



Via E-mail

Chairman Paul D. Tonko  
Ranking Member John Shimkus  
U.S. House of Representatives  
House Committee on Energy and Commerce  
Subcommittee on Environment and Climate Change  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Re: Hearing on “Mismanaging Chemical Risks: EPA’s Failure to  
Protect Workers”

Dear Chairman Tonko and Ranking Member Shimkus:

The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) submits this letter in anticipation of the March 13, 2019, hearing on the U.S. Environmental Protection Agency (EPA) role in protecting workers from chemical risks, as announced by the U.S. House Committee on Energy and Commerce’s Subcommittee on Environment and Climate Change. The TSCA NCC is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under amended TSCA and to work collaboratively with EPA and other stakeholders to address them. We thank you for the opportunity to make its members aware of some of the issues and concerns we have encountered under the revised TSCA Section 5 notification and review process.

TSCA NCC members have met with EPA and congressional staff on several occasions. Coalition members have also participated in public fora organized by EPA to discuss these and other aspects of the new chemical review process, and to express the Coalition’s willingness to continue working with EPA to strengthen the Section 5 program and improve its timely completion of scientifically and legally supportable determinations and regulatory actions.

### **OSHA Regulates Workplace Safety**

TSCA NCC members have worked with EPA to address many issues with the new Section 5 process. We note two key issues here. One key area of concern to TSCA NCC member companies, and a focus of this hearing, involves worker protection issues related to TSCA new chemicals. The Coalition recognizes that workers are included among the subpopulations specified in the definition of “potentially exposed or susceptible subpopulation” in amended TSCA<sup>1</sup> and that Section 5(f)(5) requires that EPA “shall consult” with the U.S. Occupational Safety and Health Administration (OSHA) prior to prohibiting or restricting a new

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<sup>1</sup> TSCA Section 3(12).



chemical. It is TSCA NCC's view that EPA's approach to assessing and managing new chemicals under Section 5 must be done in a way that adequately recognizes the significance and effect of OSHA's statutory authorities and regulations, its guidance and enforcement mechanisms, and its overarching regulatory scheme in the workplace. We believe this is entirely consistent with the purposes of Section 5(f)(5). As discussed in detail in a letter and position statement provided by TSCA NCC to EPA which we append for your convenience, EPA's approach to new chemicals under TSCA must be implemented in a way that recognizes key OSHA statutory authorities, regulatory requirements, and enforcement mechanisms, including:

- OSHA's detailed regulation for use of Personal Protective Equipment (PPE) when needed to further limit exposure beyond that afforded by OSHA's preferred approach of engineering and process controls. Relevant to the situation with new chemicals, the OSHA regulatory standard requires use of gloves that are impervious to the substance under the conditions of use, eye protection, and respiratory protection for employees where such protection is otherwise necessary to protect employee health.
- The General Duty clause of the Occupational Safety and Health Act (OSH Act) that, among other provisions, requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm. The "likely to cause" aspect of the General Duty requirement is particularly relevant to new chemicals, given the limited information that is often available.

EPA has an obligation to review and make Section 5(a)(3) determinations that include consideration of worker exposure issues and, when required, to regulate new chemicals under TSCA Section 5(e) "to the extent necessary to protect against an unreasonable risk." TSCA NCC believes that in taking such regulatory actions, EPA must evaluate the adequacy of the existing OSHA statutory and regulatory elements and adopt additional restrictions or prohibitions only when needed to protect against unreasonable risks not otherwise addressed by OSHA. Accordingly, TSCA NCC believes that the proper role for EPA should be to provide written hazard identification and risk assessment information to the new chemical notifier and to OSHA to make these parties fully aware of EPA's assessment and its identified occupational concerns and precautions, if any. Once informed of EPA's assessment, the notifier/employer will be aware of and be known by OSHA to have in its possession information that must be considered in the context of engineering and process controls and in selecting respiratory protection and other PPE needed to comply with OSHA's broadly applicable regulations and with the General Duty clause requirement that employers provide a safe working environment.



Chairman Paul D. Tonko and  
Ranking Member John Shimkus  
March 12, 2019  
Page 3

TSCA NCC was challenged by EPA’s Office of Pollution Prevention and Toxics (OPPT) management to demonstrate that appropriate PPE are routinely used in the workplace. TSCA NCC research found a database of violations issued by OSHA dating back to the 1970s. The database included 12 million records of OSHA violations. Less than one percent of violations related to lack of eye protection, lack of general dermal protection, and lack of glove use (or inappropriate glove use), despite the fact that these violations are relatively easy to observe.

Once appropriately informed of EPA’s concerns, any downstream employer having a commercial relationship to the premanufacture notification (PMN) notifier must be made aware of and must consider the full hazard assessment (including hazards identified by EPA) and respond appropriately to meet the obligation to protect workers and provide for a safe workplace. The fact that OSHA has also been informed of EPA’s concerns puts to rest any questions about the level of information and the hazard, exposure, and risk assessments that the notifier and affiliated employers have access to, and establishes a factual written record that can be considered during any OSHA inspections or enforcement actions. For these reasons, TSCA NCC believes that for many, if not most, new chemicals for which EPA has identified workplace concerns, once EPA has informed OSHA and the notifier of its occupational risk assessment and the notifier has made conforming revisions to the Safety Data Sheet, unreasonable risk to workers is, accordingly, “not likely” and not “reasonably foreseeable.”

By acknowledging the efficacy of worker protection measures under OSHA, EPA ensures worker safety, does not add unnecessarily to its own workload, and reduces the “new chemical bias” in which new chemicals often face regulatory burdens that do not apply to existing, incumbent substances.

### **U.S. Innovation Hindered by Delays and Uncertainty That Still Exist in New Chemicals Program**

This point is important to TSCA NCC’s second major concern, which is the significant delays in the Section 5 review process. Protracted delays are adversely impacting the commercialization of new chemicals developed by TSCA NCC companies that, in most cases, are safer and greener alternatives to existing chemicals on the market. According to the information posted by EPA,<sup>2</sup> as of February 26, 2019, over 43 percent of the over 1200 valid

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<sup>2</sup> EPA, *Statistics for the New Chemicals Review Program under TSCA*, available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tasca/statistics-new-chemicals-review#stats>. For this analysis, “Total PMNs” (the sum of PMNs completed and PMNs under review) is distinguished from “Total Cases” stated on the website as “Total Cases” includes exemption notices.



PMNs reviewed under amended TSCA still await a final determination and for EPA to take any necessary actions (*e.g.*, issuing a consent order under Section 5(e)). Completion of this step by EPA is required before the notifier can legally commence manufacture and commercialization of the new chemical.<sup>3</sup> In addition, it is unknown how many of the 226 cases withdrawn were a result of submitters “giving up” on the process due to the delays encountered, but is reasonable to assume that many were.

The delays encountered by TSCA NCC members ranged from many months to years beyond the initial 90-day review period. Some difficulty was to be expected in implementing amended Section 5 with its surprisingly extensive changes (certainly compared to those in the bill passed by the House (H.R. 2576, 114th Congress, June 23, 2015) that did not amend Section 5 at all). Other delays have resulted from EPA decisions (including “resetting” the 90-day clock on all cases that were pending on June 22, 2016) -- a decision that does not seem to be permitted in the statute. The delays experienced by TSCA NCC members, however, have proved hugely disruptive to the development and commercialization of new chemicals that were designed and developed in many cases as safer and greener alternatives to the currently used existing chemicals. While EPA has taken steps to improve its completion rates, the scale of this backlog of unfinished new chemical reviews is of great concern to TSCA NCC members. Even now that OPPT has largely settled on a set of policies that permit more consistent and timely decisions, the underlying risk assessments are often flawed because information that was included in a PMN was ignored or because of outright errors in EPA’s assessments. TSCA NCC and its member companies have brought such issues and concerns directly to EPA. Reworking such assessments only adds to EPA’s workload and to the backlog of and the delays seen in case reviews.

TSCA NCC companies are committed to doing business in the U.S. in ways that foster economic health and deliver environmental benefits to society. As a consequence of increasing concerns due to the delays and difficulties encountered in introducing new chemicals in the U.S., however, some TSCA NCC member companies have decided to introduce and commercialize the technologic and other benefits of new chemicals elsewhere in the world. This situation, relating to one company, was outlined in the recent report by the Government Accountability Office (GAO) on TSCA implementation, among other topics.<sup>4</sup> It is important to

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<sup>3</sup> TSCA Section 5(a)(4).

<sup>4</sup> GAO, Chemical Assessments: Status of EPA’s Efforts to Produce Assessments and Implement the Toxic Substances Control Act, at page 38 (March 4, 2019), available at [https://www.gao.gov/products/GAO-19-270?utm\\_campaign=usgao\\_email&utm\\_content=topic\\_naturalresources&utm\\_medium=email&utm\\_source=govdelivery](https://www.gao.gov/products/GAO-19-270?utm_campaign=usgao_email&utm_content=topic_naturalresources&utm_medium=email&utm_source=govdelivery).



Chairman Paul D. Tonko and  
Ranking Member John Shimkus  
March 12, 2019  
Page 5

note that the circumstance in the GAO report involved a company opting to commercialize in the European Union, which requires a substantial investment for dossier preparation; the company did not look to commercialize in a country that had more relaxed standards than the U.S.

To be clear, the issue of delays in EPA's review process in many cases is directly related to worker protection from chemicals. Today's new chemical innovators are focused on finding safer, greener replacement chemicals. While new chemicals may not be risk-free (nor does the law require them to be), they could be relatively or even significantly safer/less risky than the incumbent, existing chemicals to which workers are exposed, but this factor seems to be getting short shrift in EPA's reviews.

We appreciate this opportunity to share our views with this Subcommittee. If you have any questions, please let me know.

Respectfully submitted,

A handwritten signature in black ink that reads "Kathleen M. Roberts". The signature is written in a cursive style with a large initial "K" and "R".

Kathleen M. Roberts

Attachment



December 1, 2017

Via E-Mail

Jeffery Morris, Ph.D.  
Director, Office of Pollution Prevention and Toxics  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
1300 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004

Dear Jeff:

This letter is submitted on behalf of the Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC), a group of representatives from over 20 companies that have come together to identify new chemical notification issues under the amended Toxic Substances Control Act (TSCA) and to work collaboratively with you and your team to address them. Thank you for the opportunity to meet on November 16; we appreciate the discussion that we had.

One of the topics that we raised concerned the mandated consultation process with the U.S. Occupational Safety and Health Administration (OSHA) at TSCA Section 5(f)(5), and the significance of restrictions included in the Safety Data Sheets (SDS) on new chemicals. As we discussed, the TSCA NCC believes that the U.S. Environmental Protection Agency (EPA) needs to implement an appropriately robust and ongoing consultation process with OSHA “prior to adopting any prohibition or other restriction” per TSCA Section 5(f)(5) that addresses occupational exposure issues. We believe that such a procedure is needed to ensure that EPA’s adoption of restrictions fully considers and avoids conflicts with OSHA’s established regulatory programs in addressing and mitigating worker exposure risks to new chemical substances, a result Congress seemed to intend in amending TSCA.

Picking up on a point raised in our meeting, we note for your information that EPA’s *Instruction Manual for Reporting under the TSCA § 5 New Chemicals Program*,<sup>1</sup> requires that the notification include, among others:

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<sup>1</sup> Available at [https://www.epa.gov/sites/production/files/2015-06/documents/instruction\\_manual\\_2015\\_5-26-2015.pdf](https://www.epa.gov/sites/production/files/2015-06/documents/instruction_manual_2015_5-26-2015.pdf).

Jeffery Morris, Ph.D.  
December 1, 2017  
Page 2

- A description of each specific worker activity during which workers may be exposed to the new chemical substance. Activities must be described even if workers wear protective equipment. The SDSs indicating recommended protective equipment should be submitted as part of Hazard Information in Part I, Section C, subsection 3 of the notice form.
- Information on the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the new chemical substance (*i.e.*, type of gloves, type of goggles, National Institute for Occupational Safety and Health (NIOSH)-certified 21c respirator, NIOSH-certified 19c respirator, closed containment system, nitrogen blanket, and related measures).
- Information on the physical form of the new chemical, the maximum number of workers exposed, and the maximum duration of exposure in hours/day and days/year.

The information elements noted above are not developed strictly for EPA review purposes. These information elements are required under OSHA which, as further articulated in the attached paper, has broad authority to regulate workplace exposures. Based on these reporting requirements for new chemical reviews, EPA staff will have access to available understanding concerning occupational exposures to the new chemical and the engineering controls or personal protective equipment (PPE) that the notifier believes is needed to protect workers, and on which the notifier will be regulated under OSHA.

As discussed in more depth in the attached paper, the TSCA NCC does not believe that EPA's approach under TSCA adequately appreciates and recognizes the significance and effect of OSHA's statutory authorities and extensive regulatory scheme, as well as its enforcement mechanisms, governing workplace chemical exposures, including to new chemicals. These include:

- OSHA's detailed regulations for use of PPE when needed to further limit exposures beyond that afforded by OSHA's preferred approach of engineering and process controls. The regulatory standard, for example, requires use of respiratory protection to protect employees from exposure to air contaminants

Jeffery Morris, Ph.D.  
December 1, 2017  
Page 3

above an exposure limit, or where such protection is otherwise necessary to protect employee health. The standard places a range of OSHA enforced responsibilities on employers, requiring that a written program of respiratory protection must be in place including procedures for respirator selection, use, fit, testing, and so forth, training in use and hazards, and medical evaluations of employees who use such PPE.

- The General Duty clause of the Occupational Safety and Health (OSH) Act that, among other provisions, requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm. The “likely to cause” aspect of the General Duty requirement is, as you recognize, particularly relevant to new chemicals given the limited information that is often available.

We believe that Congress did not intend to alter the scope of the effect of these OSHA requirements in amending TSCA. It, however, recognized the issue of overlapping authority concerning workplace regulation of new chemicals. For this reason, while additional authority was provided to EPA in making determinations and taking required actions, Congress included the OSHA consultation provision at Section 5(f)(5) to ensure that EPA’s regulation of new chemicals did not create or result in conflicts with requirements implemented by OSHA.

Although EPA has an obligation to review and make determinations regarding worker exposure issues and to formulate and adopt TSCA Section 5(e) actions that include measures to protect workers, this duty applies “to the extent necessary to protect against an unreasonable risk.” When this duty is juxtaposed with the mandatory consultation requirement, it is clear that EPA is required to evaluate the adequacy of the existing OSHA regulatory scheme and to adopt additional restrictions or prohibitions only when needed to protect against unreasonable risks not otherwise addressed.

Accordingly, the proper role for EPA should be to provide hazard identification and risk assessment information to the new chemical notifier and to OSHA to make these parties fully aware of EPA’s assessment and its identified occupational concerns, if any. Once informed of EPA’s assessment, the employer will be known to have information that must be considered in selecting respiratory protection and other PPE needed to comply with OSHA’s broadly applicable regulations and with the General Duty clause requirement that employers provide a safe working environment. By the same token, once OSHA has been informed of EPA’s



Jeffery Morris, Ph.D.  
December 1, 2017  
Page 4

assessment, it will be in a position to enforce its regulations and to ensure that the General Duty clause requirements are being satisfied.

For these reasons, and others elaborated in the attachment, the TSCA NCC believes that EPA should disfavor issuing TSCA Section 5(e) orders that mandate use of particular PPE or other workplace-specific measures to mitigate occupational exposure. Instead, the TSCA NCC recommends the following approach if EPA identifies a workplace-specific risk concern:

1. EPA should consult with OSHA on the workplace risk concern.
2. EPA should inform the notifier of its assessment and concerns.
3. After the OSHA consultation and notifier communications are completed, EPA should no longer engage but instead rely on the employer's responsibilities mandated by OSHA, as well as OSHA's established expertise and robust existing regulatory program, to ensure worker protection.

Failure to follow a procedure as outlined above risks creating disputes over whether EPA's action preempted or created conflicts with OSHA's general authority and its regulations.

The TSCA NCC recognizes that the approach being advocated is at odds with EPA's longstanding practice in assessing and regulating new chemicals. Nonetheless, for the reasons provided above and elaborated in the attachment, TSCA NCC believes that EPA's prior and current approach is mistaken in that it does not give due recognition to OSHA's authorities and regulations and their role in ensuring a workplace free from recognized or potential occupational hazards. We believe that a modification in EPA's approach is necessary, given the changes in amended TSCA, including the OSHA consultation requirement. While EPA may have believed that, whenever an OSHA Permissible Exposure Limit (PEL) (or similar enforceable limit) is not in place, there is no enforceable requirement for companies to protect their workers from new chemical exposures, this belief is mistaken; and, as explained in this communication, does not have a basis in law or policy. Quite to the contrary, once EPA has informed the notifier and OSHA of its hazard and risk assessments, it has had the effect of triggering and setting in motion the existing regulatory requirements on employers to protect workers from recognized or likely occupational harms. Thus, any belief by EPA that, in the



TSCA  
NEW CHEMICALS  
COALITION

Jeffery Morris, Ph.D.  
December 1, 2017  
Page 5

absence of a TSCA Section 5(e) or Significant New Use Rule (SNUR) requirement to protect workers, it cannot ensure the presence of an enforceable regime of workplace protections is in fact a mistaken and erroneous belief.

Put another way, EPA's current practice under amended TSCA to equate any potential health hazard to represent an unreasonable and unmanaged risk to potentially exposed workers represents a misreading of the broadly applicable and pervasive regime that is implemented and enforced based on the OSH Act and OSHA's regulations and policies. On the contrary, once appropriately informed of EPA's concerns, any employer having a commercial relationship to the notifier must be made aware of and must consider EPA's assessment conclusions and respond appropriately to meet their obligation to protect workers and provide for a safe workplace. Furthermore, the fact that OSHA has also been informed of EPA's concerns puts to rest any questions about the level of information and the hazard, exposure, and risk assessments that the notifier and affiliated employers have access to, and establishes a factual written record that can be considered during any OSHA inspections or enforcement actions.

The TSCA NCC believes that for many, if not most, new chemicals for which EPA has proposed workplace restrictions under new TSCA, once EPA has informed OSHA and the notifier of its occupational risk assessment, that will be sufficient to ensure adequate workplace protection and to make any unreasonable risk to workers "not likely." Having made such a determination regarding occupational risks, EPA should proceed to meet its obligations to assess and determine other exposure risks, such as to the environment and general population, and to take the steps required depending on the final determination. Such a change in EPA's approach would avoid the issues associated with overlapping authority and imposing duplicative, if not conflicting, requirements for workplace exposures while also allowing EPA to focus its regulatory resources on other potential risks that are not subject to the overarching and comprehensive requirements that otherwise apply in the workplace.



TSCA  
NEW CHEMICALS  
COALITION

Jeffery Morris, Ph.D.  
December 1, 2017  
Page 6

We hope you find these comments helpful. We would be pleased to discuss them with you and your staff in more detail prior to the **December 6, 2017**, public workshop if that is of interest.

Sincerely,

Kathleen M. Roberts

Attachment

cc: Nancy B. Beck, Ph.D., DABT (w/attachment) (via e-mail)  
Kevin W. McLean, Esquire (w/attachment) (via e-mail)  
Brian P. Grant, Esquire (w/attachment) (via e-mail)