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**Response to Comments on the
Significant New Uses of Chemical Substances; Updates to
the Hazard Communication Program and Regulatory
Framework; Minor Amendments to Reporting
Requirements for Premanufacture Notices
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Introduction

This document is an addendum to Unit IV of the final rule on significant new uses of chemical substances, identified by docket identification number EPA-HQ-OPPT-2014-0650.

On July 16, 2016 (81 FR 49598; FRL 9944-47), EPA proposed amendments to the regulations governing significant new uses of chemical substances under the Toxic Substances Control Act (TSCA) to align these regulations with revisions to the Occupational Safety and Health Administration's (OSHA) Hazard Communications Standard (HCS), which are cross referenced. EPA further proposed the July 2016 amendments to align with changes to the OSHA Respiratory Protection Standard and the National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements for the respiratory protection of workers from exposure to chemicals. EPA also proposed revising the regulations governing Significant New Use Rules (SNURs), based on issues that have been identified by EPA and raised by stakeholders through the public comment process. Additionally, EPA proposed making a minor change to reporting requirements for premanufacture notices (PMNs) and other TSCA section 5 notices.

EPA is finalizing amendments to general requirements for SNURs in 40 CFR Part 721, Significant New Uses of Chemical Substances. Based on public comments received on proposed changes to 40 CFR 721.63, EPA will move certain language which was proposed at 40 CFR 721.63(a)(1) and (4) to new paragraphs at 40 CFR 721.63(a)(7) and (a)(8), respectively, to ensure the new provisions only apply to SNURs issued after the finalization of this rule (see Unit III.A of the Final Rule). With the exception of amendments proposed at 40 CFR 721.63(a)(1) and (4), all other amendments are being finalized as proposed. Most of the changes relate to the standard significant new uses for new chemical SNURs identified in 40 CFR 721 subpart B,

which EPA cross-references in individual SNURs in subpart E. Other changes are procedural changes to the general provisions in subpart A that apply to all SNURs. EPA also clarified in the preamble of the proposed rule some definitions contained in 40 CFR part 721 and is making a minor change to reporting requirements for TSCA section 5 notices in 40 CFR parts 720.38, 720.45 and 723.50.

EPA received 18 public comments on the proposed rule. Commenters included potentially affected businesses, trade associations, environmental and public health advocacy groups, and other Federal agencies. In the preamble of the final rule, EPA responded to many of the significant comments relevant to proposed rule; however, this Response to Comment document summarizes all the comments relevant to the proposal and EPA's response to those comments.

Hazard Communication

1. Comment Summary: Several commenters (ACA, ACC, AFPM) suggested that required hazard and precautionary statements duplicate requirements prescribed by the Occupational Safety and Health Administration (OSHA). One commenter (ACA) stated that they do not believe there is a benefit or need for human health hazard and precautionary statements to be prescribed by the rule, as they would pose duplicative and unnecessary burdens on industry and imply that EPA is assuming the role of classifying the hazards of substances, which they believe to be OSHA's responsibility. They also wrote of concern for workers' confusion by the presentation of hazard communications in multiple forms due to the separate requirements of OSHA and EPA. Similarly, another commenter (ACC) stated that these requirements are unnecessary, as they duplicate already-applicable OSHA requirements. They claimed that

workplace protection is OSHA's core responsibility and said that Congress has recognized this repeatedly by requiring that EPA consult with OSHA before imposing workplace restrictions. They acknowledged that SNUR requirements are technically not restrictions but argued that submitters claim they effectively operate as restrictions and should be treated as such. They also drew attention to the fact that, at the time the letter was written, only 52 significant new use notices (SNUNs) had been submitted since 1979, which they said shows that, in practice, SNURs are restrictive.

Response: EPA's mandate under TSCA section 5 to apply restrictions to protect human health and the environment from potentially harmful exposures in the manufacture, processing, or use of certain new chemical substances includes the authority to require human health hazard and precautionary statements in individual SNURs. The commenters' suggestion that EPA is acting beyond its authority by imposing restrictions in the workplace and supplanting and duplicating OSHA's responsibilities does not properly acknowledge the differing programs and mandates of EPA and OSHA. Pursuant to TSCA, EPA is authorized to determine potential risk associated with new chemicals for which there is usually little data available and to determine appropriate restrictions. OSHA covers chemicals where hazards are generally known and the employer determines mitigation approaches. These key differences and their underlying rationale were discussed in the Preamble to the July 1989 Rule finalizing general provisions for new chemical follow-up: "The most significant differences are: (a) The OSHA standard requires an employer to make a hazard determination, while in the EPA standard, the hazard determination is made by EPA; (b) the OSHA standard allows the employer to develop language for labels and for the MSDS [(material safety data sheet)], while in § 721.72 EPA provides certain language to be included on the label and MSDS; [...] and, (d) § 721.72 requires that environmental hazards be

listed on the container label and the MSDS while the OSHA standard does not. The primary reason for the first two differences is that, in evaluating new substances, EPA is most often relying on a finding that a substance may present an unreasonable risk, pending the development of additional data. OSHA's standard applies to substances for which more definitive data are available and which are known to present certain hazards. [...] The fourth difference stems from EPA's broader mandate to protect the environment, as well as human health, from unreasonable risk." (54 FR 31301) (Ref. 2).

Further, the updated hazard and precautionary statements and warnings are not and do not operate as generally applicable restrictions. Instead, the rule describes the statements and warnings that EPA might use on a case-by-case basis in individual SNURs, depending upon EPA's assessment of the individual chemical substance involved. This rule updates the regulations to reflect the statements that EPA has already been using in individual SNURs and will continue to apply on a case-by-case basis. EPA may also propose and finalize SNURs containing other statements and warnings that are not included in the amendments or existing regulations. In addition, manufacturers and processors may choose at any time to submit a SNUN with information seeking to modify an individual SNUR. Upon submission, EPA will review a SNUN to determine whether the available information on a chemical substance warrants modifying a SNUR and any restrictions put into place to protect against potential risk to human health and/or the environment.

The amendments do not result in multiple forms of the communication of the hazards associated with a new chemical. To the extent possible, the hazard and precautionary statements coincide with OSHA's updated Hazard Communications Standard (HCS) requirements and the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals

(GHS) recommendations. EPA identifies the potential risk and the hazard and precautionary statements needed for a specific new chemical substance. Therefore, the PMN submitter and in the case of a SNUR, the regulated community, has clarity as to which statements and warnings, if any, are required for the new chemical substance. Any hazard and precautionary statements required by a SNUR would be a minimum set of hazard warnings needed to ensure protection against potential risk and cannot be altered or superseded by alternate forms. The source for any additional hazard communications requirements over and above the statements required by EPA would be pursuant to the OSHA HCS requirements or GHS recommendations. These additional statements, if any, would supplement the EPA-required statements.

Commenter's concerns that this rule duplicates OSHA requirements and imposes unnecessary and duplicative burdens on industry or is contrary to TSCA section 9 (b) are misplaced. The clarity, consistency and seamlessness of the rule reduces duplication and burden. The rule further parallels OSHA's standards and cross-references OSHA regulations to incorporate any future updates to those standards. In their comments in support of the rule, OSHA makes clear that by cross-referencing and ensuring consistency with OSHA HCS, the revisions reduce duplication and burden on those subject to these requirements (Ref. 1). For persons that are subject to TSCA and OSHA regulations for the same activity, the rule maintains consistency in compliance under both TSCA and OSHA. In addition, this rule applies not only to PMN submitters subject to OSHA regulations but also PMN submitters that are not subject to OSHA regulations.

2. Comment Summary: One commenter (ACA) stated that they support EPA's effort to communicate environmental hazards, though they recommend that these hazard and

precautionary statements be aligned with the statements used in the GHS to the greatest extent possible. Another commenter (ACC) supported changes to 40 CFR 721.91 and suggested that EPA consider adopting at least minimum reductions in concentrations based on wastewater treatment for the hundreds of existing SNURs with release to water provisions.

Response: The rule's environmental hazard and precautionary statements are aligned with the GHS statements to the greatest extent possible. The rule incorporates the updates that OSHA has made to their regulations to reflect the GHS statements and includes environmental statements aligning with GHS statements. Also, while EPA anticipates it will apply the updated environmental hazard and precautionary statements to the bulk of SNURs issued after the final rule is effective, EPA may also specify other GHS hazard and precautionary statements on a case-by-case basis as appropriate.

The changes to 40 CFR 721.91 to make consideration of control technology part of the calculations for the equation to calculate surface water concentrations will not apply to existing SNURs where a removal percentage has not been identified. As stated in the proposal, EPA will not identify a percentage of removal from wastewater for each chemical substance subject to an existing SNUR but will do so in future SNURs issued after the final rule is effective. Such an undertaking would be very resource-intensive and time consuming. Instead, manufacturers and processors may submit a request to EPA for modification of an individual SNUR. If there is a sufficient basis to support a modification based on information known about the chemical, EPA will consider modifying the SNUR.

3. Comment Summary: Two commenters (AFPM, B&C) expressed concern about the addition of paragraph (j) to 721.72, which they suggest requires the use of prescriptive, hazard-based cautionary statements. One commenter (AFPM) wrote that these statements are based on hazard, not risk, while SNURs under TSCA section 5 are based on risk, not hazard. They stated that it seemed that the statements are vague and do not consider a chemical's concentration, which would make it challenging to implement in a meaningful and effective manner. Both commenters urged EPA to engage with stakeholders to better understand potential implications of the proposed changes.

Response: A SNUR is not based on a risk assessment. Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular use of a chemical substance is not based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. EPA is not required to determine that a particular new use of any chemical substance will present, nor even that it may present, an unreasonable risk to human health and the environment. Rather, EPA issues a SNUR for a particular use of a substance if it has reason to anticipate that the use would raise significant questions related to potential exposure, so that it should have an opportunity to review the use before such use could occur. EPA bases this judgment on a consideration of all relevant factors, including the specific factors identified at TSCA section 5(a)(2). If a person decides to begin manufacturing or processing any of these chemicals for a significant new use, the notice to EPA allows the Agency to evaluate the use according to the specific parameters and circumstances surrounding the conditions of use.

The new paragraph (j) describes specific statements and other warnings that could be required for SNURs for substances identified in subpart E and are similar to the hazard

statements that have been incorporated in revisions to paragraphs (g) and (h), which are being made to remain consistent with statements required under the OSHA HCS and recommended by the GHS. The difference is that the new paragraph (j) in conjunction with the new paragraph (i) applies when hazard communication requirements are included in individual SNURs issued after the effective date of the final rule. The statements parallel the updated OSHA standards and GHS recommendations to the extent possible. The cautionary statements in paragraph (j) to 40 CFR 721.72 are not prescriptive. Instead, EPA will determine on a case-by-case basis the appropriate hazard statement for an individual SNUR based on the information available on the substance, including the concentration of the substance, if available and relevant.

EPA expects that, whenever the statements in paragraphs (g), (h), and (j) are required and the determinations for the SNUR are published, manufacturers and processors subject to the SNUR will also consider if they trigger any other corresponding hazard communication requirements under the OSHA HCS or recommendations under GHS recommendations. EPA may also propose individual SNURs or issue section 5(e) SNURs under 40 CFR 721.160 using other specific statements, signal words, symbols, hazard category, and pictograms as hazard communication requirements.

Hierarchy of Controls (HOC)

4. *Comment Summary:* Several commenters (ACA, ACC, API, and B&C) stated that they're concerned about retroactive implementation of the hierarchy of controls (HOC) provision, which one commenter suggests would alter approximately 230 SNURs and affect all groups that manufacture or process any of the affected chemicals. They expressed concern about the implications of the proposed changes applying to existing SNURs which could immediately

throw users into non-compliance with the regulations in Subpart B. One commenter (ACA) requested that the Agency either publish a list of SNURs that would be subject to the retroactive application of the rule or establish a cut-off date for applicability. One commenter (B&C) suggested that EPA cannot impose engineering controls if that requirement was not in play when the SNUR was issued without adequate due process for each existing SNUR.

Response: Pursuant to TSCA, EPA has the authority to make changes to SNUR requirements based upon information that becomes available. For example, EPA may modify SNURs in response to SNUNs where available information supports modifications. By requiring application of HOC in worker protection provisions for SNURs issued prior to July 26, 2013, EPA sought to update SNUR requirements to incorporate best practices and information presently available that affords better protection from potential risk of chemical exposures. After further consideration of the retroactive implications of the proposal, however, EPA has decided to move the HOC language that was proposed at 40 CFR 721.63(a)(1) and 40 CFR 721.63(a)(4) to new paragraphs 40 CFR 721.63(a)(7) and 40 CFR 721.63(a)(8), respectively. These new paragraphs will not affect previously issued SNURs and will only be for individual SNURs issued after the effective date of the final rule. Given this change, EPA will not “retroactively” implement hierarchy of controls provisions on previously issued SNURs. As a result, a list of impacted SNURs, or a cut-off date for applicability, is not necessary.

While EPA is not updating the language referenced by existing SNURs, EPA continues to affirm that a hierarchy of controls should be applied, and that PPE should be the last option to control exposures. Additionally, EPA believes that most companies are already following a hierarchy of controls as required by OSHA regulations. OSHA’s policy, since its inception in 1971, is that employers must reduce exposures to hazardous chemicals by first implementing

engineering and work practice controls before relying on respiratory protection. OSHA explains that “[t]his hierarchical approach of controlling hazards as close to the source as possible through containment, worker isolation, or ventilation, is widely accepted by the safety and health professional community and has been a fundamental principle of industrial hygiene since the first half of the 20th century.” (Ref. 1) While respirators can be an effective supplement to engineering and work practices to protect workers from exposure to air contaminants, OSHA continues to consider the use of respirators as the least satisfactory approach to exposure control. OSHA explains that respirator effectiveness ultimately relies on the practices of individual persons who must wear them, while the effectiveness of engineering controls is not reliant on an individual’s actions, and accordingly, provide a more reliable means of controlling exposures.

EPA has long encouraged the use of engineering and other practices to prevent or reduce exposures to chemical substances in the workplace. For example, in the Preamble to the 1989 Rule, EPA encouraged employers to evaluate their work areas and to implement industrial hygiene programs that consider the use of engineering controls to reduce or eliminate inhalation exposure (54 FR 31300) (Ref. 2). More recently, in SNURs published on June 26, 2013, EPA made known its decision that a hierarchy of controls should be applied, and that PPE should be the last option to control exposures (78 FR 38210) (Ref. 3). At that time, the Agency noted that its New Chemicals Exposure Limits language in TSCA section 5(e) consent orders already stated that attempting to prevent exposures through controls higher in the hierarchy than PPE is EPA’s preferred method for protecting workers (Ref. 3). Going forward, EPA has applied HOC in SNURs where applicable.

At the time the June 2013 SNURs were issued, EPA recognized that most PMN and SNUN submissions described engineering controls and other steps that will be taken to reduce

worker exposures (78 CFR 38210, 38215). (Ref 10) EPA continues to believe that most companies subject to the requirements of 40 CFR 721.63(a)(1) and 40 CFR 721.63(a)(4) are already following a hierarchy of controls because it is a general industrial hygiene practice.

5. Comment Summary: Several commenters (AFL-CIO, AFSCME, Earthjustice, EDF, ICWUC, NIOSH, and OSHA) stated their support for the inclusion of HOC in the proposed rule. They stated that the proposed changes are aligned with OSHA's requirements and that the changes codify what has been a matter of practice for several years, which increases clarity and predictability. These comments pointed out that OSHA has incorporated HOC into every health standard it has issued since 1971. The comments also mentioned the numerous health and safety outcomes that are improved when the hierarchy is implemented. Some commenters (Earthjustice, NIOSH) urged EPA to be more explicit in its description of HOC. One commenter (Earthjustice) stated that if Congress did not want EPA to include failure to implement HOC as a significant new use, they could have provided clear direction in LCSA, as EPA was issuing SNURs using similar terms during the period of TSCA reform. The same commenter requested that EPA identify the elimination and substitution of less hazardous materials, processes, operations, or equipment as necessary components of the hierarchy. At a minimum, the commenter suggested that EPA's regulations should be as protective as OSHA's regulations, which define engineering control measures to include "substitution of less toxic materials."

Response: EPA appreciates the comments in support for the inclusion of HOC. All new chemical SNURs published since June 26, 2013, have included the same language requiring the consideration and implementation of engineering controls and administrative controls where feasible when the SNUR contained a significant new use pertaining to the lack of PPE for

workers. These requirements to consider engineering and administrative controls are based on and consistent with the OSHA requirements at 29 CFR 1910.134(a)(1).

The Pollution Prevention Act of 1990 declared that it is the national policy of the United States that pollution should be prevented or reduced at the source whenever feasible, and that EPA must consider the effects of its regulations to determine their effects on source reduction, also called pollution prevention (P2). P2 is any practice which reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment prior to recycling of discarded material, treatment, or disposal. P2 practices include: equipment/technology modifications; process/procedure modifications; and reformulating or redesigning products to reduce or eliminate hazardous materials or pollutants. See: <https://www.epa.gov/p2/pollution-prevention-law-and-policies>, “Memorandum - May 28, 1992, Subject: EPA Definition of ‘Pollution Prevention’” (Ref. 4). EPA provides tools and guidance that encourage manufacturers and processors to assess and understand pollution prevention benefits of new chemical substances and invites PMN submitters to identify those benefits in their PMNs.

Once a PMN has been submitted, EPA is required to determine whether there are any potential risks of the intended use of the chemical substance if it is manufactured, processed, or used in commerce in the manner specified in the individual PMN (and, to determine any potential risks associated with foreseeable uses). If based on the PMN’s specific manufacturing, processing or use scenario potential exposures can be mitigated, this rule requires manufacturers and processors to consider whether there are feasible alternatives to mitigating exposures before using PPE through “engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace

policies and procedures).” These examples are not inclusive of all potential practices that PMN submitters might consider. However, because EPA evaluates PMN substances assuming that they will be used in commerce, the rule does not require elimination or substitution of less toxic materials as part of HOC which would result in a substance not being used in commerce. Further, EPA will not require elimination and substitution of less hazardous processes, operations, or equipment as necessary components of the HOC though submitters are welcome to consider these approaches. If based on the specific manufacturing, processing or use as described in the PMN, potential exposures cannot be mitigated, pursuant to TSCA, the substance will not be permitted to enter commerce in the first instance. The final sections 721.63(a)(1) and (a)(4), as proposed, are clear and maintain consistency with 29 CFR 1910 in describing examples of engineering controls while omitting the reference to substitution of less toxic materials.

6. Comment Summary: Two commenters (AFPM, API) argued that HOC requirements are not within EPA’s scope and that the proposed changes create inconsistencies with OSHA’s requirements. They stated that the proposal to include HOC as a factor in determining significant new uses is beyond EPA’s regulatory authority and in potential conflict with OSHA’s regulations. They stated that the proposed changes “go far beyond what Congress envisioned when crafting Section 5 of TSCA” and that Congress “clearly did not intend for EPA to use SNURs as a method to regulate the workplace, since there is no mention of HOCs” in LCSEA. They stated that the SNUR HOC requirements are different, lengthier, and more complicated than OSHA’s requirements cited at 29 CFR 1910.134(a)(1), and they felt it was not appropriate for EPA to go above and beyond what OSHA requires. They suggested that EPA reference OSHA’s requirements rather than create new regulatory text.

Response: In certain instances, as described in this rule, it is considered a significant new use to not to use HOC prior to using PPE to protect workers. Further, EPA has identified the lack of establishing a program including HOC as a significant new use in individual SNURs since June 26, 2013. TSCA section 5 authorizes EPA to use restrictions to prevent potential unreasonable risk to human health and the environment in reviewing new chemicals entering commerce, and the discretion to determine what constitutes a “significant new use.” EPA bases this judgment on a consideration of all relevant factors, including the specific factors identified at section 5(a)(2). Under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) amendments to TSCA, Congress maintained, without revision, EPA’s authority under section 5(a)(2) to determine what constitutes a significant new use. In doing so, Congress specifically chose not to delineate what is or is not a new use and instead, decided to continue to leave those determinations to the discretion of EPA. Therefore, commenter’s assertion that because TSCA does not explicitly discuss HOC, EPA cannot consider HOC in the issuance of a significant new use, is misplaced.

OSHA commented in support of this rule requiring those subject to SNURS to determine and use appropriate exposure controls per the hierarchy of controls to ensure worker protection (Ref. 1). The *Response to Comment 4* above discusses OSHA’s support of the HOC provision of this rule.

Also, commenters’ suggestion that EPA is acting beyond its authority by imposing restrictions in the workplace or is supplementing and duplicating OSHA’s responsibilities is inaccurate. The scope of EPA’s mandate under TSCA section 5 is to protect against unreasonable risk to human health and the environment during the manufacture, processing and use of new chemical substances in commerce which inherently includes protections against those

risks in the workplace. The Lautenberg Act amendments affirmed EPA's authority to place restrictions that protect against risks from new substances and to determine what constitutes a significant new use. Commenter's fail to recognize the differing programs and mandates of EPA and OSHA which is discussed in the *Response to Comment 1* above.

Personal Protective Equipment (PPE)

7. Comment Summary: Several commenters (B&C, AFPM, ACC) cautioned the Agency to clarify the requirements for respirator selection, including any requirements for test data, and what is meant by encouraging the use of "next generation" respirators, including how "next generation" upgrades are defined. One commenter (ACC) was concerned that, in the absence of undescribed test data, all air purifying respirators and supplied air respirators with helmets or hoods would be treated as loose-fitting facepiece respirators with an APF of 25. They requested that EPA explain why it has proposed to add this provision to some respirator listings but not all, and what testing would be sufficient to meet the proposed requirements. Additionally, they stated that OSHA's standard, found at 29 CFR 1910.134, contains extensive requirements regarding selection of respiratory protection equipment and proposed that EPA defer completely to OSHA and NIOSH requirements rather than try to "catch up" Subpart B of the SNUR regulations with the already-applicable requirements of OSHA and NIOSH. Another commenter (AFPM) advised EPA to be consistent with OSHA requirements and not surpass any of the OSHA requirements to avoid confusion within the regulated community. OSHA's comments provided support for the alignment with OSHA regulations and respirator certification requirements, and two other commenters (AFL-CIO, AFSCME) commented in support of the revised respiratory protection requirements.

Response: The final rule maintains consistency with the OSHA and NIOSH requirements by updating section 721.63 to identify the current categories of NIOSH respirators found at 29 CFR 1910.134 and 42 CFR part 84. OSHA supports EPA updating the respiratory protection requirements to be consistent with 42 CFR part 84. As OSHA notes in their comments, most manufacturers and processors are already subject to and complying with the most updated NIOSH regulation for testing and certifying respirators. As OSHA explains, this change also achieves compliance with 29 CFR 1910.34(d)(1)(ii), OSHA's requirement that employers select NIOSH-certified respirators for the protection of workers should respirators be necessary. However, the rule does not adopt commenter's suggestion to defer entirely to OSHA and NIOSH respirator requirements. To do so would be contrary to TSCA, which requires EPA to evaluate hazards and implement restrictions needed to protect against potential risk of new chemicals for which limited information is usually available. EPA does so in this rule by setting the minimum level of protection against inhalation exposure by identifying the category of NIOSH respirators from which submitters may choose specific respirators. In contrast, under OSHA, the company determines the inhalation hazard and chooses the respirator for substances where more definitive data are available and which are known to present certain hazards.

The categories of NIOSH respirators identified provide notice to persons subject to SNURs as to the minimum level of protection required and provides notice and clarification for persons, using the older respirators listed in section 721.63, who wish to identify an equally or more protective NIOSH-approved respirator under the newer requirements. The rule does not, however, prescribe which specific respirator to use within a category. Instead, as in the proposed rule, section 721.63(a)(4) of the final rule specifically refers manufacturers and processors to 29 CFR 1910.134 and 42 CFR part 84 for requirements on the selection, use, and maintenance of

respirators, including establishing respiratory protection program, medical determination, and other administrative and programmatic requirements for respiratory protection. Nor does the rule prescribe which testing a company must conduct. Instead, as in the proposed rule, manufacturers and processors should continue to conduct testing in compliance with 29 CFR 1910.10 under the rule.

Section 721.63(a)(5)(li) does treat all air purifying respirators and supplied air respirators with helmets/hood as loose-fitting facepiece respirators with an APF of 25 unless testing data demonstrates protection of 1000 or greater. The rationale underlying this provision is that, unlike the sealed respirators listed section 721.63(a)(5), which ensure greater protection, loose-fitting face-piece respirators cannot be presumed without demonstrated test data to provide higher than an APF of 25. Therefore, the final rule permits manufacturers and processors, if they chose, to demonstrate greater protection levels by conducting testing in compliance with 29 CFR 1910.10.

The final rule does not reference the term “next generation” and therefore does not include a definition of the term. In the proposal, EPA used the term “next generation” to connote the modernization and upgrading of protective equipment in order to incorporate new technological advances and innovations that enhance protection of human health and the environment. As new advances and understanding of respirator protections have evolved, so have the OSHA standards and NIOSH-approved respirators. While this rule includes a minimum set of PPE requirements, EPA encourages users to modernize and upgrade protective equipment in order to incorporate new technologies, such as measures that provide real-time information on the efficacy of PPE. For example, upgrading to respirators modernized to include features like an electronic chip to identify when personnel use and discontinue use of a respirator. An electronic chip might also monitor the condition and maintenance of the respirator. However, modernized

respirators ultimately can only be used if they are NIOSH-approved and meet standards under OSHA and EPA requirements. While EPA encourages innovation and enhancements in PPE, the rule does not require such modernization.

Coordination with OSHA

8. Comment Summary: Several commenters (ACC, B&C, API) are concerned that EPA has not been transparent about coordination with OSHA. One commenter (ACC) stated that they did not see any evidence of coordination with OSHA in the proposed rule, which is required by section 9(d) of TSCA. They stated that they hope EPA's consultation with OSHA will lead the Agency to conclude that their requirements are unnecessary. They acknowledged EPA's assertion that cross-referencing OSHA's standards in Subpart B of the proposed rule is consistent with 9(d), but claimed it fails on the grounds there is no evidence of coordinating between the two groups in the preamble or in the docket and that EPA has not explained why duplicative requirements are necessary, even if they are consistent with OSHA standards. Another commenter (API) stated that EPA needs to give the public more information about how it is working with OSHA in the drafting of the rule.

Response: Under TSCA, EPA reviews new chemicals for unreasonable risk to public health or the environment before they can be brought to market. The Lautenberg Act added new requirements for EPA to work with OSHA on issues regarding workplace exposures to new chemicals. Following the Lautenberg Act, EPA has implemented regular coordination with OSHA and has collaborated on workplace exposures generally by discussing and implementing

procedures for regular reporting to OSHA on workplace exposure issues, and handling of confidential business information.

On January 8, 2021, EPA and OSHA announced a Memorandum of Understanding (MOU) that advanced collaboration and communication on EPA's review of new chemicals under TSCA. This MOU provides a framework for coordination and communication between the two agencies on exposure to new chemicals in the workplace and will help achieve the agencies' shared goal of ensuring workers are protected from potential health and environmental risks. The MOU formalized coordination efforts that EPA and OSHA have already implemented and provides a framework for additional opportunities for collaboration. The MOU established designated staff and management points of contact from each agency to discuss and resolve workplace exposure issues related to EPA's review of new chemicals; outlined how EPA will provide OSHA with regular updates on EPA's new chemical determinations, including any necessary worker protection identified during EPA's review; and documented EPA's role in identifying and notifying OSHA of the need for formal consultation on EPA's review of new chemicals. See: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/memorandum-understanding-between-epa>, Memorandum of Understanding Between EPA and OSHA for Implementation of TSCA Section 5 and Sharing of Confidential Business Information.

Confidential Business Information (CBI)

9. Comment Summary: Several commenters (ACA, AFPM, B&C) requested clarification about when CBI would be disclosed. They stated that under no circumstance would it be acceptable for EPA to disclose the identity of any submitters, whether they be the original PMN submitter or a subsequent submitter of a notice or bona fide. Concerns were raised about the addition to 721.11

that states, "...and identify any confidential significant new use designations." They asserted that, depending on what the Agency means by "identify", it's possible that information claimed confidential could be disclosed without notifying the original claimant, which they feel is unacceptable.

Response: The confidential identities of other persons who submitted a section 5 notice concerning a chemical are not disclosed in response to a bona fide notice. In response to a bonafide notice made in accordance with the rule, EPA will disclose chemical identity and confidential significant new uses. "[C]onfidential significant new use designations" do not include company identifiers.

10. Comment Summary: Several commenters (B&C, AFPM, API, ACA) stated that they're concerned about the information disclosed in response to a bona fide notice. They felt that an anticompetitive environment could be created if CBI is disclosed in response to a bona fide notice. They suggested that the submitter of a bona fide should be required to specify their intended use, not only the chemical identity, and EPA should solely inform the company whether or not they are subject to the SNUR (as well as providing the necessary information for compliance). It was stated that downstream users also need to have enough information to ensure compliance with any applicable SNUR requirements, so it was proposed that EPA should require manufacturers to notify customers of compliance obligations. One commenter (ACA) pointed out that the amendment does not sufficiently address the case where a chemical identity is known and only the significant new use is confidential. In those cases, they stated that EPA should inform a submitter whether their use of a SNUR chemical is considered a significant new use without the requestor having to provide detailed identity information, as the chemical identity is

already known. They also suggested moving the provision found in 40 CFR 721.1725(b)(1) to Subpart B.

Response: The amendments do not represent substantive changes to existing requirements. Therefore, commenter's suggestion that the revision will lead to an anti-competitive environment is misplaced. Pursuant to sections 721.11 and 721.1725(b)(1), EPA already discloses the confidential identity of chemical substances or the confidential significant uses to the submitter of a *bona fide* if the requirements are met. Rather than continuing to separately reference section 721.1725(b)(1) in individual SNURs in subpart E when confidential uses are involved, the final rule integrates the two into a single provision as the amended section 721.11. The amended language is based on 40 CFR 721.1725(b)(1).

Informing *bona fide* submitters of the confidential significant new uses is the necessary information for their compliance and is therefore retained in the rule. To not do so would be extremely burdensome and an inefficient use of resources. If EPA were to only inform persons submitting *bona fides* that their intended use is not a significant new use then persons will not be aware that other uses, such as increased production volume, for example, are new uses. Persons would then be required to repeatedly submit separate *bona fides* to understand how to be in compliance.

The rule requires that a *bona fide* submitter identify the chemical or the use which means both if applicable. Section 721.11(a) states that a person "may ask EPA whether the substance or a proposed use is subject to the requirements of this part."

Also, manufacturers and processors are already required to notify downstream customers about a SNUR (See 721.5(a)(2)). In addition to requiring sufficient information in order to determine if SNUN is required, the purpose of requiring detailed chemical identity information

even if the chemical identity is not confidential is to ensure that the *bona fide* submitter has an intent to manufacture or process. Therefore, the final rule retains the requirement to provide detailed identity information even when the chemical identity is known.

Finally, section 721.11 as amended remains in Subpart A, General Provisions. The suggestion to move 721.1725(b)(1) to Subpart B is not accepted since Subpart B addresses Certain Significant Uses which does not have the broad applicability afforded by Subpart A. Moreover, as discussed above the amended section 721.11 integrates sections 721.11 and 721.1725(b)(1).

11. Comment Summary: One commenter (ACC) suggested that EPA ask if SNUR submitters would like to relinquish any claims of confidentiality, perhaps as part of EPA's CBI Declassification Challenge. Claims of confidentiality complicate the ability of others to know whether they may be subject to the SNUR, and many of the claims may no longer be necessary. Additionally, they requested that EPA identify if chemicals are the subject of SNURs when they are moved from the confidential Inventory to the public Inventory, as well as systematically amend SNURs to disclose information no longer claimed CBI. They referenced an example at 40 CFR 721.4587, where the SNUR identifies a chemical by generic name, but under section 12(b) the chemical is identified by CAS number and stated that the SNUR should be updated to include the CAS number.

Response: For certain SNURs, EPA has identified when chemicals are moved from the confidential inventory to the public inventory and will continue to do so as resources permit. Submitters of prior PMNs and SNUNs may at any time amend their submission to withdraw claims, either by accessing the submission via CDX, or by sending notice to EPA identifying

themselves, the affected TSCA submission(s), and the CBI claims they wish to withdraw. In addition, for CBI claims made beginning in June 2016, many CBI claims expire automatically after ten years, unless reasserted in accordance with TSCA section 14. The process by which submitters may relinquish any claims of confidentiality, however, is beyond the scope of this rule.

Recordkeeping

12. Comment Summary: One commenter (ACC) stated that they are strongly opposed to required recordkeeping. They said it is an onerous process of little utility to EPA and with little direct impact on protection from hazards and risks. They wanted it to either be limited or omitted fully, and said recordkeeping is an unnecessary burden for downstream processors that may result in misplaced market deselection or users choosing alternative substances that do not require recordkeeping. They stated that small businesses are most likely to opt out of using a chemical that has a SNUR, and they stated that SNUR recordkeeping requirements stifle technology and the innovation of potentially less hazardous materials.

Response: This rulemaking did not propose any substantive changes to recordkeeping requirements under section 721.125. Therefore, EPA cannot take any action in the final rule to address the substance of the issues raised in comments. Instead, the amendments to section 721.125 only remove references to “importer” or “importation” consistent with other amendments in the rule since these terms are redundant and unnecessary since the term “manufacture” as defined under TSCA includes “import.”

5(e) and Non-5(e) SNURs

13. Comment Summary: One commenter (ACC) stated that is unclear whether or not the PMN submitter is subject to a 5(e) SNUR, and they voiced concern that New Chemicals staff have suggested that non-5(e) SNURs will no longer be issued due to LCSA. They stated that they believe EPA still has the authority to issue non-5(e) SNURs and that it should continue to do so.

Response: Under the amended rule the PMN submitter continues to be subject to the 5(e) Order while all other manufacturers and processors continue to be subject to the 5(e) SNUR.

Additionally, EPA continues to have the authority to issue non-5(e) SNURs, but whether or not EPA chooses to do so is beyond the scope of this rule.

Terminology

14. Comment Summary: One commenter (ACC) raised concern about the terminology “predictable of purposeful release” in reference to the release to water provisions. They stated that the passage proposed does not define the totality of what is not predictable or purposeful, and they were concerned that accidental spills may not meet the “true emergency condition” that is required for a release to not be deemed purposeful or predictable and that the preamble’s further clarification of the phrase was inconsistent with previous EPA statements.

Response: In the preamble to the proposal EPA further clarified the meaning of the phrase “predictable or purposeful release” in section 711.90, which has been in place since 1989 (54 FR 31298) (Ref. 2). When proposed on April 29, 1987, “predictable or purposeful release” was described to not include releases where emergency conditions exist and significant new use notification is not possible (52 FR 15594) (Ref. 5). In response to questions received over time EPA is further clarifying that therefore, routine or repeated activity that results in releases to

water or non-routine releases to water that are not due to emergency conditions would be included in the phrase “predictable and purposeful,” as stated in the preamble to the proposal. The commenter correctly notes that EPA previously indicated in the preamble to “*Multi-walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules*,” 75 *Fed.Reg.* 56880, 56884 (Sept. 17, 2010), that purposeful or predictable releases to water would not include accidents or spills and that any water releases of the PMN substance identified in the PMN would qualify as purposeful or predictable releases (Ref. 6). However, contrary to the commenter’s suggestion these earlier statements are consistent with the clarification provided here and in the preamble to the proposal. When making the earlier statements EPA explained: “Purposeful or predictable releases to water include any intentional or reasonably foreseeable releases to water from a waste stream that is identified as part of a manufacturing process or other industrial process. For example, when filling out a PMN (EPA Form 7710-25), submitters are asked to identify environmental releases of the PMN substance from their manufacturing process and other known industrial processes. section 5(d) of TSCA, which specifies the required content of the PMNs, refers to TSCA section 8(a)(2) which specifies a standard of requiring information that is “known to or reasonably ascertainable by” the PMN submitter. Any water releases of the PMN substance identified in the PMN would qualify as purposeful or predictable releases” (Ref. 6). Spills and accidents are emergency conditions where making notification is not possible and therefore are not included in purposeful or predictable releases to water.

15. Comment Summary: Several commenters requested revision or clarification about the use of “where feasible” when talking about the proposed HOC changes. Some commenters (AFL-CIO, AFSCME, Earthjustice, EDF, ICWUC, NCOSH) stated that the “where feasible” language

should be changed to be consistent with the spirit and practice of hierarchy of controls, in that they need to be implemented in sequential and prioritized order, and cannot be rejected based on cost alone, only under specific and proven feasibility constraints. It was suggested that the terminology be adjusted to “to the extent feasible”, which matches OSH Act’s wording and which the Supreme Court has held to mean capable of being done, irrespective of cost. Another commenter (ACA) stated that they interpret “where feasible” to mean that a significant new use is not triggered when a processor or manufacturer provides reasonable evidence that they evaluated engineering and administrative controls and an explanation of why they are not feasible prior to using PPE.

Response: The term “where feasible” in the rule is meant to permit manufacturers and processors to consider cost although they cannot reject HOC based on cost alone. As stated in the preamble, the amended 721.63(a)(1) is based on and consistent with OSHA 1910.134(a)(1) and therefore “where feasible” carries the same meaning as 1910.134(a)(1) with some exceptions. The exceptions, discussed in Response to Comment 5 above, are that this rule excludes requirements to consider elimination and substitution when considering HOCs. Therefore, the rule maintains the reference to the phrase “where feasible” recognizing that it is based upon and consistent with 1910.134(a)(1).

Pursuant to section 721.63, paragraphs (a)(1) and (a)(4) of the rule, the failure to establish an HOC program triggers a significant new use unless the required evaluation of the feasibility of HOC is undertaken prior to using PPE. When engineering, work practice and administrative controls are not feasible or inhalation exposure is still reasonably likely, manufacturers and processors must provide adequate NIOSH-certified respirators. Since the phrase “where feasible” in 721.63(a)(1) is intended to be interpreted consistent with the 1910.134(a)(1) the rule does not

adopt the commenters proposed definition. Regarding the information needed to support HOC feasibility evaluations the record-keeping requirements of sections 721.40 and 721.125 apply. On a case-by-case basis, as substances are added to subpart E, EPA will continue to specify the appropriate recordkeeping requirements which correspond to the significant new use designations for the particular chemical substance and EPA will continue to consider information that a manufacturer or processor submits in a SNUN.

16. Comment Summary: Two commenters (Earthjustice, NCOSH) requested that language be clarified to state that the proposed provisions in 721.63 apply to not only manufacturing and processing, but any manner or method of distribution in commerce and disposal.

Response: TSCA section 5 SNURs apply only to manufacturers and processors of new chemicals substances. The amended section 721.63 (a) retains the original scope of applicability to manufacturing (including importing) and processing associated with any use of a substance considered a significant new use unless a program is established as delineated under protections in the workplace provisions. However, the rule leaves intact section 721.63(c) which ensures that restrictions applicable to the manufacturers and processors will be applied in the distribution in commerce. Section 721.63(c) sets forth procedures that manufacturers and processors subject to SNURs must follow if they become aware at any time after commencing distribution in commerce of a chemical substance that a recipient is engaging in an activity that is not consistent with the implementation of a worker protection program as specified in section 721.63(a). Since these protections through the distribution in commerce are already built into the regulations the rule does not include the revisions that commenters suggest.

17. Comment Summary: One commenter (API) noted that there are many instances where “manufacture or import” was replaced with just “manufacture”. They acknowledged that under TSCA, import is included within the definition of manufacture, but they believe that the deletion is unnecessary and confusing, as the word “import” has been present in the regulation for many years and it was not made clear why this needed to be changed.

Response: The amendments remove references to “importer” or “importation” consistent throughout the rule since these terms are redundant and unnecessary since the term “manufacture” as defined under TSCA includes “import”.

References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket.

1. OSHA. Comment submitted by David Michaels, PhD, Occupational Safety and Health Administration (OSHA). October 25, 2016. Comment ID: EPA-HQ-OPPT-2014-0650-0041.
2. EPA. Significant New Use Rules; General Provisions for New Chemicals Follow-up; Final Rule. Federal Register (54 FR 31298, July 27, 1989) (FRL-3504-6).
3. EPA. Significant New Use Rules on Certain Chemical Substances; Final Rule. Federal Register (78 FR 32810, June 26, 2013) (FRL-9390-6).

4. EPA. Memorandum - May 28, 1992, Subject: EPA Definition of “Pollution Prevention”; <https://www.epa.gov/p2/pollution-prevention-law-and-policies>.
5. EPA. Significant New Uses of Chemical Substances; General Provisions for New Chemical Follow-up; Proposed Rule. Federal Register (52 FR 15594, April 29, 1987) (FRL-3153-6).
6. EPA. Multi-walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules. Federal Register (75 FR 56880, September 17, 2010) (FRL-8835-5).