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 “The Frank R. Lautenberg Chemical Safety for the 21st Century 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 thereof. The text that reflects an interest in the part of Congressional negotiators to remove EPA’s authority to consider future or reasonably anticipated risks in evaluating whether a chemical substance presents an unreasonable risk to health or the environment.

In fact, a new definition of the part of Congressional negotiators to rewrite TSCA language to evaluate the risks of the chemical substance, including its incorporation into mixtures, where relevant, concludes that EPA to invoke this authority.

The text also suggests that the requirement that EPA determines “that the chemical substance a chemical substance that such substance does not meet the standard 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 text also suggests that the information available to the Administrator at the end of such an extension [for testing of a chemical substance in order to determine whether it is a priority substance] is 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 has both sufficient information and, based on that information, affirmatively concludes that the substance does not warrant a finding that 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 intent that the Administrator “shall” ensure that the percentages be met. Also, clause (E)(ii) makes clear that industry requests for risk evaluations “shall” be subject to a system that ensures that 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. Face of and Long-Term Goal for EPA Safety Reviews of Existing Chemicals

EPA’s Chemical Substance Inventory contains thousands of chemicals to the inventory without requiring any review of their safety. The Frank R. Lautenberg Chemical Safety for the 21st Century Act creates a long-term process under which FEMA will for the first time systematically review the safety of chemicals in active commerce. While this will take many years, the long-term 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 resources. These targets represent floors, not ceilings, and Senate Democratic negotiators expect that as EPA begins to collect fees, gets productivity up, and begins reviewing more chemicals, these targets can be exceeded in furtherance of the legislation’s goals.
Section 6(c)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, now includes direction to EPA to take certain actions to “the extent practicable” in selecting the restrictions imposed. The Administrator shall consider and publishes as required by statute, the well-defined terms “extent practicable” as determined by House and Senate negotiators. See S 697 as reported by the Senate be inferred from that agreement.

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 “as proposed and reported” as recommended by the Senate that actions be taken to “the maximum extent practicable.” During House-Senate negotiations on the bill, Senate negotiators suggested that House-Senate Counsel believed the terms “extent practicable” and “maximum extent practicable” are synonymous, and ultimately Congress agreed that the term “extent practicable” in the Frank R. Lautenberg Chemical Safety for the 21st Century Act with the expectation that EPA must consider the least-cost alternative to achieve the purposes of the exemption. That 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 preclude the Administrator from taking actions beyond the scope of the referenced section.

9. Cost Considerations in Rulemaking

EPA’s consideration of whether to use non-TSCA EPA authorities in order to address unreasonable chemical risks identified under TSCA, the term “maximum extent practicable” merely consolidates existing language which was previously split between section 6(c) and section 7 of TSCA. It only applies if 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 nonethe- less if it is certain 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 Administration.” The provision is 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.

11. Critical Use Exemptions

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12. Regulatory Compliance

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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 inter-agency referral process and the intra-agency consideration process established under Section 9 of TSCA have been substantially expanded under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Thus, the congressional intent that any information required pursuant to discovery, subpoena, court order, or any other judicial process is not protected by the Federal, State, and Federal law, and not protected from disclosure.

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14. Disclosure of Confidential Business Information

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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 exceptions from protection of information from health and safety studies: for information where disclosure would disclose either how a chemical is manufactured 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 or any 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 that 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. Section 18(b)(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 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 line 1, but was not 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(b)(1) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, references “risk evaluations” on chemical substances that may be conducted by states or political subdivisions of a State to continue to enforce any statute enacted, criminal penalty assessed, or administrative action taken. 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(b)(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 comments compiled by the states regarding a risk evaluation of a chemical substance, to provide warnings or to label products or chemicals with certain information regarding risks and recommended actions to reduce exposure to a chemical. Section 18(b)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, specifies that nothing in the provision is intended to preempt the Administrator prior to the effective date, responding to concerns that prior EPA action or inaction on an environmental release of that substance 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, authorizes the Administrator prior to the effective date of the act to continue to enforce any state law that was in effect on August 31, 2003.

Section 18(b) 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. As noted earlier, the Senate’s clear intent was not to preempt or limit in any way by EPA action or inaction on a chemical 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), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, could be read to exclude the cost of risk evaluations, which are industry-initiated risk evaluations, from the costs that can be covered by fees. This was not the intent and is not consistent with the clearly indicated in section 26(b)(1), the amended law provides that manufacturers and processors of chemicals subject to risk evaluations, which are funded at the 50% 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 section 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, evaluate chemical evidence. This term indicates that evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon the limitations of the individual evidence. 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(c) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, states: “(4) CHEMICAL SUBSTANCES WITH CONSIDERABLE RISK—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 shall, in a timely manner, take action 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.” EPA has completed risk assessments for 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 briefing, EPA dedicated those areas with the view that, rather than reexamine and perhaps broaden the scope of those assessments, it is better to proceed with proposed and final rules for covered chemicals in order to avoid any delay in the imposition of important public health protections that are known to be needed. Congress shared these concerns with this 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 substances containing 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, based on relevant factor in applicant 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. EPA already determines to bring to EPA’s attention and enable it to evaluate uses of chemicals that could present unreasonable risks, a reasonable expectation of potential 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 the norm. To realize the risk reduction five years, this should be the exception and not the rule.” This language clarifies that potential exposure to the chemical substance through the article or category of articles subject to the rule justifies notification. This language clarifies that potential exposure, based on relevant factor in applicant 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. EPA already determines to bring to EPA’s attention and enable it to evaluate uses of chemicals that could present unreasonable risks, a reasonable expectation of potential 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.

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