UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 2 0 2016

THE ADMINISTRATOR

The Honorable Frank Pallone Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Pallone:

The Administration commends the Senate Environment and Public Works Committee and the House Energy and Commerce Committee on their bipartisan efforts to pass Toxic Substances Control Act (TSCA) reform legislation. In 2009, the Administration released Essential Principles for Reform of Chemicals Management Legislation (Principles) to help inform Congressional efforts on TSCA. The Administration is pleased to share the additional views in this letter, and would welcome the opportunity to work with Congress on more technical drafting issues during the reconciliation process.

Under TSCA, insufficient progress has been made in determining whether the tens of thousands of chemicals in commerce today are safe for the American people and the environment. When TSCA was enacted, it grandfathered in, without any evaluation, over 60,000 chemicals that were in commerce at the time. TSCA did not impose any requirement or schedule for the EPA to review these chemicals for safety. Even for chemicals with known risks, TSCA's "unreasonable risk" standard and "least burdensome" regulatory requirement have generally prevented the EPA from taking necessary and timely actions to protect human health and the environment.

The Administration appreciates that Congress took a comprehensive look at TSCA when it developed its reform bills. While there are many aspects to overhauling TSCA, the Administration encourages Congress to ensure several important issues are addressed sufficiently in any legislation to emerge from the reconciliation process. The views provided in the attachment are intended to assist Congress in reconciling the two pieces of legislation. The lack of a workable safety standard, deadlines to review and act on existing chemicals, and a consistent source of funding are all fundamental flaws in TSCA that should be addressed.

The Administration strongly supports Congress's efforts to strengthen TSCA to provide the EPA with the necessary tools and authorities to target and assess chemicals, and effectively regulate risks. Chemicals are vital to our nation's economy, but safety should continue to be of paramount importance. We need to restore confidence that chemicals used in commerce will not endanger the health and welfare of the American people. The Administration looks forward to continuing to work with Congress toward these goals.

Sincerely,

Gina McCarthy

Enclosure

Identical letters sent to the Honorable James M. Inhofe, The Honorable Barbara Boxer, The Honorable Fred Upton, and the Honorable Frank Pallone Jr.

Administration Views on the TSCA Reform Bills (H.R. 2576 and S. 697)

Deadlines for Action

Essential to a reformed TSCA are statutory mechanisms that drive EPA action to review chemicals and regulate those that are unsafe. In its Principles, the Administration calls for "clear, enforceable and practicable deadlines."

On this point, the Senate bill is preferable. It provides certainty about the progress that the EPA is required to make reviewing chemicals. The Senate bill imposes an absolute requirement to have completed or at least begun a certain number of assessments (20 high-priority assessments within 3 years, and 25 high-priority assessments within 5 years), and imposes a requirement to repopulate the high-priority list as each assessment is completed until all chemicals on the TSCA inventory have been evaluated.

Elimination of the "Least Burdensome" Requirement

The Administration supports the elimination of current TSCA's "least burdensome" requirement, which the court in *Corrosion Proof Fittings* – an often-cited TSCA case – has interpreted to impose a tremendous analytical burden on the agency. The EPA's failure to meet this requirement – after over a decade of rulemaking and thousands of pages of analytical record – resulted in the overturning of the asbestos rule. Both the House and Senate bills include new, different considerations for the EPA when selecting among risk management measures ("Analysis for Rulemaking" in Section 6(d)(4) of TSCA as amended by the Senate bill and "Requirements for Rule" at Section 6(c)(1)(B) of TSCA as amended by the House bill).

Whatever the resolution, the Administration urges Congress to establish considerations that are sufficiently circumscribed so that the EPA will not be required to assess the costs and benefits of an indefinite number of regulatory alternatives, or otherwise be obligated to pursue alternatives analyses beyond the realm of analytic practicability. Such requirements would likely undermine the operation of a revised law even if it contains a clear safety standard and practicable deadlines.

The Administration prefers the consideration requirements under the Senate bill because they expressly provide that they do not extend the EPA's analytical burden beyond what can be practicably accomplished, based on reasonably available information. Subject to these bounds, the EPA would be required to consider the costs and benefits of alternative methods to achieve the safety standard for a particular chemical substance. The EPA would also be required to incorporate such consideration into a statement accompanying each risk management rule, which would then be part of the administrative record for the rule, and thus allow for judicial review of the adequacy of the agency's reasoning.

By contrast, the House bill requires the EPA to defend one of two affirmative alternative findings in order to issue a risk management rule: either that the rule is cost effective or that a non-cost effective alternative is necessary. The scope of analysis required for making these findings may be bounded by the information that is "reasonably ascertainable," under section

6(c)(1)(A). Even if the analysis is so bounded, this provision leaves uncertainty about how many cost effective options the EPA would have to analyze and reject as inadequate before selecting a non-cost effective option.

Prioritizing Chemicals for Review

The Administration's Principles make clear that the EPA should have the authority to prioritize chemicals for review based on relevant risk and exposure considerations. Both the House and Senate bills also include provisions that would allow manufacturers to identify their own priority chemicals for review by the EPA. If a similar mechanism is included in a final bill, it is essential that it not overrun the EPA's ability to prioritize chemical reviews. For this reason, the Administration strongly prefers the Senate version since that bill explicitly caps the number of risk evaluations that can be initiated based solely on manufacturers' interest and it requires both full payment of the costs of the assessment and, if necessary, defrayment of the ensuing costs to develop risk management regulation. Without a meaningful cap or similar measures, manufacturer priorities have the potential to overrun the EPA's chemicals management program and prevent the agency from addressing chemicals with greater potential risks. Without appropriate funding for risk management costs, the EPA may not be able to complete work on manufacturer priorities as Congress presumably intended. The House bill has no cap on manufacturer initiated risk evaluations, and no requirement for industry to pay for the risk management actions that the EPA may find itself legally obligated to undertake after completing the requested risk evaluations. The House language would allow the EPA to put risk evaluations on hold if it receives more industry requests than it has resources to handle, but this provision could be interpreted to allow the EPA to put on hold *EPA initiated evaluations* as well as manufacturer initiated evaluations.

Sustained Source of Funding

The Administration's Principles state that the EPA work under TSCA should be "adequately and consistently funded" and that manufacturers should "support the costs of Agency implementation." The Administration is pleased that both the House and Senate modify Section 26 to establish a dedicated TSCA implementation fund and expand fee collection authority.

The House bill's fee provisions would not defray the EPA's costs of reviewing existing chemicals (aside from those initiated by industry) or any of the costs associated with regulatory risk management actions. It could also be argued that the fees that the EPA could collect for the submission of test data would not cover the EPA's costs to assess the data as part of a chemical risk evaluation.

The Administration prefers the Senate bill's funding provisions, which explicitly add new fee collection authority for the costs of reviewing confidential business information (CBI) claims, reviewing notices under section 5, making prioritization decisions, conducting and completing safety assessments, and conducting rulemakings.

The EPA should have broad authority to use its fees to cover the costs of agency implementation. Giving the EPA this authority generally would avoid the concerns raised above about the EPA's spending authority in specific scenarios. Further, imposing spending caps and the Senate bill's minimum appropriations requirements for assessing fees could still create implementation challenges.

Implementation Challenges

The Administration encourages Congress not to impose on the EPA extensive, prescriptive requirements to develop policy and procedure documents. The dedication of resources to meeting these process development expectations could frustrate the EPA's efforts to timely and directly implement the substantive requirements of TSCA.

The Senate bill, particularly in sections 3A and 4A, establishes pressing deadlines for the EPA to develop various policy and procedure documents, and prescribes numerous specifications for the content of such documents. Meeting these document generation requirements may unnecessarily slow progress on more substantive issues, limit the EPA's flexibility to allocate resources appropriately, and lead to burdensome litigation regarding the process development requirements.

The EPA has already developed and promulgated numerous policies, procedures, and scientific guidances. The EPA continues to invest resources in hosting open public debate on pressing scientific issues and the development of policies and guidances, and does so in accordance with existing objectivity and transparency requirements. For highly impactful or controversial issues, the EPA continues to engage the National Academies of Science, Engineering and Medicine to ensure the development of robust policies and procedures.

The Administration strongly prefers the House bill on this matter since it only requires the EPA to develop new policies, procedures, and guidelines to the extent necessary. If the detailed procedural specifications of the Senate bill are retained, the Administration supports also retaining the accompanying savings provisions that the Senate bill adds to TSCA Section 6(b), which allow the EPA to continue its ongoing work to protect public health and the environment while the required policies, procedures and guideline are under development.

Safety Standard

The Administration's Principles call for a new safety standard that is "based on sound science and reflect[s] risk-based criteria protective of human health." The Administration encourages Congress to apply the new safety standard consistently throughout the revised statute.

If a clear directive for the EPA to apply the new safety standard is expressed only with respect to section 6, as is the case in the House bill, that could create uncertainty as to what standard would apply to EPA actions under other provisions of TSCA where the phrase "unreasonable risk" appears (for example, under sections 4, 5, 7, 12 and 14). Providing an upfront definition of the safety standard, as in the Senate bill, is one way to better ensure uniform

application of the new standard to all actions under TSCA. Alternatively, "unreasonable risk" could be redefined in each instance it appears.

On a related point, there are several provisions in section 6 of the House bill that could possibly be read to suggest that different standards apply in section 6(a) rulemakings in different scenarios. For example, the EPA is authorized to promulgate non-cost-effective requirements if "necessary to protect against the identified risk" (section 6(c)(1)(B)). It might be argued that this language provides a different risk management standard from section 6(a) (regulation must ensure that a chemical substance "no longer presents or will present an unreasonable risk"). A similar issue appears with respect to regulation of replacement parts (section 6(c)(1)(D)) and articles (section 6(c)(1)(E)).

In general, the Administration appreciates that both the House and Senate bills allow for exemptions to otherwise applicable risk management requirements where necessary to maintain a critical use, or to protect national security or avoid disruption to the national economy. This is consistent with Administration Principle 3, which states that risk management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations. This principle should be consistent across the relevant risk management provisions of the bills.

Finally, some confusion might be caused by the House bill provision that requires rulemaking for persistent, bioaccumulative and toxic (PBT) chemicals under section 6(a) to reduce likely exposure to the extent practicable (section 6(i)(3)). Sections 6(a) and 6(i) actually impose different rulemaking standards. Both the section 6(a) rulemaking standard and several of the considerations required in promulgating section 6(a) rules (which appear in section 6(c)) assume that the EPA has identified specific risks as unreasonable. However, the EPA may not have actually performed a risk evaluation for a particular PBT which is required (under section 6(i)) to be the subject of a 6(a) risk management rulemaking.

Regulatory Flexibility

The House bill retains the current TSCA section 6(a) menu of requirements the EPA can impose in section 6 rulemakings. Although this menu is extensive, it is not comprehensive. Specifically, the menu expressly authorizes the EPA to regulate the manufacture, processing and distribution in commerce of a chemical substance only through a complete ban or ban for specific uses, or through quantity or concentration limitations. In contrast, with respect to commercial use, section 6(a) gives the EPA broader authority to impose requirements "prohibiting *or otherwise regulating*" the use (section 6(a)(5)). In operation, this menu may drive regulation that is more burdensome than necessary. The Administration prefers the approach in section 6(d) of the Senate bill, which includes "catch-all" regulatory authorities.

Safety of New Chemicals

Under current TSCA, manufacturing and processing of new chemicals can commence upon expiration of the premanufacture notice review period without the EPA determining whether or not those chemicals are safe. As stated in the Administration's Principles 2 and 4, the

EPA should conclude whether or not new chemicals meet the safety standard before those chemicals are allowed to enter the market. As such, the Administration supports the Senate bill requirement that the EPA make an affirmative safety determination regarding new chemicals.

Transparency and Confidential Business Information

The Administration's Principles outline certain improvements regarding the transparency of chemical information. The Administration is pleased that both the House and Senate make improvements to substantiation requirements for CBI claims. The House bill requires substantiation of new CBI claims, while the Senate bill requires substantiation of both new and existing claims. The Administration also supports new authority in both bills for the EPA to appropriately share CBI with others when necessary to protect public health and safety.

However, the Administration is concerned with a provision in the House bill that would allow "formulas (including molecular structures)" of a chemical substance to be withheld as CBI in health and safety studies. Under current section 14, formula information in health and safety studies can be protected as CBI only if it discloses process information. Thus, the House provision would decrease transparency and shield from the public relevant chemical information (in some cases, the specific identity of a chemical that is the subject of a health and safety study).

Authority to Require Development of Information

Another significant problem under current TSCA is the difficulty of requiring the development of information on chemicals for which information is lacking. Both bills address a major contributor to this problem: the lack of authority to require testing by order. The other contributor is substantive: section 4 of TSCA currently requires the EPA to either demonstrate that a chemical "may present an unreasonable risk," before it can require testing, or else that there is already substantial production and substantial release of or exposure to the chemical substance. The obligation to make these demonstrations has created difficulties for the EPA in requiring testing necessary to assess the safety of chemicals.

Both the House and Senate bills give the EPA new authority to require testing for specific purposes, including during risk evaluations. Under the new House authority, however, the EPA must first make a risk-based finding before initiating a risk evaluation. Although the bar is fairly low ("may present an unreasonable risk...because of potential hazard and a potential route of exposure..."), it could have the effect of perpetuating the difficulties the EPA has encountered under current TSCA. Outside of the risk evaluation context, the House bill could still require the EPA to make a "may present an unreasonable risk" finding before requiring testing under section 4. The Administration encourages Congress to ensure that the EPA is given the necessary authority and tools to obtain information relevant to determining the safety of chemicals.

Chemicals in Articles

The Administration encourages Congress to look closely at provisions in both the Senate and House bills that may make it more difficult for the EPA to review and regulate risks from chemicals contained in articles. Under current TSCA, the EPA has used its authority under

section 5 to establish notification requirements for new uses of a chemical for which the EPA has concerns, including chemicals in imported articles. Section 5 does not require the EPA to make any particular exposure or hazard finding to use this authority, presumably since the function of these significant new use rules is simply to allow the EPA to review, and regulate as necessary, new uses of existing chemicals on the same basis as new chemicals. The Senate bill imposes a new requirement: the EPA must first find the notification requirement for the article is warranted based on "the reasonable potential for exposure through the article or category of articles." This new requirement may make it harder for the EPA to require notification for uses that are not currently foreseen. Even for currently envisioned uses, it may generate litigation over an EPA finding that the potential for exposure through an article or category of articles is "reasonable". The House bill exempts from regulation all "replacement parts designed prior to" the publication of a risk management rule, unless the replacement parts "contribute significantly to the identified risk." This provision would make it more difficult for the EPA to define the scope of regulations given the likely challenges of determining when particular replacement parts were designed.

Enforcement Improvements

While the Administration's Principles do not discuss civil and criminal enforcement of TSCA, the Administration supports the decision to include provisions in the Senate bill that would strengthen civil and criminal enforcement authorities. We look forward to continuing to work with Congress on these provisions.

Federal-State Relationship

The EPA's limited ability to regulate under TSCA has encouraged states to step in, resulting in varying chemical regulations across the country. Assuming the flaws in TSCA that have prevented effective federal action are addressed in reform legislation, the Administration supports an approach to preemption that provides a consistent regulatory regime for industry while allowing appropriate additional actions by the states. These comments are intended to note provisions that could benefit from drafting changes to reflect Congress's presumed intent, as well as provisions that could result in permanent preemption of state actions to address risks not addressed by federal regulation.

The Administration supports Congress's intent to preserve existing state laws like California's Proposition 65, and other state environmental laws related to the protection of air and water, and to waste. Respecting the preservation of such laws, both the Senate and House bills would benefit from further work to reflect the drafters' intent. For example, the Senate bill should better reflect its apparent intent to preserve state regulations adopted prior to August 1, 2015, not merely to enforce actions initiated prior to August 1, 2015. Similarly, the House bill should clarify that it is wholly preserving the identified laws, not just State efforts "to continue to enforce" those laws, and also that any state requirement enacted under a law that was in effect on August 31, 2003, is saved from preemption, even if the specific requirement is promulgated after the date of the TSCA Modernization Act.

The House bill should also clarify the scope of potential preemption of state environmental laws that "actually conflict[]" with an EPA "action or determination." While two

laws might be said to actually conflict if they impose incompatible obligations or one purports to abrogate the other, it is far less clear when a state law could be said to be in actual conflict with an EPA determination that is not an action, or with an EPA action that does not impose requirements.

Respecting the preservation of state laws adopted under the authority of federal law, the Administration supports the Senate bill's clarification of the types of state laws that are intended to receive such protection from preemption. Specifically, the Senate bill makes clear that this protection also extends to laws that a state adopts using its own legal authority, but that are nonetheless authorized under federal law, or adopted to satisfy or obtain authorization or approval under federal law. This clarification furthers a common sense objective: to ensure that TSCA actions do not block the purposes of the many other federal environmental statutes (e.g., the Clean Air Act) that are implemented through a system of cooperative federalism. The Senate bill's clarification is also consistent with evidence of original Congressional intent, found in TSCA's legislative history.

Furthermore, the Administration supports an approach in which any preemption resulting from a completed EPA safety assessment or risk management rule is appropriately limited to the particular risks that the agency actually considered in the scope of that assessment or rulemaking. The Administration prefers the Senate bill's clarity on this issue. On a related issue, the House bill, which does not require an affirmative safety determination for new chemicals, nonetheless would lead to preemption of state regulation for all uses of a new chemical substance identified in a pre-manufacture notification, if the agency took action merely to address a subset of those uses.