House-Senate negotiators included above is intended to allow EPA to proceed with the regulation of these substances if the scope of the proposed and final rules is consistent with the scope of the risk assessments conducted on these substances.

21. SNURs for Articles

Section 5(a)(5) addresses the application of significant new use rules (SNURs) to articles or categories of articles containing substances of concern. It provides that in promulgating such SNURs, EPA must make "an affirmative finding . . . that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification." This language clarifies that potential exposure is a relevant factor in applying SNURs to articles. Exposure is a relevant factor in identifying other significant new uses of a chemical substance as well. It is not intended to require EPA to conduct an exposure assessment or provide evidence that exposure to the substance through the article or category of articles will in fact occur. Rather, since the goal of SNURs is to bring to EPA's attention and enable it to evaluate uses of chemicals that could present unreasonable risks, a reasonable expectation of possible exposure based on the nature of the substance or the potential uses of the article or category of articles will be sufficient to "warrant notification." EPA has successfully used the SNUR authority in the existing law to provide for scrutiny of imported articles (many of which are widely used consumer products) that contain unsafe chemicals that have been restricted or discontinued in the U.S. and it's critical that SNURs continue to perform this important public health function under the amended law.

22. Compliance Deadlines

The amended law expands on existing section 6(d) by providing that rules under section 6 must include "mandatory compliance dates." These dates can vary somewhat with the type of restriction being imposed but, in general, call for compliance deadlines that "shall be as soon as practicable, but not later than 5 years after the promulgation of the rule." While EPA could in unusual circumstances delay compliance for as long as five years, this should be the exception and not the norm. To realize the risk reduction benefits of the rule, it is expected that compliance deadlines will be as soon as practicable after the rule's effective date as directed in new paragraph 6(d)(1).

Senator Barbara Boxer, Ranking Member, Environment and Public Works Committee.

Senator Edward J. Markey, Ranking Member, Subcommittee on Superfund, Waste Management and Regulatory Oversight, Environment and Public Works Committee, and cosponsor, Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Senator Tom Udall, lead Democratic author and sponsor, Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Senator Jeffrey A. Merkley, cosponsor, Frank R. Lautenberg Chemical Safety for the 21st Century Act.