



January 23, 2018

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:

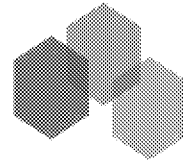
The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) submits this letter as a follow up to its December 1, 2017, letter related to the mandated consultation process with the U.S. Occupational Safety and Health Administration (OSHA) at TSCA Section 5(f)(5) (copy appended).

**Approach for Communication of Workplace Exposure Concerns
with New Chemical Notifier**

As discussed in the December 1, 2017, letter, and our other engagements with the U.S. Environmental Protection Agency (EPA), the TSCA NCC believes that 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. Should EPA identify new chemical risk concerns related to worker exposure issues in a premanufacture notice (PMN), EPA should evaluate the adequacy of the existing OSHA regulatory obligations and adopt additional restrictions or prohibitions only when needed to protect against unreasonable risks that are not otherwise addressed. Given the mandate to consult with OSHA, the proper role for EPA should be to provide hazard identification and risk assessment information to the PMN submitter, to OSHA, and to other potential manufacturers, importers, or processors to make these parties fully aware of EPA’s assessment and its identified occupational concerns, if any. Once informed of EPA’s assessment, the PMN submitter will be known to have information that must be considered in selecting respiratory protection and other personal protective equipment (PPE) needed to comply with OSHA’s broadly applicable regulations and with the General Duty clause requirement that

{01508.001 / 111 / 00230086.DOCX 7}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

Jeffery Morris, Ph.D.
January 23, 2018
Page 2

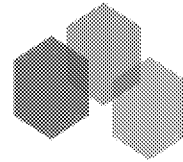
employers provide a safe working environment. By the same token, the TSCA NCC believes that once OSHA has been informed of EPA's assessment, it will be in a position to ensure that the General Duty clause requirements are being satisfied.

**Suggested Approach for Communication of Workplace Exposure Concerns
with Other Potential Manufacturers/Importers/Processors**

The TSCA NCC understands that in addition to communicating potential workplace exposure concerns to the PMN submitter, EPA must also have a mechanism to inform other potential manufacturers, importers, and/or processors of EPA's identified risk concern and the specific workplace exposure controls recommended by EPA to address that concern, including quantitative and qualitative exposure limits and suggested PPE.

The TSCA NCC proposed that this communication need can be addressed easily by using EPA's Inventory "flags." We know that before engaging in manufacturing, importing, or processing, a company must check the TSCA Inventory to confirm the subject chemical is listed on the Inventory and is active. EPA flags Inventory listings to indicate the existence of rules or other status. For example, the "T" flag indicates that the substance is subject to a test rule. An entity is thereby informed that a test rule has been promulgated and can research the terms of that rule. By flagging the subject chemical in the Inventory with a flag indicating workplace exposure concerns with a "W," EPA would appropriately inform the potential manufacturer, importer, or processor that a workplace exposure control issue has been identified and must be considered in the manufacturer, importer, or processor's OSHA compliance program. EPA can publish information concerning its occupational risk concerns and identified workplace exposure controls in a separate location, such as in the *Federal Register* or on EPA's ChemView database. Thus, the Inventory flag informs the potential manufacturer, importer, or processor that EPA has identified workplace risk concerns and the *Federal Register* or ChemView database can provide details on the concerns and the controls recommended by EPA.

As noted above and as EPA staff will recognize, this proposal for notification to potential manufacturers, importers, or processors builds off of existing EPA approaches. EPA already uses a number of Inventory flags to inform potential manufacturers, importers, or processors of critical information needed to comply with TSCA. For example, EPA uses Inventory flags to inform stakeholders of the existence of Section 5(e) or 5(f) orders, significant new use rules (SNUR), Section 6 rules, and Section 4 test rules. The flags apply to substances listed on both the public and confidential portion of the Inventory. As with the TSCA NCC



TSCA
NEW CHEMICALS
COALITION

Jeffery Morris, Ph.D.
January 23, 2018
Page 3

proposal for workplace control flags, the current EPA flags do not indicate the specific details on the TSCA action, but require the manufacturer, importer, or processor to find those details in ChemView, the *Federal Register*, or the Code of Federal Regulations.

By building off of the existing Inventory flag approach, this proposal will be easy for TSCA stakeholders to understand and implement. Such an approach would also assist in identifying cases where OSHA may want to raise questions concerning compliance with its regulations and the general duty clause.

We hope you find this additional input helpful. We will be contacting your office soon to set up a meeting with you and your staff to discuss these ideas as well as our thoughts related to the use of polymer flags for listing of exempt polymers on the Inventory.

Sincerely,

Kathleen M. Roberts

Attachment

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



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.

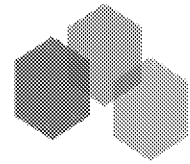
One of the topics that we raised concerned the mandated consultation process with the U.S. Occupational Safety and Health Administration (OSHA) at TSCA Section 5(f)(5), and the significance of restrictions included in the Safety Data Sheets (SDS) on new chemicals. As we discussed, the TSCA NCC believes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

{01508.001 / 111 / 00226510.DOCX 11}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

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.

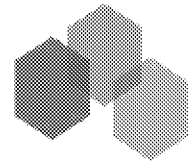
The information elements noted above are not developed strictly for EPA review purposes. These information elements are required under OSHA which, as further articulated in the attached paper, has broad authority to regulate workplace exposures. Based on these reporting requirements for new chemical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

{01508.001 / 111 / 00226510.DOCX 11}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

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.

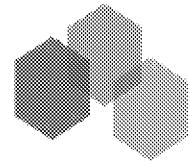
We believe that Congress did not intend to alter the scope of the effect of these OSHA requirements in amending TSCA. It, however, recognized the issue of overlapping authority concerning workplace regulation of new chemicals. For this reason, while additional authority was provided to EPA in making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

{01508.001 / 111 / 00226510.DOCX 11}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

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:

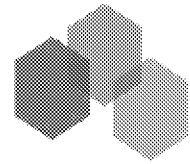
1. EPA should consult with OSHA on the workplace risk concern.
2. EPA should inform the notifier of its assessment and concerns.
3. After the OSHA consultation and notifier communications are completed, EPA should no longer engage but instead rely on the employer's responsibilities mandated by OSHA,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

{01508.001 / 111 / 00226510.DOCX 11}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

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

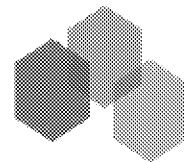
absence of a TSCA Section 5(e) or Significant New Use Rule (SNUR) requirement to protect workers, it cannot ensure the presence of an enforceable regime of workplace protections is in fact a mistaken and erroneous belief.

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.

{01508.001 / 111 / 00226510.DOCX 11}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



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,

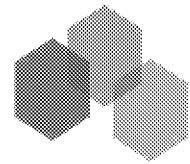
Kathleen M. Roberts

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)

{01508.001 / 111 / 00226510.DOCX 11}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

**TSCA New Chemicals Coalition¹ Position Statement Concerning the
Consultation with OSHA Required by New TSCA and EPA
Adoption of Restrictions to Address Workplace Exposures
December 2017**

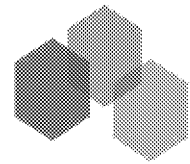
I. ISSUES TO BE RESOLVED

The TSCA that was originally enacted in 1976 was comprehensively restructured and revised in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (new TSCA). New TSCA generally requires EPA to issue an order under Section 5(e) governing the manufacture, processing, distribution, use, or disposal of a new chemical substance whenever EPA makes a determination under Section 5(a)(3)(B). EPA is directed to “prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance ... to the extent necessary to protect against an unreasonable risk of injury to health or the environment.” As part of this determination, EPA must consider risks “to a potentially exposed or susceptible subpopulation” that EPA deems relevant, which typically will include workers who are occupationally exposed to the new substance during the manufacture, processing, or use of the substance.

While EPA may issue an order under new TSCA Section 5(e) that contains prohibitions or restrictions intended to address workplace exposure, new TSCA Section 5(f)(5) requires that, prior to doing so, “[t]o the extent practicable, [EPA] shall consult with the Assistant Secretary of Labor for Occupational Safety and Health...” This required consultation with the U.S. Occupational Safety and Health Administration (OSHA) is vital as it both acknowledges a role for EPA concerning workplace exposures and explicitly recognizes OSHA’s primary responsibility for protecting worker safety and health. TSCA NCC believes that the clear intent of the consultation provision is to require that EPA, before deciding to implement separate TSCA action, will jointly evaluate the contemplated regulatory approach with OSHA, thereby assuring that EPA adequately considers OSHA’s established regulatory programs and avoids conflicts or confusion in addressing and mitigating worker exposure risks to a new chemical substance. Section 5(f)(5) addresses the need for consultations “prior to adopting *any* prohibition or other restriction” (emphasis added). Without such ongoing consultations, TSCA NCC believes that EPA’s adoption of restrictions for a new chemical to

¹ The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under the new TSCA and to work collaboratively with the U.S. Environmental Protection Agency (EPA) to address these issues.

{01508.001 / 111 / 00225476.DOCX 14}



TSCA
NEW CHEMICALS
COALITION

TSCA New Chemical Coalition Position Statement
December 2017
Page 2

address workplace exposures that are also regulated by OSHA would inevitably increase the potential for conflicts concerning -- or material differences in interpretation -- of these parallel requirements.

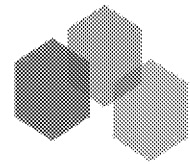
The value of coordination was recognized in a 1981 Memorandum of Understanding (MOU) between EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS), a predecessor of the current EPA Office of Chemical Safety and Pollution Prevention (OSCP) (attached). The MOU included provisions relating to sharing of information and joint participation in reviews and regulatory determinations on new chemicals presenting an occupational concern as well as sharing of confidential business information (CBI).

Section 4(b)(1) of the Occupational Safety and Health (OSH) Act, which addresses preemption of OSHA's regulatory authority in certain instances, states: "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies ... exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." An MOU entered into by EPA and OSHA on February 13, 1991, affirms that OSHA retains principal "broad authority" to regulate workplace exposures to chemicals, while "EPA responsibilities include the protection of public health and the environment." The comprehensive OSHA Field Operations Manual (FOM) (2016), in explicitly addressing the effect of this preemption provision, observes that the only group of workers for whom OSHA regulation is considered to be preempted by EPA authority are farmworkers and pesticide applicators directly exposed to pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), for which the worker protection measures in the EPA-approved label instructions preempt OSHA. While changes in the regulatory landscape may change the scope of preemption as well, as the FOM notes, how it is delineated can be a complex determination. It would be inappropriate for EPA to presume that it has been afforded broad authority under TSCA Section 5(e) to make independent regulatory decisions affecting areas that have been in OSHA's domain for decades.

TSCA NCC's reading of the effect of Section 5(f)(5) does not suggest that Congress, in amending TSCA, intended to supplant OSHA's regulatory authority over workers exposed to any chemical substance that is "new" for TSCA purposes. For this reason, it would be prudent to minimize the likelihood that EPA's regulatory activities affecting occupational exposures to new chemicals may be construed to preempt OSHA's authority to regulate exposures of those same workers. TSCA NCC believes that a robust consultation process that assures that EPA does not unnecessarily encroach on OSHA regulation should suffice to prevent any unintended preemption. Furthermore, TSCA NCC believes that the existing 1991 MOU

{01508.001 / 111 / 00225476.DOCX 14}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

TSCA New Chemical Coalition Position Statement
December 2017
Page 3

(and, as appropriate, the 1981 MOU) should be updated to clarify the effect of TSCA statutory changes, including orders and rules concerning workplace exposures for new chemical substances issued by EPA under new TSCA. Such a revision would also be an appropriate response by EPA to the directive in TSCA Section 26(l)(1) that EPA, within two years of enactment, develop any policies, procedures, and guidance that are determined to be necessary to carry out the amendments.

II. OSHA REGULATION OF OCCUPATIONAL EXPOSURE TO NEW CHEMICALS

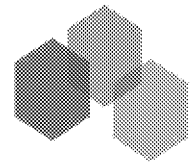
OSHA has in place an extensive regulatory scheme, as well as enforcement mechanisms, governing chemical exposure in the workplace. OSHA's longstanding policy preference is to minimize workplace exposures to chemicals through engineering and process controls, which it may specify in substance-specific standards. In those circumstances where personal protective equipment (PPE) is needed to further limit worker exposure, OSHA has adopted PPE regulations; those for General Industry are found at 29 C.F.R. Part 1910, Subpart I. Section 1910.132 describes the current OSHA standards generally applicable to PPE and provides a framework for determining whether an employer has complied with those standards, while, as discussed below, respiratory protection specifically is addressed in Section 1910.134.

In a workplace inspection, OSHA's Certified Safety and Health Official (CSHO) makes the determination whether the employer has selected the particular PPE that is necessary to protect employees from identified hazards. An employer that fails to select adequate PPE generally is subject to a citation for violating 29 C.F.R. § 1910.132(d)(1)(i) unless a provision specific to the type of PPE involved applies instead. If an employer has not provided a written certification that a hazard assessment has been conducted, the inspector is directed to cite the employer for violating 29 C.F.R. § 1910.132(d)(2). If no specific PPE standard applies to the working conditions involved, or does not fully address a workplace hazard, the OSH Act's General Duty clause in Section 5(a) nonetheless requires the protection of the affected employees.

The OSH Act's General Duty clause 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; it also requires every employer to comply with the occupational safety and health standards and all rules, regulations, and orders issued under the OSH Act. Thus, the General Duty clause adds a broad safety net and also underscores the workplace-centric nature of the OSH Act and of the intertwined responsibilities of both OSHA and individual employers in meeting specific occupational health and safety objectives. It is TSCA NCC's view that the

{01508.001 / 111 / 00225476.DOCX 14}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

TSCA New Chemical Coalition Position Statement
December 2017
Page 4

General Duty clause requires employers to implement measures to prevent or to mitigate chemical exposures that may present a risk, including instances where the potential risk is identified as part of EPA's review of a new chemical substance and not fully addressed through OSHA's regulations.

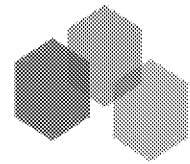
OSHA also has issued detailed regulatory provisions addressing respiratory protection in the workplace; respiratory protection is disfavored as a matter of policy whenever engineering or process controls will suffice to limit occupational exposure. Respiratory protection in the form of PPE nonetheless is of particular importance for limiting chemical exposures, and is addressed both in 29 C.F.R. Subpart I at § 1910.134, as well as in various substance-specific 29 C.F.R. Part 1910 standards. The regulatory standard requires use of respirators where they are needed to protect employees from exposures to air contaminants above an exposure limit, or where they are otherwise necessary to protect employee health.

The standard places a range of responsibilities on employers as to the written respiratory protection program that must be in place, including procedures for respirator selection, use, fit, testing, cleaning, maintenance and repair; training in use and hazards; and medical evaluations of employees who use them, among other program elements. The employer is required to select and provide an appropriate respirator (National Institute for Occupational Safety and Health (NIOSH) certified) based on the respiratory hazard(s) present in the workplace, as well as workplace and user factors that affect respiratory performance and reliability. The assessment of workplace-specific hazards is a key prerequisite to the choice of the appropriate respirator; an employer who fails to assess those respiratory hazards and to select respiratory protection suitable for the purpose intended is subject to a citation for violating 29 C.F.R. § 1910.134(a)(2). Likewise, unless a substance-specific standard applies, an inspector can cite an employer for failing to provide the type of respirator needed for the substance and level of exposure involved as required under 29 C.F.R. § 1910.134(d).

TSCA NCC's review of the relevant materials does not suggest that, in enacting new TSCA, Congress intended to alter the scope of the effect of these OSHA requirements. Absent any such indication, TSCA NCC believes that the OSHA regulatory structure, including but not limited to its approach to workplace- and employee-specific PPE requirements, continues to apply where a "new" chemical substance under TSCA is involved.

{01508.001 / 111 / 00225476.DOCX 14}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

TSCA New Chemical Coalition Position Statement
December 2017
Page 5

III. RECONCILING EPA'S OBLIGATION TO PROTECT AND EPA'S OBLIGATION TO CONSULT

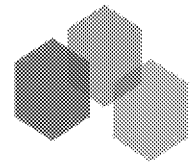
Although EPA has an obligation to formulate and to adopt TSCA Section 5(e) orders that include measures to protect workers from exposure to new chemical substances, this duty only applies “to the extent necessary to protect against an unreasonable risk.” When this duty is viewed in juxtaposition with the mandatory consultation requirement in new TSCA Section 5(f)(5), it is clear that EPA is required to evaluate the adequacy of the existing OSHA regulatory scheme, including the General Duty clause, and to adopt additional restrictions or prohibitions only when they are needed to protect against unreasonable risk.

Given the robust nature of the existing OSHA regulatory program, the proper role for EPA should be to provide hazard identification and risk assessment information that OSHA and affected employers can utilize in selecting appropriate PPE, including respiratory protection measures. For example, EPA can provide its hazard, exposure, and risk assessment information on a specific new chemical to OSHA and to the notifier, which will assist OSHA and affected employers in selecting the respiratory protection equipment and other PPE needed to comply with OSHA's regulations in 29 C.F.R. §§ 1910.134 and 1910.132. In TSCA NCC's view, when OSHA and the notifier receive EPA's hazard, exposure, and risk assessment for a new chemical substance, these materials must be considered by all employers who manufacture, process, distribute, or use the chemical in satisfying their obligation to provide a safe working environment. EPA could also make its new chemical hazard assessments more widely available, for example, by including them in its ChemView system. The chemical identity (where non-CBI), new chemical case number, and the accession number and generic name for CBI chemicals can also be included. In the case of commenced CBI new chemicals, EPA could make its appropriately sanitized hazard assessment available in responding to a *bona fide* request to ensure that future manufacturers are aware of its assessment. To ensure that this occurs, EPA could amend its *bona fide* procedures at 40 C.F.R. § 720.25 to include this step.

EPA can utilize specific restrictions in TSCA Section 5(e) consent orders to mitigate workplace exposure, but this authority is also less pervasive in nature than OSHA's broad authority to control occupational exposures. The same is true of EPA's use of Section 5(a)(2) significant new use rules (SNUR) to extend the requirements to entities beyond the notifier. Such approaches do not provide the same breadth of protection and the ongoing compliance responsibilities on the employer afforded by the OSH Act and OSHA's implementing measures. TSCA NCC believes that careful ongoing consultation with OSHA, as required under new TSCA, along with a full appreciation of the scope and effect of the OSH Act

{01508.001 / 111 / 00225476.DOCX 14}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

TSCA New Chemical Coalition Position Statement
December 2017
Page 6

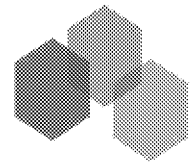
and OSHA's implementing measures, is essential to ensure adequate protection of all workers while also assuring that EPA only adopts separate restrictions in consent orders to the "extent necessary" to protect against an unreasonable risk.

On balance, 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. Even when the measures in question merely replicate what the applicant itself has suggested in a proposed Safety Data Sheet (SDS), such prescriptive orders have a variety of significant disadvantages. Such orders ignore OSHA's established expertise and the robust existing regulatory program, risk creating disputes over whether the EPA action has preempted OSHA's general authority to protect the involved workers, will inevitably lead to conflicts with or disputes over interpretation of parallel OSHA requirements, and may have applicability that is significantly limited by jurisdictional factors. It merits noting, as well, that OSHA does not give its approval or sign-off to the recommendations contained in SDSs and that recommendations in Section 8 of an SDS as to PPE are by no means determinative from a compliance standpoint. OSHA relies as well on its own considerable expertise, on the degree to which any industry consensus standards may be relevant, and on the impact of site- or employee-specific circumstances. For all of these reasons, TSCA NCC also believes that it is of paramount importance that to meet its obligation under Section 5(f)(5), EPA promptly should create a mechanism for the necessary ongoing consultations with OSHA. TSCA NCC further recommends that EPA act swiftly to meet its responsibilities under Section 26(l)(1) and commence discussions with OSHA that will lead to an update of existing MOUs to delineate clearly each agency's role in regulating exposure to new chemical substances given the changes in new TSCA.

For the reasons elaborated above, TSCA NCC is of the view that for many, if not most, of the new chemicals for which EPA has proposed workplace restrictions under TSCA, the OSH Act and OSHA's regulatory program, once EPA has informed OSHA and the notifier of its occupational risk assessment, will be sufficient to ensure workplace protection and thereby make any unreasonable risk to workers "not likely." Section 5(e) requirements to restrict workplace exposures should be reserved for those instances where EPA has determined, after consultation with OSHA, that the OSH Act and OSHA's regulatory program are not sufficient to protect against unreasonable risk from workplace exposures and that TSCA action therefore meets the "extent necessary" requirement. To the extent that EPA proceeds as recommended by TSCA NCC and relies on the OSH Act and OSHA's regulatory program, this will also have the benefit of reducing EPA's administrative burden currently spent in negotiating consent orders and promulgating SNURs for occupational concerns. Such a change in approach could also allow

{01508.001 / 111 / 00225476.DOCX 14}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



TSCA
NEW CHEMICALS
COALITION

TSCA New Chemical Coalition Position Statement
December 2017
Page 7

EPA to focus these regulatory resources on the potential risks to the environment and the general population -- areas that do not present the same level of overlapping authority and duplicative requirements as exist for workplace exposures.

Attachment

{01508.001 / 111 / 00225476.DOCX 14}

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: [202-557-3801](tel:202-557-3801) | F: [202-557-3836](tel:202-557-3836)



Memorandums of Understanding - Table of Contents

- **Information Date:** 01/19/1981
- **Agreement Agency:** The Office of Pesticides and Toxic Substances and U.S. Environmental Protection Agency

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES,
U.S. ENVIRONMENTAL PROTECTION AGENCY
AND THE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
U.S. DEPARTMENT OF LABOR
FOR

- GENERAL COOPERATION
- SHARING OF CONFIDENTIAL BUSINESS INFORMATION
- OSHA-EPA COOPERATION IN THE TSCA PREMANUFACTURE NOTIFICATION PROGRAM
- TRANSFER OF EPA INFORMATION ON SUBSTANTIAL RISK NOTICES

I. GENERAL WORKING AGREEMENT

This Memorandum of Understanding establishes a general working relationship between the Occupational Safety and Health Administration, U.S. Department of Labor, and the Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, regarding matters having or potentially having an effect on the activities and responsibilities of the two agencies.

II. COORDINATION

To achieve the coordination desired by both EPA AND OSHA, each agency hereby designates a coordinating office. The coordinating office for the Office of Pesticides and Toxic Substances (OPTS) will be the Office of Toxics Integration (OTI); for the Occupational Safety and Health Administration (OSHA), the Division of Interagency Programs. These offices shall serve as the initial communication link between the two agencies. Future specific agreements will be made by the program offices of OSHA and EPA's Office of Toxic Substances. Parts A, B and C below are directed at specific areas of coordination for sharing of confidential business information, OSHA's cooperation in the OPTS premanufacture notification program, and referral to OSHA of TSCA section 8(e) notices.

In carrying out their respective responsibilities, OPTS and OSHA will, to the extent practicable, consult and exchange information with each other through the coordinating offices. Specifically they will:

- (1) Coordinate programs, including the development of standards, to avoid duplication of effort, to assist in setting priorities, and share information and research;
- (2) When appropriate, consider the development of joint regulatory efforts. If no joint efforts are possible, both agencies will coordinate the development of any regulations concerning occupational exposure to new chemicals, to the extent feasible;
- (3) Exchange information and report on general enforcement matters and on particular situations of common concern to each agency;
- (4) Make every effort to achieve uniformity of approach in long-range planning;
- (5) Obtain legal and policy positions on statutory authority regarding the extent to which the other agency can remedy a particular condition or matter that may be within the regulatory purview of the agencies;
- (6) Use communication systems available to both agencies for educational services to the public about safety and health topics.

A. Confidential Business Information Exchange

PURPOSE:

This section allows OSHA to have access to confidential business information (CBI) submitted to EPA under the Toxic Substances Control Act (TSCA). OSHA will use this information to assist in fulfilling its duty to protect worker health under the Occupational Safety and Health Act of 1970.

SCOPE:

OSHA is permitted access to all confidential business information submitted to EPA under TSCA. When OSHA requests transfer of specific CBI, a justification of the need for access will be submitted through the OSHA Document Control Office (DCO) to any DCO in OPTS. OSHA will treat all such information in accordance with the Memorandum of Understanding. When OPTS initiates the transfer of CBI, a justification of OSHA's need for access should be prepared by the appropriate EPA program official and submitted to an OPTS DCO prior to the transfer of any documents containing confidential business information. The appropriate OPTS DCO must approve the justification prior to transfer of CBI.

PROVISIONS:

- (1) OSHA will protect information received from EPA under this agreement by following the procedures set forth in its "OSHA TSCA Confidential Business Information Security Manual." The procedures have been approved by EPA's Inspector General's Office, and they meet or exceed the requirements of EPA's own "TSCA Confidential Business Information Security Manual."
- (2) OSHA agrees that it will not release or transfer TSCA confidential business information outside of OSHA without the prior approval of EPA.
- (3) OSHA will normally return confidential documents to EPA within one year, but with approval by the OPTS Document Control Officer, will be granted extensions. In addition, with approval of the OPTS Document Control Officer, OSHA may destroy the documents according to the requirements of the EPA TSCA Security Manual instead of returning them to EPA.

(4) OSHA personnel will be made aware of the possible criminal liabilities that may result from unauthorized release of CBI and will sign the TSCA-Federal non-EPA employee confidentiality agreement (Appendix 14).

(5) The Information Control Branch of the Management Support Division of OPTS (EPA) will provide initial CBI training to appropriate OSHA staff.

(6) A physical inspection of OSHA's security facilities will be made by EPA. No exchange of TSCA CBI will be made until such facilities are found to be satisfactory. There will be future periodic inspections of OSHA's security program by EPA.

(7) Following inspection and approval of OSHA's security facilities, a Federal Register notice will be published announcing this agreement and will provide the required ten days of notice, covering all future sharing of data under this section, pursuant to section 2.209 of EPA's regulations on confidentiality of business information, 40 CFR Part 2, Subpart B.

B. Premanufacture Notification (PMN) Data Exchange Procedure

PURPOSE:

This section deals with the exchange of PMN data between OSHA and OPTS. PMNs can provide information about possible worker exposure to new chemicals before they are produced on a large scale, enabling both OSHA and OPTS to discuss any possible hazards to exposed worker populations and, if necessary, coordinate action on these chemicals.

SCOPE:

OSHA and OPTS will work to assure that complete and timely notification is made concerning PMNs which may involve or affect occupational exposures to chemical hazards, and also to assure necessary coordination between OPTS and OSHA, including joint review of selected PMNs. This will permit OPTS to have the benefit of OSHA expertise in assessing occupational exposure risks, and will alert OSHA to possible chemical threats to worker health.

PROVISIONS:

To assure the above conditions are met, the following procedures are established:

(1) Contacts with OSHA concerning PMNs will be initiated by the Notice Manager for a particular PMN or by OTI through the designated individual in the OSHA Division of Interagency Programs. This individual will receive all data and information from EPA and be responsible for the response from OSHA. This individual shall coordinate the OSHA response or refer the EPA Notice Manager to the appropriate OSHA staff.

(2a) In order to assure that OSHA is informed of the status of EPA actions on PMNs, EPA's Chemical Control Division (CCD) will forward to the OSHA representative, as available, a copy of EPA's weekly PMN report. OSHA will use the report to identify PMNs of potential concern about which OSHA has not been contacted by OTI or the Notice Manager.

(2b) If the occupational exposure to a chemical is a concern during initial review, the Notice Manager or OTI will notify OSHA. EPA may request OSHA data concerning the chemical or its analogue or may refer the PMN to OSHA for information or consideration if no TSCA action is to be taken.

(2c) If a PMN for which there is concern regarding potential occupational exposure, goes into a more detailed review, the Notice Manager or OTI will notify OSHA. During the detailed review, Chemical Control Division may request technical assistance from OSHA to aid in EPA's assessment of the PMN and invite OSHA to participate in the work group.

(3) During the development of any regulatory action on a PMN for which occupational exposure is of concern, CCD will consult with OSHA. OSHA may be asked to participate in the detailed review work group for the PMN to assist in development of regulatory options. At that time, OPTS will provide OSHA with copies of documents generated by the OPTS initial review which describe the problem. As a member of this group the OSHA staff may be involved in reviewing draft regulatory actions and will be provided with a copy of the package which enters the EPA official rulemaking and clearance process.

(4) EPA will notify OSHA representatives of the final action taken by EPA on any PMN where occupational exposure is a concern.

C. Notices of Substantial Risk

PURPOSE:

This section provides a mechanism for EPA to provide OSHA with information submitted by industry under section 8(e) of TSCA, Notices of Substantial Risk.

SCOPE:

Section 8(e) of TSCA requires that any person who manufactures, processes, or distributes a chemical substance or mixture and who obtains information which reasonably supports the conclusion that the substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform EPA.

For each 8(e) notice received, the OPTS Chemical Hazard Information Branch (CHIB) prepares a status report. CHIB will, by this agreement, refer to OSHA any 8(e) notices in connection with which CHIB identifies an occupational exposure of concern. OTI will coordinate any necessary follow-up work with OSHA, such as plans for further evaluation or discussion of regulatory action.

III. AUTHORITY

The Office of Pesticides and Toxic Substances enters into this agreement under the authority of Sections 9 and 14 of the Toxic Substances Control Act (15 USC 2601, et seq.). Section 9 of TSCA requires certain coordination of actions taken under TSCA with actions taken under other Federal laws. Section 14 of TSCA provides that confidential business information may be disclosed to any officer or employee of the United States in connection with the official duties of such officer or employee under any law for the protection of health or the environment.

The Occupational Safety and Health Administration enters into this agreement under authority of the Occupational Safety and Health Act of 1970 (29 USC 651, et seq.), Section 7(c)(1). That section allows the Secretary of Labor to "use, with the consent of any Federal agency, the services, facilities, and personnel of such agency, with or without reimbursement..."

IV. PERIOD OF AGREEMENT

This Memorandum of Understanding shall continue in effect unless modified by mutual assent of the parties or terminated by either party upon a 30-day advance written notice to the other party.

This Memorandum does not preclude the parties from entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such special agreement.

Nothing in this agreement is intended to diminish or otherwise affect the authority of either agency to carry out its respective statutory functions.

This Memorandum will become effective on the date of the last signature.

Marilyn C. Bracken
Associate Assistant Administrator
for Toxics Integration

Warren R. Muir
Deputy Assistant Administrator
for Toxics Substances