

TSCA  
NEW CHEMICALS  
COALITION

**TSCA New Chemicals Coalition<sup>1</sup> 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The TSCA that was originally enacted in 1976 was comprehensively restructured and revised in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (new TSCA).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.

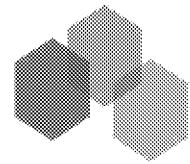
While EPA may issue an order under new TSCA Section 5(e) that contains prohibitions or restrictions intended to address workplace exposure, new TSCA Section 5(f)(5) requires that, prior to doing so, “[t]o the extent practicable, [EPA] shall consult with the Assistant Secretary of Labor for Occupational 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

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<sup>1</sup> 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.

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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.

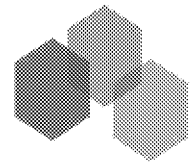
The value of coordination was recognized in a 1981 Memorandum of Understanding (MOU) between EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS), a predecessor of the current EPA Office of Chemical Safety and Pollution Prevention (OSCP) (attached). The MOU included provisions relating 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

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(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

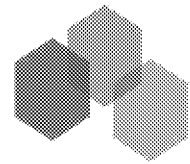
OSHA has in place an extensive regulatory scheme, as well as enforcement mechanisms, governing chemical exposure in the workplace. OSHA's longstanding policy preference is to minimize workplace exposures to chemicals through engineering and process controls, which it may specify in substance-specific 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

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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.

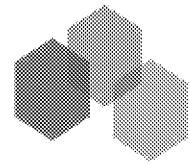
OSHA also has issued detailed regulatory provisions addressing respiratory protection in the workplace; respiratory protection is disfavored as a matter of policy whenever engineering or process controls will suffice to limit occupational exposure. Respiratory protection in the form of PPE nonetheless 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.

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

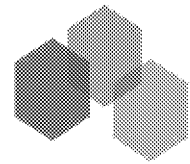
Although EPA has an obligation to formulate and to adopt TSCA Section 5(e) orders that include measures to protect workers from exposure to new chemical substances, this duty only applies “to the extent necessary to protect against an unreasonable risk.” When this duty is viewed in juxtaposition with 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

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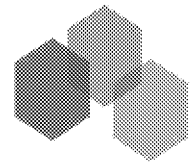
and OSHA's implementing measures, is essential to ensure adequate protection of all workers while also assuring that EPA only adopts separate restrictions in consent orders to the "extent necessary" to protect against an unreasonable risk.

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

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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

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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