



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.

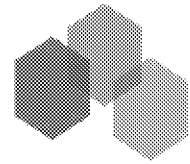
One of the topics that we raised concerned the mandated consultation process with the U.S. Occupational Safety and Health Administration (OSHA) at TSCA Section 5(f)(5), and the significance of restrictions included in the Safety Data Sheets (SDS) on new chemicals. As we discussed, the TSCA NCC believes 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*,¹ requires that the notification include, among others:

¹ Available at https://www.epa.gov/sites/production/files/2015-06/documents/instruction_manual_2015_5-26-2015.pdf.

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- 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.

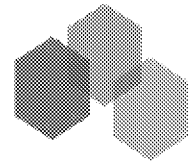
The information elements noted above are not developed strictly for EPA review purposes. These information elements are required under OSHA which, as further articulated in the attached paper, has broad authority to regulate workplace exposures. Based on these reporting requirements for new chemical 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

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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.

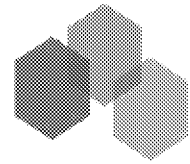
We believe that Congress did not intend to alter the scope of the effect of these OSHA requirements in amending TSCA. It, however, recognized the issue of overlapping authority concerning workplace regulation of new chemicals. For this reason, while additional authority was provided to EPA in making 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

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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:

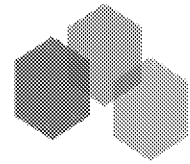
1. EPA should consult with OSHA on the workplace risk concern.
2. EPA should inform the notifier of its assessment and concerns.
3. After the OSHA consultation and notifier communications are completed, EPA should no longer engage but instead rely on the employer's responsibilities mandated by OSHA, 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

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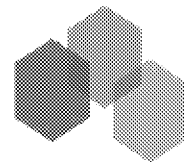
absence of a TSCA Section 5(e) or Significant New Use Rule (SNUR) requirement to protect workers, it cannot ensure the presence of an enforceable regime of workplace protections is in fact a mistaken and erroneous belief.

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.

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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)

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