RESPONSE TO PUBLIC COMMENTS

TSCA Section 8(d) Certain Existing Chemicals; Request to Submit Unpublished Health and Safety Data Under TSCA

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Note: Each comment summary is followed by the end portion of the Federal Docket Management System (FDMS) ID numbers (0360). The next set of numbers indicate the submission number of the comment within FDMS. Some comment numbers include "A1", which specifies that the comment was submitted as an attachment by the commenter. The comments were submitted to the rulemaking docket during the comment period for the proposed rule (Docket # EPA-HQ-OPPT-2023-0360).

List of Abbreviations

6PPD	N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine
6PPD-Q	N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine quinone
ANPRM	Advance Notice of Proposed Rulemaking
CBI	Confidential Business Information
CDR	Chemical Data Reporting Rule
CDX	Central Data Exchange
COU	Conditions of Use
ECHA	European Chemicals Agency
EPA	United States Environmental Protection Agency
EU	European Union
FDMS	Federal Docket Management System
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HPS	High-Priority Substance
HPV	High Production Volume
IARC	International Agency for Research on Cancer
ICR	Information Collection Request
ITC	Interagency Testing Committee
IUCLID	International Uniform Chemical Information Database
LCA	Life cycle analysis
NAICS	North American Industry Classification System
NGO	Non-Governmental Groups
OECD	Organization for Economic Cooperation and Development
OHT	OECD Harmonized Templates
OMB	White House Office of Management and Budget
OR	Only Representative
OSHA	Occupational Safety and Health Administration
PFAS	Per- and polyfluoroalkyl Substances
PRA	Paperwork Reduction Act
PROC	Process category
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SDS	Safety Data Sheet
TDR	Tiered Data Reporting Rule
TSCA	Toxic Substances Control Act
WHO	World Health Organization

Response to Comments: TSCA Section 8(d) Certain Existing Chemicals; Request to Submit Unpublished Health and Safety Data Under TSCA

Introduction

This document is an addendum to the final rule under the Toxic Substance Control Act (TSCA) Section 8(d) Health and Safety Data Reporting Rule, identified by docket number EPA-HQ-OPPT-2023-3060. This rule, which was proposed on March 26, 2024 (89 FRN 20918 (FRL-11164-01-OCSPP), requires manufacturers (including importers) of 16 chemical substances to submit copies and lists of unpublished health and safety studies to the U.S. Environmental Protection Agency (EPA). This final rule aims to enhance the collection and use of data under TSCA section 8(d) and to facilitate informed decision-making regarding the potential health and environmental impacts of the 16 chemical substances. Specifically, the rule seeks to improve transparency, ensure timely reporting, and strengthen EPA's ability to assess and manage risks associated with these substances.

This document summarizes comments submitted during the public comment for the proposed rule and EPA's responses to them. During the 60-day comment period, 35 unique comments were received from different groups, all of which addressed the proposed TSCA section 8(d) Health and Safety Reporting Rule. Comments were submitted by individuals (13 comments), environmental groups and non-governmental organizations (NGOs) (4 comments), industry/trade organizations (17 comments), and a State agency (1 comment).

The public comments revealed varied perspectives across different groups. Industry stakeholders were generally supportive of the need for comprehensive chemical data to address all conditions of use (COUs). Some industry stakeholders, however, expressed concerns about the utility of studies involving low concentrations of chemicals. They requested concentration thresholds for reporting impurities and assurances that sensitive information would be protected as Confidential Business Information (CBI). While some supported the use of Organization for Economic Cooperation and Development (OECD) Harmonized Templates (OHTs) and International Uniform Chemical Information Database (IUCLID) formats, others expressed concerns about the administrative and financial burdens of compliance, particularly with submitting OHTs and reporting on impurities. Some industry stakeholders suggested extending the reporting deadlines from 90 to 180 days to allow more time for compliance. Environmental groups and NGOs strongly supported the rule, including the requirement to report on chemicals substances when they are present as impurities. They highlighted the importance of gathering data on 6PPD and its degradant, 6PPD-q, and urged EPA to finalize the rule quickly. The State agency supported the rule, requested the inclusion of additional chemicals and their degradants/transformation products, and emphasized the importance of reporting, including when chemical substances are present as impurities or transformation products. Private citizens broadly supported the rule, emphasizing the need for comprehensive chemical data to assess the health and safety risks associated with the listed chemicals.

EPA appreciates and values the feedback received from stakeholders on the proposed rule under Section 8(d) of TSCA. This document serves to respond comprehensively to the comments submitted during the public comment period focusing on the proposed amendments to the reporting requirements for manufacturers (including importers) of certain chemical substances. Throughout this document, EPA addresses key themes and concerns raised by stakeholders and explains how this feedback has influenced the final rule. EPA remains committed to fostering a transparent and collaborative regulatory process that promotes the protection of human health and the environment.

1. Support for the Proposed Rule

Summary: Twelve commenters voiced general support for the proposed rule. One commenter suggested that healthcare professionals and environmental and public health activists agree with the proposed rule. Two commenters noted that the proposed rule may benefit both humans and the environment.

Commenters who voiced support for the rule also stated that the proposed rule protects public health and/or public healthcare. Five of these commenters stated that the proposed rule may help inform future rulemaking, which would be a preventative approach to protect human health and healthcare. In addition, two commenters suggested that the rule would help address "a critical gap in the regulatory framework that has allowed potentially hazardous chemicals to be used without a full understanding of their health impacts."

Three commenters voiced support for the proposed rule and addressed EPA's estimated economic impact and burdens. Two of these commenters noted the similarity between the proposed rule and other EPA regulations such as under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), stating that "the reporting requirements on manufacturers under the EPA's new proposed rule are similar to other mandates placed on manufacturers and thus should be similarly feasible in implementation." One of the commenters stated that while the proposed rule "may create some additional compliance costs for manufacturers, the potential benefits to public health and healthcare outweigh these burdens."

Sources: 0005, 0006, 0007, 0008-A1, 0009, 0010, 0011, 0012, 0013-A1, 0014, 0015, 0017, 0018-A1, 0022-A1, 0032-A1.

Response: EPA appreciates the support from the commenters for the proposed rule and emphasizes that the proposed rule will safeguard public health and public healthcare. EPA appreciates the observations that the rule addresses a significant gap in the regulatory framework concerning the use of potentially hazardous chemicals and the full understanding of their health impacts.

EPA understands concerns with addressing the economic impact and burdens associated with the proposed rule. EPA acknowledges the support from the three commenters who provided insights into this aspect. The comparison to other existing EPA regulations, such as under FIFRA, fall outside the scope for this rulemaking. EPA also understands the concerns about potential additional compliance costs for manufacturers as noted by one commenter, the benefits to human health and the environment justify these costs. EPA appreciates the feedback to balance the effective implementation of this rule with practical considerations.

EPA notes that reporting required by this rule involves submission of information to EPA that should not be unduly burdensome given that reporting is generally required, as applicable, for information possessed, conducted by, known to, or reasonable ascertainable by the entity being required to report (TSCA section 8(d) provides for which standard applies to which type of information). Additionally, EPA has decided to not expand reporting requirements to processors or distributors, restricting the reporting requirement to manufacturers (including importers) of the identified substances who fall within the following list of North American Industrial Classification System (NAICS) codes: Chemical manufacturing (NAICS code 325) and Petroleum refineries (NAICS code 324110).

2. Does Not Support the Proposed Rule

Summary: Two commenters did not support the process that EPA is using to conduct this rulemaking. One commenter stated that the proposed rule would "essentially invert the EPA's settled TSCA rulemaking practice by first requiring submission of the studies pursuant to TSCA section 8(d) prior to any ITC [Interagency Testing Committee] action on the substances proposed." The commenter claims that promulgating an 8(d) rule prior to any ITC recommendation to test those substances is a departure from precedent and that the proposal lacked scientific assessments or other documents (other than the draft economic analysis) to support the listing of chemicals at 40 CFR 716.120. They further claimed that the proposal would effectively allow section 8(d) reporting requirements "to be attached to any chemical substance that EPA has 'screened' without any information about the screening process itself." This commenter requested that EPA withdraw the proposal on the basis of allowing the ITC to be able to fully consider the subject chemicals. A separate commenter suggested EPA provide separate deadlines for each chemical identified in the proposal, rather than apply one deadline for all 16 chemicals. Additionally, generally citing differences between the 16 chemicals, this commenter suggested focusing individually on each chemical would allow EPA to justify and apply the impurities exemption at 40 CFR 716.20(a)(9) to individual chemicals.

Beyond comments on the approach for this rulemaking that EPA is undertaking, certain commenters also expressed concerns with the content of the proposal. Three of the commenters expressed concern that EPA has not justified the need for this rule and that the rule "is not tailored to EPA's information needs for its work under TSCA section 6, nor does it comport with the Agency's planned framework for tiered data reporting (TDR)." Two of these commenters suggested that the agency should consider available data, identify critical data gaps, and then propose rules to specifically address those gaps.

Sources: 0020-A, 0021-A1, 0029-A1, 0036-A1.

Response: EPA acknowledges the commenters' request to withdraw the proposed rule, however, respectfully declines the request**.** EPA also appreciates the utility of the ITC in assessing health and safety data for chemicals added to the TSCA section 4(e) Priority Testing List. However, EPA is authorized to collect health and safety studies pursuant to rulemakings under section 8(d) – which is not limited to the ITC's activities or the presence of a chemical on the Priority Testing List. TSCA authorizes EPA to promulgate rules under which the Agency shall require reporting of health and safety studies and lists. TSCA does not require that EPA make any finding with regard to how the Agency selected the chemicals to subject to section 8(d) reporting requirements or that the Agency conduct scientific assessments or prepare other such documents to support a section 8(d) rulemaking.

Additionally, the 8(d) framework rule, promulgated to assist EPA in conducting TSCA section 8(d) rulemakings, stipulates that chemicals may be added to 40 CFR 716.120 following notice-and-comment rulemakings (40 CFR 716.105(a)), which is what the Agency has done here. EPA has identified a need to review existing health and safety studies for these 16 chemicals for the purpose of carrying out obligations under TSCA, therefore the Agency proceeded with the notice-and-comment rulemaking.

Regarding the suggestion to issue separate section 8(d) rules for each individual chemical on a staggered basis, EPA is issuing a single rule covering all 16 chemicals to streamline the regulatory process and reduce administrative burden. EPA considered comments suggesting a staggered deadline for some of the 16 chemicals but has decided not to implement this change. The reasons for finalizing the proposed submission deadline are explained in detail in Section 5. Similarly, EPA is not required to provide

separate justifications for each chemical for not allowing for the impurities exemption, since the explanation provided applies equally to all of the chemicals subject to this rulemaking.

EPA also acknowledges the commenters' concerns in regard to providing a justification for the proposed rule for the information needs under TSCA section 6. This action will provide existing health and safety information to inform EPA's prioritization and risk evaluation activities and enhance EPA's ability to manage potential risks associated with these chemicals effectively under TSCA section 6. EPA provides an explanation of how this rule aligns with the Agency's data needs and framework under TSCA section 6 in the notice for the final rule (see Unit II.F.).

With regards to the alignment with the EPA's tiered data collection framework, this rule does not conflict with the EPA plans for TDR, which has not yet been proposed. Waiting to ensure that this collection of data will align with a prospective rulemaking would deprive the Agency of information in the meantime and could undermine EPA's efforts to complete risk evaluations in a more timely manner. Further, EPA anticipates that TDR will align and support EPA's understanding of chemicals (e.g., their physical properties, health and safety data, and use information) by collecting data that aligns with a portion of the information that EPA is considering for the forthcoming TDR (i.e., the proposed TDR is anticipated to include use of TSCA section 8(d) data that aligns with what this final rule will require).

2.a Rule Should be Refined to Only Request Studies that will be Substantively Useful to Inform Risk Evaluation

Summary: Seven commenters expressed opposition to the proposed rule, suggesting that EPA should only request studies that will be substantively useful to inform a risk evaluation. Of these, three commenters indicated that EPA should provide clearer justification for why the requested studies are needed for the risk evaluation process, and two asked that EPA provide an analysis demonstrating how the requested studies would be used. One commenter requested that "EPA explain how it has used other information collected under TSCA section 8(d) for activities akin to TSCA section 6 risk evaluation in providing a better explanation" for how the requested studies would inform a risk evaluation.

Regarding the types of studies that should be included in the proposed rule, four commenters stated that the proposed rule request for studies is too broad and will include studies with little value to inform a risk evaluation. Three commenters stated that studies in which a subject chemical is present as an impurity will have no value for risk evaluation. One commenter suggested that emissions monitoring data would be more appropriate in such situations than test data. One commenter suggested that EPA could refine the proposed rule by focusing first on existing data gaps for the subject chemicals.

Sources: 0020-A1, 0023-A1, 0025-A1, 0027-A1, 0029-A1, 0035-A1, 0036-A1.

Response: EPA appreciates the feedback regarding the need for a clearer justification of the requested studies. To address these concerns, EPA is providing more detailed explanations of the need for the requested studies for the risk evaluation process in the preamble for this final rule. While EPA has not initiated prioritization activities for all the subject chemicals, the Agency is issuing this data call in anticipation of such activities. Having existing information from chemical manufacturers and petroleum refineries in hand will allow EPA to identify potential data gaps and address them before prioritization begins and/or within potential risk evaluations.

All industry data relevant to characterizing hazards and various uses of chemicals is important for accurately identifying Conditions of Use (COUs) and assessing occupational exposure through different processes. Data submitted in previous years are still important for identifying COUs and evaluating current exposures. Among other factors, data gaps may arise when the composition of a substance changes and when COUs for a substance change. Thus, determining which data is of higher quality or more pertinent for current action cannot be assessed until such data is submitted and reviewed.

Combining this information with the knowledge that EPA will actively be conducting data gathering to inform annual prioritization actions means that data submitted under TSCA section 8(d) will be valuable for near-term prioritization efforts. This will help to identify data gaps and guide outreach efforts as needed. Similarly, information gained through this collection will inform risk evaluation activities by helping to ensure that EPA is aware of all available information on a given chemical substance.

EPA acknowledges the concerns raised by several commenters about the breadth of the current request for studies and their value in studies in which a chemical is present solely as an impurity. Nonetheless, aggregations of monitoring data on mixtures containing reportable substances, even in low concentrations or as impurities, can provide insights into exposure levels under specific conditions of use. These insights are crucial for understanding the potential risks associated with these substances. EPA understands, however, that some listed chemicals may be present as impurities and byproducts at such low concentrations that they are not identified in related studies. For this rulemaking, EPA is requiring submission of information only on those studies in which the listed chemical is specifically identified in the studies. While monitoring data on mixtures containing reportable substances can provide insights to exposure levels, EPA does not agree that this data should be valued over comprehensive test data. Both types of data are important, and robust test data is essential for a complete understanding of risks associated with the subject substances.

The suggestion to prioritize addressing existing data gaps for the subject chemicals is noted, however, EPA has only recently initiated prioritization for the subject chemicals, making it difficult to define the specific data gaps at this stage. Furthermore, receiving these studies will support section 6 efforts for these chemicals and help determine whether additional or new information is needed after reviewing available existing studies. This approach aligns with our goal of ensuring that the data collected and analyzed under this rule are relevant and contribute meaningfully to informed decision-making regarding chemical risks.

2.a.i) Unpublished Studies are Not Reliable

Summary: Four commenters expressed concern regarding the inclusion of unpublished studies in the proposed rule. The commenters listed several reasons for why they believe such studies may be unreliable, including that they may have been rejected by peer reviewers, may be incomplete or unfinished, or may have deficiencies in methodology or samples. Two of commenters stated that including unpublished studies, especially those including uncontextualized data, may lead to misinterpretation and inaccuracies in EPA's risk evaluations.

Sources: 0016-A1, 0020-A1, 0029-A1, 0038-A1.

Response: EPA disagrees with the assertion that unpublished studies should be categorically excluded or viewed as inherently unreliable for several reasons.

First, while unpublished studies may vary in quality and completeness, they may still provide valuable data and insights that contribute to a comprehensive understanding of chemical risk. Many unpublished studies undergo rigorous internal review processes within research institutions or industry standards, which can sometimes be comparable to peer-reviewed publications in terms of scientific rigor.

Second, excluding unpublished studies could overlook significant data that may not yet have been published due to timing constraints or other logistical reasons but could still be relevant and impactful for risk assessment purposes.

In addressing these issues, EPA's Quality Program plays a crucial role in ensuring that all studies, whether published or unpublished, meet stringent standards for reliability and relevance. By establishing clear guidelines and criteria for the inclusion of unpublished studies, EPA aims to uphold the highest standards of scientific integrity while enhancing transparency and accountability in our regulatory processes.

3. Scope of Affected Chemicals

Summary: Three commenters made statements regarding the selection of the 16 chemicals in the proposed rule. One commenter was concerned that EPA has not provided sufficient justification for including the 16 subject chemicals, specifically regarding the scientific basis for listing these chemicals. The same commenter also noted that the ITC had not reviewed these chemicals prior to inclusion in the proposed rule.

Another commenter requested that EPA expand the list to include chemical substitutes, known and potential transformations, and chemicals in mixtures with the subject chemicals. The commenter suggested that this may proactively protect public health by discouraging manufacturers from using "potential regrettable substitutions." Specifically, the commenter listed other phenylene diamines, bisphenol S, toluene, and xylenes as chemicals to add to the proposed rule due to their nature as substitutes, transformation products, and presence in mixtures with the subject chemicals.

One commenter requested that EPA narrow the list of 16 chemicals to only include the five chemicals currently in the TSCA prioritization process. The commenter noted that doing so would "enable the Agency to determine if the 8(d) data mechanism produced useful information for TSCA section 6 purposes" before pursuing the remaining 11 chemicals.

Sources: 0018-A1, 0021-A1, 0029-A1.

Response: The inclusion of 13 of these 16 chemicals in the proposed rule stemmed from the TSCA Work Plan, as well as certain chemicals identified by stakeholders (i.e., 6PPD, 6PPD-q, and hydrogen fluoride). EPA identifies and prioritizes chemicals for risk evaluation and potential regulation based on various factors, including hazard potential, exposure pathways, and regulatory priorities outlined in the TSCA Work Plan. The EPA employs scientifically rigorous criteria and methodologies in this process, aiming to ensure that chemicals selected for further assessment pose potential risks to human health or the environment.

While the ITC was created to make recommendations to EPA on prioritizing and selecting chemicals for testing, the ITC was not intended to review each data gathering action undertaken by EPA. In identifying chemicals for the full range of section 8(d) regulatory actions, EPA follows established processes and

criteria for identifying various sources of information including scientific data, hazard assessments, exposure considerations, and stakeholder input. This adaptive approach allows the Agency to respond to emerging scientific information, regulatory priorities, and stakeholder input to protect public health and the environment effectively under TSCA.

EPA acknowledges and appreciates the commenter's input regarding the expansion of the list of chemicals in the proposed rule to include substitutes, transformation products, and chemicals found in mixtures, as well as the inclusion of studies on impurities. As part of EPA's response to the TSCA section 21 petition submitted in November 2023 requesting action regarding 6PPD, EPA has included 6PPD-q, a transformation product of 6PPD, in the list of chemicals. Additionally, EPA has finalized the requirement to include studies on impurities in this final rule. At this time, EPA disagrees with expanding the list of 8(d) chemicals to capture potential substitutes and other chemicals, though the Agency will consider additional chemicals for potential, future 8(d) rulemakings.

Stakeholders have expressed interest in EPA conducting risk evaluation on hydrogen fluoride. Thus, while hydrogen fluoride is not on the TSCA Work Plan, it has previously been identified by EPA as a chemical substance under consideration for prioritization. Accordingly, EPA considers the chemical substance as a potential candidate for prioritization and seeks to increase its information on the chemical pursuant to this rule.

EPA acknowledges the commenter's suggestion to narrow the list of 16 chemicals to include only those currently in the TSCA prioritization process. EPA appreciates the intent to focus resources, however, the Agency disagrees. Including additional chemicals will streamline the regulatory process and reduce administrative burden. Also, a staggered approach is not recommended due to the impacts it would have on subsequent prioritization efforts.

4. Scope of Affected Entities

Summary: In this section, commenters presented differing views on the scope of the affected entities. The comments are categorized into two main topics, 1) narrowing the scope and 2) expanding the scope of applicability.

Narrowing the Scope of Applicability One commenter stated that the scope of affected entities is "unnecessarily broad" and made two key suggestions:

- Limit to Recent Manufactures**:** The commenter suggested that EPA narrow the scope to cover only manufacturers from the current or previous year, as these manufacturers "are likely to be the historical manufacturers that might have studies."

- Exclude "propose to manufacturer" and those who import chemicals within mixtures: The commenter suggested that EPA exclude companies that have only "proposed to manufacture" those chemicals and those who imported chemicals only within mixtures, formulated products, and articles. The commenters also stated that studies from importers who do not import the chemicals as discrete substances would have "diminishing returns". Regarding companies that have only "proposed to manufacture" chemicals, the commenter argues that including such entities would be inefficient because their proposed manufacturing activities might not yet have generated the type of data necessary for meaningful risk assessment.

Expanding the Scope of Applicability Four commenters requested that EPA expand the scope of applicability for covered entities.

- Need to Cover Additional Entities: All four expressed concern that not expanding the proposed rule to cover additional entities "will fail to provide EPA with the full range of information sources it needs" to create accurate risk assessments.

- Specific Suggestions for Expansion: One commenter suggested that EPA require every entity covered under TSCA 8 (d) with occupational monitoring data to report under the proposed rule. Inclusion of Occupational Monitoring Data: commenter offered a specific suggestion for expanding the scope of affected entities.

- Legal Authority and Inclusion of Processors and Distributors: Three of the commenters also noted that EPA has the ability and precedent under TSCA to expand the scope of the proposed rule to processors and distributors, with one stating that "EPA is legally required to include processors and distributors in commerce" under TSCA Section 8(d).

Sources: 0029-A1, 0019-A1, 0028-A1, 0030-A1, 0032-A1.

***Response: Narrowing the* Scope:** Under TSCA section 8(d), EPA has the authority to gather health and safety data from a broader range of entities to effectively evaluate the potential risks and exposures associated with chemicals.

Response: Limit to Recent Manufacturers: Limiting the scope to manufacturers from the last year or two might restrict EPA's ability to gather comprehensive data on chemicals that may have been in use or studied over a longer period. Historical manufacturers, even if not currently manufacturing those chemicals, may hold valuable health and safety data that can contribute to a more complete understanding of chemical safety and potential risk, and EPA would not otherwise have access to that unpublished data without this rule.

Response: Exclude "propose to manufacturer": Commenter's concerns regarding the inclusion of persons who have "proposed to manufacture" and importers of mixtures, formulated products, and articles in the scope of covered entities, EPA is authorized to gather information from a broad spectrum of entities to carry out statutory requirements under TSCA. This includes not only current manufacturers but also those who propose to manufacture or import chemicals, as well as importers of mixtures. EPA has determined that, to carry out its obligations under TSCA section 6, the Agency needs existing information that is available through unpublished health and safety information from a broader scope of chemical manufacturers than just those who have imported as discrete substances, or just those who have manufactured the chemical within two years. The inclusion of these entities (i.e., those who import a chemical other than as a discrete substance) will ensure that all relevant sources of information are available to EPA.

Response: Those Who Import Chemicals with Mixtures:
EPA also understands that manufacturers who are considering manufacturing (including importing) a chemical for commercial purposes are likely to have conducted their own health or safety studies involving that chemical – even if they ultimately determine to forgo that manufacturing effort. Therefore, EPA is finalizing the scope of covered entities as proposed: manufacturers (including importers) of listed chemicals, including those who have manufactured the listed chemicals in the

preceding 10 years, and those who have proposed to manufacture those chemicals. This includes manufacturers (including importers) of the chemical when it occurs in mixtures, formulated products, or articles. The scope of industry sectors is also limited to NAICS codes 325 (chemical manufacturers) and 324110 (petroleum refineries). EPA's understanding is that the burden to comply with Section 8(d) (i.e., to consider information available to the manufacturer) as compared with the burden of including the period of time, as well as entities that intend to manufacture the chemical substances subject to the rule, weigh in favor of ensuring that such entities that have reportable information provide such information to the Agency.

Response: Legal Authority and Inclusion of Processor and Distributors

Commenters requested that EPA expand the applicability of this rule to include processors and distributors. They note that TSCA section 8(d) states that EPA shall promulgate section 8(d) rules that apply to "any person who manufactures, processes, or distributes in commerce" the chemicals subject to the given rule. EPA has implemented TSCA section 8(d) reporting requirements via a regulatory framework provided at 40 CFR part 716. This framework indicates that the specific decision to include them in a rule is based on the EPA's evaluation of what is necessary to fulfill the objectives of TSCA section 8(d). EPA established that processors would only be included in a given application of section 8(d) in a 1998 rulemaking (63 FR 15765-01). At the time, EPA analyzed roughly 11,000 submissions of TSCA section 8(d) information that it had received to date, categorizing them by submitter type. The Agency found that the vast majority of submitters were individual chemical manufacturers or associations representing chemical manufacturers. Thus, the Agency determined, at the time, that narrowing the overall scope of persons who must report on a routine basis would likely have a negligible impact on the type and comprehensiveness of the information submitted under section 8(d). Accordingly, EPA updated its implementing regulations of TSCA section 8(d) such that in a specific section 8(d) rule, EPA may require reporting of health and safety studies from a broader universe (e.g., including the processors of identified chemical substances). In this way, EPA reserved the ability to require more information from a much wider audience, as appropriate, while reducing the burden to industry on a routine basis.

For this final rule, EPA has decided not to expand the scope to include processors and distributors in the scope of applicability. As explained, above, in section 2 of this document, the Agency requires information on the chemicals subject to this rule to inform prioritization and risk evaluation activities. EPA recognizes that processors and/or distributors may also possess information that could be useful to such activities. Accordingly, the Agency will consider their inclusion in future section 8(d) rules. However, given the timing considerations alongside the burden both to EPA (in terms of assessing whether including processors at this time would be useful and appropriate) and to processors to be required to comply with this rulemaking, the Agency finds it appropriate to proceed without including processors at this time. Processors are welcome to submit voluntarily health and safety studies on these chemicals.

Further, EPA retains the authority to require such entities to submit studies under section 8(d) for future rulemaking.

5. Proposed Requirements

Summary: Several commenters shared their thoughts on the exemptions under the proposed rule. Specific topics addressed include impurities, articles, de minimis, studies previously submitted to EPA,

and impacts on due diligence. Each of these topics is addressed separately in the following sub-sections. Other comments related to exemptions are summarized in this section.

5.a) Exemptions

Two commenters expressed that EPA should not allow the exemptions at 40 C.F.R. § 716.20(a)(6)–(8) to apply; one expressing this sentiment for vinyl chloride, the other for 6PPD and 6PPD-q. The exemptions at 40 C.F.R. § 716.20(a)(6)–(8) stipulate that certain types of studies do not need to be reported: certain human health studies; analyzed aggregated monitoring data over five years old; and analyzed aggregated monitoring data that were not analyzed to determine exposure or concentration levels of the listed chemical. The two above commenters state that "these exemptions would deprive EPA of information about these chemicals' effects on health and the environment that is reasonably available to the agency and would be relevant and valuable to EPA's assessment and regulatory efforts under TSCA section 6."

Another commenter requested confirmation that the following exemptions related to mixtures would apply under the proposed rule:

- Exemptions for mixtures in 40 C.F.R. § 716.20(a)(6)(i)-(vii) including for physical and chemical property studies of mixtures that include the subject chemical. Corresponding exclusion for studies of mixtures in 40 C.F.R. § 716.10(a)(2).
- Exemption for mixtures in 40 C.F.R. § 716.20(a)(8), exempting monitoring reports for mixtures known to contain a subject substance if the study data are not already analyzed to determine the exposure or concentration level of a reportable substance, remains applicable.

One commenter stated that EPA should ensure that the exemptions in the proposed rule align with the current Globally Harmonized System for Hazard Communication.

Sources: 0020-A1, 0023-A1, 0027-A1, 0028-A1, 0030-A1, 0032-A1, 0016-A1.

Response: EPA is clarifying that the exemptions in 40 CFR § 716.20(a)(6)–(8) apply. Note that reporting on chemicals subject to this rule is required when they are part of a mixture as per 40 CFR 716.10(a)(2) and 40 CFR 716.45(a). These specific exemptions limit reporting requirements for certain subsets of data as described by the provision of the given exemption. Certain commenters highlighted that allowing for the use of these specific exemptions might limit EPA's access to critical health and environmental data for chemicals such as vinyl chloride, 6PPD, and 6PPD-q. In response, and especially for these specific chemicals, EPA has information on many of the physical and chemical properties identified by 716.20(a)(6) such that gathering such data for when the chemical is in a mixture is not an anticipated need at this time –. Similarly, monitoring reports for mixtures without analyzation to determine the exposure or concentration of the reportable substance will have limited benefit as compared with the burden of providing such data to the Agency. However, EPA continues to review its information on those chemicals as they enter the section 6 workflow and may identify needs for other data and exercise its information gathering authority later.

Regarding the suggestion to align proposed exemptions with the Globally Harmonized System for Hazard Communication, EPA notes the commenter did not elaborate which exemption(s) under the Globally Harmonized System for Hazard Communication the commenter is discussing. Lacking additional details in the comment, EPA reiterates that certain exemptions are not necessary for the purpose of this

8(d) rule, which is an existing health and safety study data call, and not a chemical classification and labeling requirement.

5.a.i) Impurities

Summary: Eight commenters indicated that EPA should not lift the impurities exemption. One commenter added that allowing the exemption is a reasonable approach because it focuses collected data on those substances likely to have a direct impact on health outcomes. Another commenter stated that without the exemption it would be very hard to determine whether a study was in scope or not. Specifically, "it is not clear whether the study would need to explicitly state that the subject substance is present as an impurity. It is unclear if a study of a mixture or Class 2 substance would be in scope if it does not mention the subject chemical, but the chemical is noted as present on the mixture safety data sheet (SDS) or is otherwise expected to be present."

Six commenters stated that EPA hasn't adequately explained or justified why the impurities exemption should not apply under the proposed rule, suggesting that EPA's justification is vague and generic and does not "provide any support for why information on incidental production as an impurity is needed" nor how it would be meaningful to EPA. Regarding mixtures, one commenter remarked that "a study that is conducted on a mixture that contains impurities is intended to analyze the health and safety of the substance and not those impurities. It can be difficult to tell what is driving an adverse health effect in a mixture if the listed substance is present at a very low concentration." Another commenter said that "if EPA does not exempt impurities or include a de minimis level, EPA will receive hundreds of studies on products containing impurity levels listed as 'less than X ppm'. These studies would not provide any useful information to inform prioritization, risk evaluation, or risk management of the chemical substance when it is an impurity." Further, one of these commenters questioned EPA's scientific justification for not allowing the exemption and asked for "the scientific basis for its requirements with specific discussion on the inapplicability of cutoffs, as used by EPA's Office of Pesticide Programs, the U.S. Food and Drug Administration, and as published by EPA's own scientists."

Four commenters indicated that not having the impurities exemption would significantly increase the reporting burden on industry and two added that it would also increase burden on EPA to review submitted information. One of the commenters said that "as proposed, the rule would require every study owner to review every study report to see if any listed substances are present at any level. This means that each manufacturer or importer of any substance in the last ten years (substantially more than the estimated 161 firms and 299 sites) will incur this burden." Another commenter remarked that searching for studies of mixtures where impurities are present will be very burdensome "as studies are unlikely to be easily searchable by impurities." A third commenter suggested that requiring reporting on impurities at any measurable concentration will greatly expand the number of studies and monitoring data that would have to be considered under the proposed rule. They request that EPA remove the "any measurable content" qualifier.

Meanwhile, two commenters expressed support for EPA's decision not to allow the impurities exemption under the proposed rule. One of the commenters stated that "exempting impurities under EPA's proposed new rule undermines the effectiveness of the initiatives the requirements seek to achieve, especially considering that, in some instances, impurities are more toxic than the chemical substances they contaminate."

Other comments related to the impurities exemption include: a claim that not allowing the exemption will lead to many submitted studies for multiple products and many will be duplicates because multiple companies may produce the same product; a request that EPA only collect those health and safety studies where the test material is one of the 16 subject substances if they do not allow the impurity exemption; and an acknowledgments that "in certain circumstances, impurities or presence of a listed chemical in an article may warrant a thorough evaluation." Where this is the case for any of the 16 chemicals, the commenter asks that EPA "propose specific requirements (and its analysis in this regard) for those substances."

Sources: 0004-A1, 0023-A1, 0018-A1, 0020-A1, 0021-A1, 0022-A1, 0024-A1, 0028-A1, 0029-A1, 0034-A1, 0035-A1, 0036-A1.

Response: EPA understands the concerns and acknowledges the practical implications of lifting the impurities exemption. However, under the final rule, EPA requires reporting on the listed chemicals of interest, even when they are present at small concentrations (i.e., as impurities) in a health and safety study. This approach aims to provide a comprehensive understanding of the substances, including when present at low concentrations, which is crucial for accurate risk assessment and effective regulatory actions. The presence of some chemicals, even at low concentrations, can significantly influence the associated overall health and environmental impacts. Specifically, exposure to low concentrations during a sub-chronic and/or chronic exposure may result in hazard effects that are important for EPA to understand and characterize. Similarly, relatively low exposures individually may contribute to unreasonable risk when considered in aggregate. To this end, even where a condition of use is not expected to be a significant contributor to risk from a particular chemical, TSCA nonetheless requires EPA to include it in the scope of the risk evaluation. Accordingly, this rulemaking seeks to inform EPA's understanding of the health and safety effects of chemicals, especially where companies have information accessible to them that EPA lacks.

EPA also notes this is consistent with the 8(d) final rule in 2021, which EPA finalized pursuant to the addition of 50 chemicals to the Priority Testing List by the Interagency Testing Committee (see 86 FR 34147; June 29, 2021).

Additionally, to address the commenter's concerns regarding whether the study would need to explicitly state that the subject substance is present as an impurity: EPA clarifies the rule does not require the submission of studies where the subject substance is not specifically identified in the study, even if the subject substance's presence could be inferred from other data. In other words, if a study does not explicitly name one of the listed chemicals as included in the study (at any concentration), then the study need not be submitted. EPA may require the submission of such studies in a future TSCA section 8(d) rulemaking, but with this rule, the Agency is not requiring submission of studies that do not explicitly state that the subject substance is present. For this rulemaking, EPA is requiring submission of information only on those studies in which the listed chemical is specifically identified in the studies.

Regarding the concern that claim that not allowing for the impurities exemption will lead to redundant reporting because multiple companies may produce the same product, EPA anticipates that companies conducting their own studies would have unique studies to report, and where redundancies may be submitted in the form of submitted studies, companies may rely on 40 CFR 716.20(a)(10) should a trade association submit the study for them (in accordance with the provisions of 716.30)).

Explanation for Lifting the Impurities Exemption:

To address questions from some commenters regarding the justification for lifting the impurities exemption, it is important to clarify that requiring information on impurities is integral to achieving a comprehensive understanding of the potential risks associated with chemical substances. EPA disagrees with commenters who suggested that meaningful information on chemicals included in studies as impurities cannot be derived. Health and safety studies of a listed chemical, including when present as an impurity in a tested mixture, inform EPA's understanding of both hazard and potential risk of that chemical. The presence of some chemicals, even at low concentrations, can significantly influence the overall health and environmental impacts of a mixture. Specifically, exposure to low concentrations during a sub-chronic and/or chronic exposure may result in hazard effects that are important for EPA to understand and characterize (especially if these types of exposures reflect what may be reasonably foreseen). Collecting existing studies that reflect lower concentrations of these chemicals in mixtures ensures that EPA has a fuller understanding of the potential hazards of a chemical in different exposure scenarios. Section 6 requires the assessment of a chemical's potential risk per condition of use irrespective of its concentration. EPA considers conditions of use associated with circumstances where a chemical substance subject to a risk evaluation even where the chemical substance is an impurity. To that end, health and safety information associated with the conditions of use, whether as a pure chemical, part of a mixture or article, or as an impurity helps inform such risk evaluation. EPA would not otherwise have this unpublished health and safety information on these listed chemicals to assess their potential health impacts at low concentrations, therefore is finalizing this requirement.

Scientific Basis and Comparisons to Other Agencies:

Regarding the scientific basis for not allowing an exemption and comparisons to cutoffs used by EPA's Office of Pesticide Programs and the U.S. Food and Drug Administration (FDA), the EPA acknowledges that different regulatory contexts may employ varying approaches. The purpose of this 8(d) rule is to provide EPA with existing health and safety studies of a chemical substance, including those associated with the chemical's presence as an impurity, to support EPA's understanding of a chemical's potential hazard and to inform diverse exposure scenarios. Unlike section 6, which focuses on assessing potential risks by weighing scientific evidence and considering the data quality, the 8(d) reporting rule is designed to capture all relevant information needed for chemical safety and risk assessments. This broader data collection approach supports a thorough evaluation of chemical substances.

Concern Over Burden:

In response to commenters' concerns over the burden of requiring studies that include the listed chemicals in any concentration (including as impurities), EPA notes that the Agency has revised its burden estimate in the economic analysis. The Agency considered input from public commenters to refine this estimate, including the burden associated with the requirement to submit studies showing "any measurable content" of the listed chemicals. EPA addresses comments related to the draft economic analysis in greater detail in Section 9 below.

5.a.ii) Articles

Summary: One commenter expressed support for reporting on subject substances as part of imported articles, stating that "exposure can still occur during secondary manufacturing, use, and disposal of consumer products originally manufactured outside the United States."

One of the commenters added that article importers 1) might not know that articles they import contain the subject chemicals and thus wouldn't know they should report and 2) are not likely to have health and safety studies in their possession that would be useful to EPA. Moreover, the commenter claims that the existence of the information EPA is requesting is unlikely. These two commenters suggested alternate methods for EPA to collect information on subject substances in imported articles. First, "if EPA has a reasonable basis that the presence of any of the subject substances in an article truly requires the provision on additional information for risk evaluation purposes, EPA should address that need on a substance-by-substance basis." Second, "if EPA's intent is to identify articles containing the substance for the purposes of assessing exposures for subsequent risk evaluation, that information should be collected as part of the Agency's scoping process for risk evaluation or by other means. Use of Section 8(d) authority is not the appropriate method." Finally, one commenter requested clarification of which NAICS the proposed rule applies to and confirmation that "the importation of finished articles does not trigger a reporting requirement."

Sources: 0018-A1, 0023-A1, 0036-A1, 0037-A1.

Response: EPA appreciates and agrees with the commenter's support for incorporating reporting requirements for manufacturers of the listed substances when imported in articles. The concern that exposure can occur during secondary manufacturing, use, and disposal of consumer products originally manufactured outside the United States is a valid and important consideration. For this final rule, EPA is requiring submissions of health and safety studies from companies manufacturing the identified chemical substances, including when a company is importing the chemical substance as a pure substance, mixture, formulated product, or article containing the subject chemical substance. If importers of articles who are covered by this action have unpublished health and safety studies including those chemicals, they must submit that health and safety study to EPA.

In response to the comment requesting clarification on the applicable NAICS codes and the impact on finished articles, EPA notes that the rule does not apply to all industrial sectors but is intended for entities involved in manufacturing, importing, or processing chemicals and targets certain industry categories based on the nature of the chemicals and substances involved. Pursuant to 40 CFR 716, the reporting requirements are limited to the following North American Industrial Classification System (NAICS) codes:

- Chemical manufacturing (NAICS code 325);
- Petroleum refineries (NAICS code 324110)

Thus, not all article importers are covered by this rule; it is limited to the above sectors. These sectors were specifically chosen as the types of manufacturers most likely to have relevant studies in response to this rule, even if they manufactured a listed chemical through its import as an article.

Regarding the importation of finished articles, the proposed rule does not trigger a reporting requirement solely based on the importation of such articles. Reporting is only required if the covered entity is in a covered NAICS code and has unpublished health and safety data encompassed in this regulation. Therefore, many businesses that import articles as retailers or in other NAICS codes will not be required to report under this rule. EPA agrees with the commenter who asserted that the use of an 8(d) rule for the sole purpose of identifying imported articles to assess exposures is not the most appropriate method in this case. EPA is not promulgating this 8(d) rule to collect information on the

presence of listed chemicals in articles; as explained above and in the final rule, this action was promulgated for the purpose of collecting unpublished health and safety data on the listed chemicals.

5.a.iii) De Minimis

Summary: Four commenters requested that EPA adopt a minimal threshold concentration for the proposed rule. Two of these commenters added that a de minimis level is needed because some manufacturers and importers may not even be aware that subject substances are present in their products "because they may not have conducted testing for 'any measurable content'", which could lead to their noncompliance with the proposed rule. Three commenters mentioned OSHA's requirement that chemicals be listed on safety data sheets (SDS) if concentrations are above 1% (or 0.1% for carcinogens) as an example of a de minimis threshold for a chemical's concentration in studies that could be adopted for this rule. One of these commenters also suggested, in lieu of a de minimis threshold, that EPA "specify that downstream importers can rely on information provided in an SDS." Finally, one commenter posed the following two related questions to EPA regarding chemicals in very low concentrations: 1) How will EPA interpret studies in which one of the listed substances is present at such low concentrations? 2) How will observed effects found in the studies be attributed to the listed substance?

Sources: 0021-A1, 0023-A1, 0033-A1, 0038-A1.

Response: EPA has decided not to include a de minimis threshold for reporting under the final rule. This decision is based on the need for comprehensive data collection from entities that EPA anticipates would have data (i.e., manufacturers of the chemical substance), including data where the chemical is present as an impurity. Such comprehensive data collection is essential for assessing and managing the risks associated with chemical substances. As described in the above discussion on the lack of impurities exemption (Section 5.a.i), the presence of chemicals at low concentrations can have significant effects, and by not setting a de minimis threshold, EPA may gather critical information potential hazards associated with varying concentrations, which is particularly helpful when assessing chronic and sub-chronic exposures. This approach supports the goal of identifying and managing risks associated with all relevant chemical exposures. Exempting submitters based on a de minimis threshold could lead to the omission of relevant information about chemicals that, even at low concentrations, might have significant health or environmental impacts. By maintaining the requirement to report by manufacturers all measurable levels (note that EPA's generally understanding is that processors and distributors are less likely to have such information and thus is not requiring them to comply as per this final rule; however, the Agency is considering whether to expand reporting requirements to such entities in future TSCA section 8(d) rulemakings), EPA aims to ensure that all pertinent information is captured, thus providing a more comprehensive understanding of hazards and potential risks. Note that companies have to search for and submit only studies that include a listed substance. If the study does not mention a listed substance that may be present as an impurity, that study is not reportable under the rule.

Furthermore, OSHA's SDS requirements set thresholds for reporting and notifications. The purpose of TSCA section 8(d) is to gather a health and safety data necessary for risk assessment and regulatory decision making, and EPA is not persuaded by the argument to establish a de minimis threshold for this rule on the basis of SDS requirements. Whether a manufacturer is required to include a chemical substance on an SDS does not bear on whether that manufacturer would have health and safety studies on that same chemical.

Additionally, the extent of SDSs and other information on chemicals manufactured (including imported) does not alter the record search and due diligence standards of this rule: manufacturers of listed chemicals must submit studies that are in their possession. As codified at 40 CFR 716.25, an adequate record search is limited to the locations where the required information is typically kept and to records kept by responsible personnel. This rulemaking is also not a product testing requirement, therefore manufacturers who do not know they have manufactured (including imported) a listed chemical in de minimis concentrations do not need to conduct testing to determine whether such low concentrations of a listed chemical are present in order to comply with this rule. If a manufacturer does not know they have manufactured (including imported) a listed chemical – if the company has no documentation or knowledge of having manufactured (including imported), processed or distributed a listed chemical (or proposing to do so), then they are not required to submit studies on that listed chemical.

Finally, in response to the questions that one commenter asked regarding the interpretation of studies under TSCA, please see the response below:

1. **Interpretation of Studies with Low Concentrations:** For studies including chemicals at low concentrations, EPA will appropriately consider the quality of the study and the study's design in interpreting the data, as part of the section 6 process. All measurable levels of listed substances are considered to ensure a thorough assessment of hazards and potential risks. EPA's risk assessment process considers the full range of data and weight of scientific evidence, including studies with low concentrations, to identify any potential unreasonable risks. As EPA has described in the 2024 risk evaluation framework rule, "relatively low exposures individually may contribute to unreasonable risk when considered in aggregate. Further, as EPA noted in the proposed rule, even where a condition of use is not expected to be a significant contributor to risk from a particular chemical, TSCA nonetheless requires EPA to include it in the scope of the risk evaluation." (89 FR 37028; May 3, 2024).

For more information on EPA's procedures for interpreting low-concentration data, you can refer to the "Framework for Human Health Risk Assessment to Inform Decision Making" and the "Guidelines for Carcinogen Risk Assessment". These documents outline the methodologies used for evaluating data across varying concentrations and assessing risks.

2. **Attribution of Observed Effects:** When attributing observed effects to a listed substance in studies, EPA will consider the study's methodology, which will include the consideration of factors such as concentration of the substance, the presence of other chemicals, and the framework used to conduct the study. EPA uses established scientific methods to determine whether the effects observed can be reasonably linked to the listed substance. This involves assessing dose-response relationships and potential interactions with other substances. By adhering to these standards and guidelines, EPA aims to ensure that risk assessments are comprehensive and scientifically sound, incorporating data from all relevant studies to protect public health and the environment.

5.a.iv) Previously Submitted Data

Summary: Two commenters requested that EPA clarify that studies submitted under the HPV program do not need to be submitted under the proposed rule. One of the commenters also requested that EPA make it explicit that studies previously submitted under EPA's testing program or that are already in EPA databases such as ChemView do not need to be re-submitted.

Sources: 0027-A1, 0029-A1.

Response: EPA acknowledge and clarify the commenter's concerns regarding submitting studies that were previously provided to EPA, including the HPV program submissions. EPA is finalizing the proposed language at 40 CFR 716.20(a)(11), which states, in part: "Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA section 4 action are exempt from the submission of lists of health and safety studies required under 40 CFR 716.35 and the submission of studies required under this rule." Thus, if a submitter has previously provided studies to EPA pursuant to a TSCA requirement or a voluntary submission, they need not resubmit that information to EPA for this action. Note that a study submitted without a requirement but nonetheless used for TSCA purposes is considered to have been submitted under the Act for purposes of TSCA section 14, among other things.

Studies that are already in ChemView or other EPA databases, need not be resubmitted if they were submitted to EPA pursuant to a TSCA requirement or of the submitter's own accord. However, studies submitted to EPA offices pursuant to requirements under statutes other than TSCA must be resubmitted and/or included on the list of studies required under 40 CFR 716.35.

Additionally, the section 8(d) framework rule relieves manufacturers of the requirement to submit studies or copies of studies that were previously sent to other Federal agencies without a CBI claim (40 CFR 716.35(a)(4)). Under the framework rule, lists of non-CBI studies previously submitted to other Federal agencies should: identify the study by title, state the name and address to whom the study was sent, and the month and year in which the study was submitted. Any study identified will be treated as if it were submitted under section 8(d) and will be available for public disclosure.

5.a.v) Impact on Due Diligence

Summary: Three commenters requested that EPA confirm that the Agency's due diligence requirements would not be changed under the rule. One of these commenters stated that "EPA must maintain and reaffirm the current regulatory provision that states, "The scope of a person's responsibility to search records is limited to records in the location(s) where the required information is typically kept, and to records kept by the person or the person's individual employee(s) who is/are responsible for keeping such records or advising the person on the health and environmental effects of chemicals." [40 CFR 716.26]".

The other two commenters brought up studies of polymers, requesting clarification that the rule would not require reporting where "the subject substance is not specifically analyzed for in that study, even if the presence of the subject substance could be inferred or determined from other information in the company's possession (e.g., polymers may contain unreacted monomer at very low or not feasibly detected levels)."

One of these commenters requested further confirmation that "manufacturers may limit their searches to "records in the location(s) where the required information is typically kept," including use of indexing systems used by a company to track health and safety information." Another commenter asked that EPA confirm that under the rule, "the due diligence standard has not been altered in respect of responsibility by reporting companies for information held by affiliates" such that reporters would not be required to search files of foreign or domestic affiliates.

Sources: 0020-A1, 0027-A1, 0029-A1.

Response: EPA confirms that the rule does not alter the current due diligence requirements as outlined in 40 CFR 716.25. The Agency will maintain the existing provision, which limits the scope of adequate record searches to the locations where the required information is typically kept and to records managed by responsible personnel.

Additionally, to address the commenters concerns regarding reporting requirements for studies involving polymers, the rule does not require submission of studies where the subject substance is not known to be included in the study. Manufacturers may continue to use indexing systems and limit their searches to records in the locations where such information is usually kept. Furthermore, as previously stated in section 5.a.iii, the commenters' concerns as codified at 40 CFR 716.25, an adequate record search is limited to the locations where the required information is typically kept and to records kept by responsible personnel. This rulemaking is also not a product testing requirement, therefore manufacturers who do not know they have manufactured (including imported) a listed chemical in de minimis concentrations do not need to conduct testing to determine whether such low concentrations of a listed chemical are present in order to comply with this rule. If a manufacturer does not know they have manufactured (including imported) a listed chemical – if there are no SDSs or other documentation or knowledge of having manufactured (including imported) a listed chemical, and mixtures and products are not "known to contain" a listed chemical – then they are not required to submit studies on that listed chemical.

For further clarification, if a manufacturer becomes aware of studies conducted by their affiliates during the file search, they should include these known studies in their submission, even if they do not have physical copies in their possession, as outlined in 40 CFR 716.35(a)(3).

5.b) Types of Studies and Data Required

5.b.i) Composition or Purity of Substance

Summary: Three commenters remarked on the requirement to report on the composition or purity of subject substances under the proposed rule.

The first commenter stated that the requirement does not apply to occupational exposures, asserting that "in general, occupational exposures are assessed in a workplace that handles a variety of substances, and only very rarely do these reports reference the composition or purity of a substance as part of the study." The commenter further described that interpreting occupational exposure data can be complex, particularly without a clear understanding of the conditions at the time the sample was taken.

The second commenter requested that EPA clarify that "it is enough to scan "the study and appended formulation information, or information known to the searcher, to see if listed substances are identified. If the substances cannot be identified, no other search is required." The third commenter indicated that studies should not be required unless the concentration of the subject chemical is known.

Sources: 0016-A1, 0029-A1, 0036-A1.

Response: In response to the commenters' concerns regarding the requirement to report on the composition or purity of subject substances under the proposed rule, EPA acknowledges the feedback and provides the following clarifications:

1. **Occupational Exposures:** The requirement to report on the composition or purity of subject substances is designed to ensure comprehensive risk evaluation. However, EPA recognizes that in many occupational exposure assessments, the specific composition or purity of a substance may not always be directly referenced in studies. The requirement aims to capture all relevant health and safety data that could impact risk evaluation, including composition and purity where available. As EPA has described previously, it is important to know what the purity of the chemical is so that EPA knows if there is anything else contributing to the exposure. For the purpose of understanding both hazard and risk, mixture studies are useful in the absence of other data on the chemical. In cases where the chemical grade or purity of the listed chemical substance is not noted in the study, the submitter is not required to note it.
2. **Scope of Search:** EPA confirms that it is sufficient to review the study and appended formulation information to identify the presence of listed substances. If the substances cannot be identified from these sources, no further search is required. This approach is intended to balance thoroughness with practicality in reporting.
3. **Concentration Requirements:** EPA is finalizing the requirement to submit any relevant study including the chemical substance, regardless of concentration. If the study does not identify the concentration of the chemical in a tested mixture, but still indicates the chemical's presence in the test, manufacturers must submit it to EPA in accordance with 40 CFR 716.

5.b.ii) Monitoring Data

Summary: Two commenters said that the language in the preamble of the proposed rule does not agree with the original definition of monitoring data in § 716.3(2)(iv). Their comments aligned with three other commenters who requested that EPA limit the required submission of monitoring data to meet the original definition such that only monitoring data that have been aggregated and analyzed would be required to be reported. Four commenters expressed support for continuing the exemption for reporting monitoring data that is more than 5 years old, indicating that EPA should rely on more recent data and that older data are not likely to be useful in risk evaluations. Commenters also added that the requirements for biomonitoring data are unclear, and that confirmation is needed that daily or routine monitoring data do not need to be submitted if they are only collected to confirm that permissible emissions levels have or have not been exceeded.

One commenter stated that EPA should not include requirements for submission of monitoring data in the proposed rule. As an alternative, EPA should "make targeted requests for specific monitoring-related studies to address data gap for risk evaluation." This commenter also asked EPA to "consider that monitoring results are often prohibited from disclosure due to health privacy laws around the world. For instance, multinational companies with operations in EU states are generally prohibited from sharing biomonitoring or biometric data."

Six commenters expressed general disagreement regarding the submission of raw monitoring data, asserting that EPA has not justified its need for such data or explained how they will use it. They emphasized that the purpose of the proposed rule is to collect "unpublished studies not to compel the generation of new studies using data that have not been previously turned into a report as defined under §716.3;" raw monitoring data that has not been aggregated and analyzed is of no value to EPA; and raw monitoring data are not defined by the proposed rule and requirement to submit will lead to a massive data collection that will be burdensome for both industry and the Agency. Four commenters requested that EPA clarify that raw monitoring data is not required under the proposed rule. Two of

them specifically said that EPA should remove the statement "raw monitoring data (regardless of having been aggregated or analyzed) of human or environmental exposure assessment" currently listed in the proposed rule. Commenters added that the preamble language discussing the use of OECD templates creates confusion regarding submission of raw monitoring data, which should be clarified. One commenter suggested that if EPA maintains the requirement to submit raw monitoring data, the 5-year cut off for aggregated and analyzed monitoring data should apply.

One commenter stated that they supported the collection of raw monitoring data in the proposed rule. They indicated that it would be easy to collect these data for many of the 16 subject substances given that OSHA already "requires employers to conduct periodic, representative monitoring of exposures[1] and therefore, chemical manufacturers and downstream users should have these data available on an ongoing basis."

Sources: 0016-A1, 0019-A1, 0020-A1, 0021-A1, 0025-A1, 0025-A1, 0027-A1, 0029-A1, 0036-A1,0037-A1.

Response: In response to the commenters' concerns regarding the regulatory definition at 40 CFR 716.3(2)(iv) and the proposal's discussion thereof, EPA reiterates that TSCA 8(d) grants EPA the authority to require data submissions of health and safety studies on specified chemical substances and mixtures. Further, TSCA defines "health and safety study" to mean "any study of any effect of a chemical substance or mixture on health or the environment or on both, *including underlying information* and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter." [emphasis added] (TSCA 3(8)). Further, under the 8(d) framework rule, the definition of "health and safety study" includes the statutory definition, as well as examples of the scope of such term (see 40 CFR 716.3). One example of this term at 40 CFR 716.3 is "Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture." Thus, underlying information, such as monitoring data, are considered part of the study.

Regarding commenters' questions on the scope of monitoring data that must be submitted, EPA is clarifying that certain requirements and limitations of initial submission of monitoring data are unchanged from the 8(d) framework rule. This rule is being finalized as proposed, with specific limitations on the scope of the studies based on monitoring data:

- Studies that are based on analyzed aggregations of monitoring data acquired more than five years prior to the chemical or mixture's effective date on the list under § 716.120 are excluded. (40 CFR 716.20(a)(7))

- Studies that are based on monitoring data of mixtures of one or more listed chemicals or mixtures, when that monitoring data are not analyzed to determine exposure or concentration levels of the listed substances, are excluded from submission requirements. (40 CFR 716.20(a)(8))

The 8(d) framework rule also limits the type of monitoring data that must be submitted with a study. For submitted studies that do not contain CBI claims, certain underlying data need not be submitted initially (including medical or health records, or daily monitoring records). However, EPA may request such data

[1] 29 C.F.R. § 1910.1045(e) (acrylonitrile); 29 C.F.R. § 1910.1017(d)(vinyl chloride); 29 C.F.R. § 1910.1028(e)(benzene).

at a later date under § 716.40 (see 40 CFR 716.10(a)(4)). While this requirement is unchanged for studies without CBI claims, this may impact studies that contain CBI claims and are to be submitted using OHTs and underlying data. See Sections 5.e and 6 of this document for more discussion on the submission of studies with CBI claims and the OHT requirement.

In response to questions of whether routine data that involves daily monitoring that confirms permissible emissions would need to be submitted, EPA is clarifying that such data are not necessarily required to be submitted at this time. To the extent that such routine monitoring data that are collected pursuant to permitting or other regulatory requirements are a "health and safety study" because they have been analyzed and aggregated, or otherwise have informed such a study, they would be required under this rule.

EPA acknowledges the commenters' concerns regarding the submissions of raw monitoring data. The mention of raw monitoring data in the preamble was intended as an example. As described above, the section 8(d) rule does not require the *initial* submission of raw monitoring data that has not been aggregated. As provided at 40 CFR 716.10(a)(4): "Underlying data, such as medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies do not have to be submitted initially. EPA may request underlying data later under § 716.40." Instead, the rule focuses on the submission of analyzed data that meets the definition of a "health and safety study" as outlined in 40 CFR § 716.3. The section 8(d) rule defines "health and safety study" to include "monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture."

5.b.iii) Clarifications of Reporting Requirements

Summary: Two commenters requested that EPA clarify the definition of "unpublished" and "published in the scientific literature" under the proposed rule. Specifically, they both stated "any final rule must clarify the definition of unpublished for the purpose of the rule and the definition should be appropriate [given that there is a range of sources that could constitute an unpublished study]. Information that is considered published should include but not be limited to any information available in the scientific literature, accessible through an Internet search, submitted to a U.S. or EU regulatory agency, or otherwise in a U.S. or EU agency docket or database (e.g., Chemview, ECHAChem)."

One commenter asked EPA to clarify what the Agency means by "study which is in their possession." They state that "studies possessed by a foreign affiliate are not possessed by the U.S. affiliate (but may be known and thus subject to the "list" requirement of this rule)." Relatedly, they ask for confirmation that membership alone in a REACH consortium does not create an obligation to submit the study under this rule.

One commenter further requested that EPA "confirm the 1989 General Guidance that studies only generally known to a U.S. manufacturer, but for which the manufacturer does not know the specific identity and contact information for a person that possesses the study, do not have to be included on lists of known studies. This is consistent with the 1989 General Guidance and the Central Data Exchange (CDX) program service data entry screen for submitting lists of studies (submission cannot be completed without specific contact information)." Another commenter sought clarification that studies undertaken for purposes related to FIFRA and or Federal, Food, Drug, and Cosmetic Act (FFDCA) are not subject to the proposed rule. Finally, commenters requested clarification that the scope of studies subject to the

proposed rule does not include data for personnel located outside of the United States and that generalized studies of certain industries and sectors that are not chemical-specific, are out of scope.

Sources: 0016-A1, 0020-A1, 0027-A1, 0029-A1, 0036-A1.

Response: In response to comments seeking clarification on the definitions of "unpublished" and "published in the scientific literature," EPA acknowledges that being precise and aligning with current information technology standards provides benefits to regulated entities when complying with TSCA section 8(d) reporting requirements. EPA's 1989 Section 8(d) guidance did not provide a comprehensive definition of "unpublished". In light of the changes in technology and in sharing of scientific information that have occurred since 1989, EPA considers studies or data that have not been formally reviewed or shared through peer-reviewed journals or other widely accessible scientific platforms to be unpublished data. In contrast, "published in the scientific literature" has a broad characterization, encompassing information available through scientific journals, online searches, submissions to U.S. or EU regulatory agencies, and entries in databases like ChemView or the European Chemicals Agency (ECHA) database. This approach ensures that the definitions are comprehensive and reflective of modern data accessibility, providing clear guidelines for identifying and reporting relevant information under the rule.

In response to the comment requesting clarification on what the EPA means by a "study which is in their possession," the Agency acknowledges the need for further explanation. A "study in their possession" refers to any study or data that an entity directly controls or has access to within their operational structure. Furthermore, EPA confirms that mere participation in a REACH consortium does not create an obligation to submit studies under this rule. Part 716 requires the submission of studies that are in the possession of the reporting entity and does not extend this obligation to studies solely known through consortium membership or similar affiliations. This approach ensures that reporting requirements are clear and manageable, focusing on data directly accessible to the entity responsible for submission.

EPA confirms that, in line with the 1989 General Guidance, studies that are only generally known to a U.S. manufacturer but for which the manufacturer lacks specific identity and contact information do not need to be included in the list of known studies. This approach aligns with the requirement for specific contact information and ensures practical reporting obligations. Additionally, studies conducted under the FIFRA or the FFDCA are excluded from the scope of this rule, as these studies are regulated under their respective frameworks. The rule also specifies that data related to personnel located outside the United States and generalized studies of industries or sectors that are not chemical-specific are not required under this rule. This clarification helps focus the rule on relevant, chemical-specific studies and maintains practical and manageable reporting requirements.

5.c) Role of Trade Associations

Summary: Three commenters made statements regarding the role of trade associations in the proposed rule, with all three commenters voicing support for the inclusion of studies submitted by trade associations. However, two commenters also expressed a need for clarification regarding the role of trade associations, stating that EPA should "reaffirm that if a trade association lists or submits a study, individual companies do not need to do so, as per 40 CFR 716.20(a)(10)." One commenter suggests that the TSCA section 8(e) program has a model allowing trade associations to submit studies through an "FYI" mechanism, which means individual companies are not required to resubmit the same studies since the EPA is already aware of that information.

Sources: 0020-A1, 0029-A1, 0036-A1.

Response: EPA appreciates the support expressed for the inclusion of studies submitted by trade associations under the proposed TSCA 8(d) rule. To clarify, if a trade association submits a study, individual companies do not need to submit the same study separately. This is in line with 40 CFR 716.20(a)(10), which specifies that individual companies are not required to duplicate submissions made by trade associations. However, trade associations are not able to submit *lists* of studies on behalf of member companies to satisfy the list submission requirements. Individual companies are still required to list studies known to them but not in their possession, although trade associations may submit the studies or copies of studies on their behalf. This requirement is unchanged from past 8(d) rules.

The submission of lists involves providing an overview of available health and safety studies related to specific chemical substances, allowing trade associations or companies to indicate what studies exist or are known to them, even if they do not possess those studies. This helps regulatory agencies grasp the breadth of available data for comprehensive evaluations. In contrast, the submission of studies entails providing actual health and safety studies or data that a manufacturer or importer possesses, offering detailed insights into the chemical's properties, risks, and associated health effects.

Under TSCA, submitting information under 8(e) does not automatically require companies to submit the same information under 8(d). TSCA 8(e) mandates companies to notify the EPA if they obtain information suggesting a substantial risk to health or the environment from a chemical, while 8(d) requires the submission of health and safety studies that companies possess. While submissions may overlap, compliance with one does not inherently necessitate compliance with the other.

5.d) Reporting Deadline

Summary: Three commenters submitted statements regarding the reporting deadline and timeline for the proposed rule.

One commenter stated that EPA's proposed 90-day period for reporting studies is insufficient and they estimated that the reporting process "will take likely thousands of person-hours (depending on the span of historical data to be retrieved) per chemical, per site." The commenter requested that EPA update the final rule to take this labor estimate into account. Another commenter addressed the reporting timeline for two of the subject chemicals, 6PPD and 6PPD-Q, and requested that the reporting period for these chemicals be within 60 days of the final rule's publication instead of 90 days. They indicated that because EPA had initiated a risk management rulemaking for 6PPD in 2023, it is "urgent that EPA promptly receive unpublished health and safety studies on 6PPD and 6PPD-Q to inform that process."

The third commenter expressed concern that the reporting deadline for the proposed rule will not "comport with EPA's proposed TSCA Section 8(d) rule and its final HPS determination on the five chemical substances." The commenter suggested that EPA may make HPS designations before the data adequacy review for the studies received by the proposed rule will be complete, given that the data adequacy review may take several months. Their concern is that "EPA will sidestep the threshold inquiry on prioritization" and that the submitted health and safety studies will not be used to inform and justify the final high priority substance (HPS) designations.

Sources: 0016-A1, 0032-A1, 0034-A1.

Response: EPA acknowledges the commenter's concern that the proposed timeline may be challenging for certain manufacturers given the reporting process and associated requirements. However, EPA is maintaining the 90-day reporting period for the final rule. Adhering to this timeline ensures that EPA receives the data to effectively analyze data for efforts under TSCA section 6, both for the Agency's responsibilities in designating high-priority substances and for evaluating risk for high-priority substances. It is necessary to receive study data by March 2025 on the five chemical substances for which EPA initiated prioritization in early 2024 to assist with associated regulatory activities (e.g., final scoping documents). For the other chemical substances, having data per the time period established by this rule enables the Agency to be better prepared for forthcoming identification of future high-priority substance candidates. Based on the statutory timeline for completing prioritization and the required public comment periods for this process, the 2025 prioritization designation documents would need to be published in Summer 2025. Thus, having the 8(d) study data for those chemicals in time for prioritization designation documents will afford both EPA and the public more time to review for chemicals that will initiate prioritization in 2025. EPA is therefore declining to implement a staggered submission period for certain chemicals in this 8(d) rule.

EPA recognizes that requiring submissions for specific chemicals, such as 6PPD and 6PPD-q, be provided earlier would, in turn, ensure that the Agency has more time to make use of such submissions. However, the 90-day reporting requirement is established to provide a consistent timeframe for all chemicals subject to the rule, and the Agency anticipates that it will have adequate time to review submissions with the 90-day reporting period, especially with regard to 6PPD and 6PPD-q, for which the Agency will be considering comments related to an ongoing Advanced Notice of Proposed Rulemaking (ANPRM) that the Agency is conducting to seek public input on potential approaches to addressing concerns relating to these chemical substances before formally proposing a rule (i.e., at this time there is not a "risk management rulemaking" on these chemical substances (this topic is discussed in further detail in section 11). EPA notes actionable data provided to the Agency in public comments regarding the time it would take to find and submit studies was incorporated to the extent practicable in the final estimates in the Economic Analysis.

Additionally, EPA acknowledges that this final rule will not coincide exactly with final high priority substance designations being made pursuant to TSCA section 6. EPA is committed to ensuring that the data adequacy review does not delay the HPS designations and that submitted studies are appropriately considered in the prioritization process. Studies submitted under TSCA section 8(d) will be reviewed and incorporated into EPA's section 6 responsibilities.

5.d.i) Request for Extension of Reporting Deadline

Summary: Eight commenters requested extensions of the reporting deadline, with seven suggesting that EPA revise the proposed rule to extend the reporting deadline, and one commenter requesting that EPA grant extension requests to individual entities. While the latter commenter did not request a general extension of the reporting deadline, they did suggest that "EPA liberally grant extension requests when requested," citing the amount of time necessary to properly use IUCLID software. Of the seven commenters, five cited the requirement to use OECD templates and four cited the scope of reportable studies as reasons for extending the deadline. Regarding the use of OECD templates, two commenters stated that the learning curve for using the templates significantly increased the amount of labor hours needed to complete the reporting requirements. The commenters who cited the scope of studies in the proposed rule as reason to extend the reporting deadline noted that the inclusion of raw monitoring data and studies with the subject chemicals present at any purity level would greatly

increase the number of applicable studies, and therefore the labor burden, for reporting entities. Some commenters also provided their own estimates of the amount of time needed to meet reporting requirements, with estimates ranging from "hundreds of man-hours" to over "500 working days." Three commenters specified that a deadline of 180 days from the publication of the proposed rule would be a more appropriate timeline for reporting entities, and one commenter suggested six months. Another commenter noted that many of the covered entities in the proposed rule are also subject to the Chemical Data Reporting rule (CDR) and the PFAS reporting rule, both of which have reporting deadlines in approximately the same timeframe as the proposed rule.

Sources: 0020-A1, 0021-A1, 0025-A1, 0026-A1, 0035-A1, 0036-A1, 0037-A1, 0038-A1.

Response: EPA is maintaining the original timeline for data submission, with reporting required by 90 days after the publication of the final rule. The schedule is set to align with ongoing TSCA Section 6 efforts and to ensure the effectiveness of our regulatory processes. Maintaining this timeline is essential for timely risk management assessments and delays could lead to inefficiencies in the process.

EPA also appreciates the commenter who provided detailed feedback on time estimates related to the development of OHTs, as that input was informative for both the final rule's economic analysis and the consideration of implementing the OHT requirement for all studies (whether CBI is included or not). The final rule specifies and clarifies that OECD templates are only required for submissions that are claiming CBI. For other data submissions, the requirement to use OECD templates will not apply to this rule. EPA anticipates that this accommodation in not requiring the templates for non-CBI submissions will significantly reduce the burden of reporting.

5.d.ii) Phased Reporting Deadlines

Summary: Three commenters suggested that EPA created phased deadlines as a way to extend reporting deadlines for reporting entities. Two of the commenters cited the requirement to use OECD templates and the scope of reportable studies as reasons for phasing in the deadline. Regarding the use of OECD templates, and as mentioned above, commenters stated that the learning curve for using the templates significantly increased the amount of labor hours needed to complete the reporting requirements. Regarding the scope of studies, the commenters noted that the inclusion of raw monitoring data and studies with the subject chemicals present at any purity level would greatly increase the number of applicable studies, and therefore the labor burden, for reporting entities. One commenter also stated that recently expanded CBI substantiation procedures, new requirements under Part 703, and the long sunset period of nearly 50 years together require a significant amount of time for entities to meet reporting deadlines. Instead of the proposed reporting timeframe, two commenters requested a two-phase deadline; one suggested that EPA create an intermediate extension for standard reporting and a longer extension for reporters to convert studies to OECD templates, and the other commenter suggested a total of 150 days from publication of the rule to submit studies and lists and 210 days to complete OECD templates. The third commenter suggested creating phased deadlines for subsets of the 16 subject chemicals and an overall extension of reporting for all reporters.

Sources: 0020-A1, 0027-A1, 0035-A1.

Response: EPA acknowledges the suggestion to create phased deadlines as a way to extend data submission deadlines to entities. However, for the finalization of this rule, EPA will finalize as proposed and will require data submissions 90-days after the final rule is published. As noted above (with regard

to other responses), and below (in this response), the OECD templates are required only for a subset of data being reporting (i.e., submissions claiming CBI), thus the concerns raised by commenters requesting staggered related to OECD templates are largely mitigated given that most of the data reported by this rulemaking will not need to align with the OECD templates. Otherwise, creating a phased reporting deadline based on the type of study would create incomplete records for chemical substances, preventing EPA from knowing what data is available and was submitted by this rulemaking until the final phased deadline, which would delay the utility and timeliness of making use of the data being required by this rulemaking until the conclusion of the final phase of reporting. This situation would, in turn, delay EPA's ability to use such information to inform prioritization and risk evaluation activities, as applicable for a given chemical substance.

EPA acknowledges the concerns raised about the learning curve associated with using the OECD templates. EPA understands that adapting to these templates can significantly increase the labor burden, however EPA is finalizing this rule to require OECD templates only on submissions claiming CBI. Additionally, the final rule on CBI, which addresses the handling and protection of CBI submissions, as well as addresses the implementation of the OECD harmonized template requirement was published June 1, 2023. EPA is aware of the additional effort needed for entities to become proficient. EPA has not yet developed detailed, TSCA specific instructions for choosing, populating, and submitting OHTs. For additional information on the CBI procedural rule and information on the Implementation for the OECD template requirement, please visit Final Rule: Requirements for Confidential Business Information Claims under TSCA | US EPA.

5.d.iii.) Requests for Extension of Sunset Date (Timeframe of Initiated Studies to Which Reporting Applies)

Summary: Four commenters submitted statements regarding the sunset date in the proposed rule. Three of the commenters requested that EPA extend the sunset date to 2 years from the published date of the final rule, as it is the maximum time allowed. All three of these commenters indicated that doing so would ensure that EPA receives "all reasonably available information" in a timely manner. Another commenter requested that the retrospective study search dates be limited to 15 years prior to the published date of the final rule, citing industry-standard company records retention policies that may make retroactive searches beyond that time frame difficult.

Sources: 0028-A1, 0029-A1, 0030-A1, 0032-A1.

Response: EPA will proceed with the final rule as proposed. The sunset date will remain at 90 days after publication of the final rule. This timeline aligns with ensuring the timely submission of data necessary for risk evaluation under TSCA section 6, while also maintaining regulatory consistency (similar discussion provided above with regard to other timing considerations proposed by commenters).

Additionally, concerns with the retrospective search dates being limited to 15 years, however, under this rule EPA is requiring that entities must submit relevant health and safety studies conducted or available in the last 10 years from the date the rule is published. The 10-year look-back period is set to ensure that EPA receives relatively recent and pertinent data for assessing risks associated with the chemicals listed under the rule. It strikes a balance between obtaining sufficient historical data and considering practical constraints related to data retrieval and submission. Further, this balance alleviates some of the burden on reporting within the deadline provided as described by commenters (e.g., see the above comment topic and response).

Furthermore, under TSCA 8(d) 40 CFR 716.35 (a)(2), there is a specific requirement for submitters to notify EPA and submit lists of studies currently ongoing. Additionally, once the study is completed, the submitter is obligated to provide the final results to EPA, regardless of the study's date of completion. This requirement ensures that EPA has access to all relevant health and safety studies, even those in progress.

5.e) Use of Templates for Collected Studies

Summary: Nine commenters discussed the requirement to submit studies using the OECD Harmonized Templates (OHTs). Five of these commenters were generally supportive of EPA's move to requiring OHTs (or a standardized format generally) in order to improve efficiency of data submission and reviews, but some of these commenters also voiced concerns with this particular proposal. Separately, three other commenters were generally unsupportive of the OHT requirement.

One commenter voiced general support for EPA's decision to require templates in the proposed rule, stating that templates will assist EPA in identifying potential exposure activities and controls in place more efficiently. The commenter further suggested implementing "a standard format to collate information and build a system to allow manufacturers and users of the substance to provide information" to EPA in a manner in which the data may be efficiently analyzed. Other commenters who were generally supportive of EPA moving to OHT formatting and harmonization with other authorities voiced some caution in requiring OHTs for this 8(d) rule. Conversely, two commenters stated that they opposed the OHT requirements for any studies under this rule. They identically stated that they understand "that EPA aims in general to move toward OECD/IUCLID formats for information and supports the Agency working with ECHA towards harmonization. However, forcing the format through this rule is premature and will not contribute to the overall aim of standardizing EPA's data." One of these commenters further stated that there "is no such requirement in the current 8(d) regulations at 40 CFR Part 716 and the requirement should not be adopted for TSCA section 8(d) purposes."

Two commenters also voiced general support for preparing OHTs for this rule but requested that EPA provide more time to prepare and submit the OHTs. A separate commenter also requested additional time or for EPA to "liberally grant extension requests" to submit templated data. One of these commenters also requested that EPA confirm that raw monitoring data need not be templated and submitted.

Six commenters also stated that the draft economic analysis did not adequately account for the burden associated with the proposed OHT requirements for all studies and urged EPA to revise the draft burden analysis to increase the burden associated with preparing and submitting OHTs. One of these commenters suggested that requiring reporters to use OECD templates exceeds the activities stated in the EPA Information Collection Request (ICR) No. 2703.01 and should therefore not be required. Specifically, the commenter pointed to the ICR's reliance on the past submission of OHTs as "voluntary" and thus templated data had comprised a small percentage of all submissions.

Four commenters stated that the language in the proposed rule implies that the requirement to use OECD templates only applies to studies with confidential business information. They cited the inclusion of language specifically requiring the use of OECD templates in Part 703, and the contrasting lack of such language in Part 716, as evidence that "EPA should not seek to impose this requirement beyond studies bearing CBI claims." One commenter added that if EPA wishes to request OECD templates be used for all studies, then the Agency must specifically add this language to Part 716.

Several commenters also requested additional support from EPA on how to prepare and submit OHTs. Two commenters requested that EPA publish additional guidance on the use of OECD templates for reporting; for example, one suggested that EPA define a required or preferred form of OECD template, and another noted that there "is no standardized approach in the U.S. to map the exposure scenarios to the European PROCs", such that industrial hygienists would still need to understand the data submitted under European chemical regulations and aggregate them for the U.S. The commenter also cited a concern that without published guidelines regarding IUCLID formatting similar to other countries, EPA may "receive a wide variety of non-consistent information" from submitted studies. Commenters also expressed concerns about the use of IUCLID software for reporting study data. One commenter stated that IUCLID software "continually evolves" and questioned EPA's decision to require reporting based on a single software. Another commenter expressed concern that studies submitted to IUCLID6 using the i6z format will not have CBI claims properly flagged.

Sources: 0016-A1, 0020-A1, 0026-A1, 0027-A1, 0029-A1, 0034-A1, 0035-A1, 0036-A1, 0037-A1.

Response: EPA acknowledges and appreciates the comments submitted regarding the requirement to use templates to collect health and study data under TSCA section 8(d). EPA believes that the use of templated studies will increase the Agency's ability to integrate submitted information into its processes because the templating (i.e., using a common format) better enables EPA to store and access data as well as share data given that the template is designed to be used for databasing, which will ultimately lead to better decision making outcomes EPA acknowledges the commenters' concerns and recognizes the challenges and the need for clarity. To clarify, the language in part 703 of the proposed rule explicitly mandates the use of OECD templates only for studies involving CBI to ensure consistent handling of confidential information. This requirement is not extended to other types of data submissions (i.e., non-CBI). Part 716, which addresses the general reporting for TSCA section 8(d), does not include a mandate for requiring OECD templates on non-CBI submissions. This was inadvertently omitted in the proposed rule. Therefore, the requirement to use OECD templates is limited to cases where CBI claims are involved. Future consideration to apply OECD templates to all studies, such changes will be clearly specified in Part 716 of the rule in future rulemakings under TSCA section 8(d). Additionally, this requirement aligns with other EPA actions that are requiring the use of these templates. Noting concerns raised by commenters regarding the burden associated with requiring all submissions to be in OHT formats, as available for the given submission, EPA is finalizing this rule to require OHT only for those submissions that claim CBI.

EPA understands the concern about the potential labor involved in creating OHTs for the first time and appreciates the commenters who provided specific burden estimates based on their experiences. For the final rule, EPA has revised the Economic Analysis and incorporated additional burden and cost estimates for reporting on costs associated with preparing OHTs for studies with CBI claims and substantiations.

EPA also acknowledges the concern about the need for clear TSCA guidelines on IUCLID/OECD formatting to ensure consistent submission. While EPA has not yet developed a detailed TSCA-specific guidance document, EPA's website offers information on the CBI final rule and the OECD/IUCLID formats, including details on implementation, requirements, and other resources to aid in understanding OECD/IUCLID formats. EPA has also been coordinating with external stakeholders to develop trainings and other resources to support IUCLID efforts. For additional information, please visit Final Rule: Requirements for Confidential Business Information Claims under TSCA | US EPA

5.f) Requests for Expansion of the Reporting Requirements

Summary: Three commenters requested that EPA expand the reporting requirements, specifically the requirements for types of studies and data required to be collected and submitted. Two commenters stated that EPA should expand the scope of monitoring data, citing the need for "actual industrial hygiene measurements" to accurately identify occupational exposures and risks for highly exposed sub-populations. One commenter also compared EPA's request for health and safety studies with OSHA's collection of personal exposure monitoring data, suggesting that the proposed rule aims to collect similarly comprehensive data. Another commenter asked for clarification that the proposed rule requires submittal of all health and safety studies for vinyl chloride. While the commenter stated that EPA should require the inclusion of "all information about vinyl chloride that TSCA allows EPA to collect," they specifically requested that EPA include epidemiological studies and additional underlying information in the proposed rule. Another commenter requested that EPA include studies where the subject chemicals were measured in consumer products, stating that data regarding consumer products may help EPA identify new or disproportionate exposure pathways.

Sources: 0018-A1, 0019-A1, 0030-A1.

Response: EPA acknowledges the comments on expanding the reporting requirements under TSCA Section 8(d). EPA understands the importance of enhancing data collection and monitoring to better address occupational and consumer exposure risks. In response, the rule mandates the submission of comprehensive health and safety data to include unpublished studies on toxicity (e.g., carcinogenicity, reproductive and developmental effects, neurotoxicity) and exposure (e.g., inhalations, dermal exposure). To further enhance data collection. At this stage in our rule making process, we are focused on gathering essential unpublished health and safety studies that will inform our regulatory actions. For future TSCA section 8(d) rulemakings, EPA will consider expanding the reporting requirements to include specific occupational exposure studies that will aid in assessing risk for highly exposed sub-populations. This will allow EPA to address immediate data needs while preparing for more detailed occupational exposure risks is subsequent evaluations. EPA acknowledges the commenter's request to include studies where the subject chemicals were measured in consumer products. EPA understands that exposure can occur during secondary manufacturing, use, and disposal of consumer products. Under TSCA section 8(d), EPA requires submissions of health and safety studies from companies manufacturing the identified chemical substances, including when a company is importing the chemical substance as a pure substance, mixture, formulated product, or article containing the subject chemical substance.

6. Confidential Business Information (CBI) Considerations

Summary: Three commenters expressed concern regarding how confidential business information (CBI) would be handled under the proposed rule, indicating that they think the rule requires certain clarifications related to CBI. First, two commenters referred to the regulatory definition of "health and safety study," noting that while TSCA Section 14(b)(2) excludes health and safety studies from being considered CBI, certain types of data included in these studies are not subject to that exclusion. They add that the proposed rule does not articulate how the TSCA Section 14(b)(2) exclusion applies under the proposed rule and requests that clarification on this point be added. The third commenter raised a similar concern regarding how CBI claims for information included in IUCLID templates should be made and substantiated. They request that EPA provide more guidance on this topic and suggest that EPA may want to split the rule in two, deferring submission of IUCLID templates until "EPA has confirmed how CBI

claims are made for the information they contain and that its systems are ready to receive the templates."

One commenter shared their concern regarding intellectual property and privacy protections that are separate from CBI claims noting that "submitting studies could risk copyright infringement or violation of data protection/data sharing agreements." They "recommend that EPA consult with legal counsel, trade associations, and others that would be sensitive to the issues regarding release of the type of information EPA seeks."

Sources: 0016-A1, 0021-A1, 0027-A1, 0029-A1.

Response: Under TSCA Section 14, health and safety studies are generally excluded from confidential protection. TSCA Section 14(b)(2) lists certain types of data that are not eligible for confidential treatment, except under specific circumstances (e.g., when the disclosure of health and safety data would reveal processes, formulas, or other proprietary details unrelated to health and safety. 40 CFR 703.3 lists additional categories of information that is not considered part of a health and safety study so may also be claimed and treated as CBI). This Section 8(d) rule is not intended to modify or explain the exclusions from the definition of health and safety study contained in section 703.3; comments on those exclusions are therefore beyond the scope of this rule.

Additionally, in response to the commenter concerns about handling CBI claims with IUCLID templates, the requirement for entities to report health and safety studies using templates are as follows: Submitters of health and safety studies or information from such studies must provide such data in templated form, using an appropriate OECD harmonized template, if such template is available for the data type (*https://www.oecd.org/ehs/templates/*). Individual test or data submission rules or orders may specify an appropriate template or templates. Submission of templated data is not a substitute for submitting a full study report where a specific TSCA rule or order requires submission of the full study report (e.g., § 720.50(a) of this subchapter, or according to the terms of a specific order under section 5(e) of the Act).

7. Rule Leads to Duplication of Existing Data

Summary: Four commenters indicated that the chemicals covered by the proposed rule are already subject to extensive study and EPA has access to information on them via the European Chemicals Agency's (ECHA) database of chemicals submitted under the European Union's regulations for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). One commenter suggested additional sources that EPA should consult "including international journals and other international sources, such as the World Health Organization (WHO), the International Agency for Research on Cancer (IARC), ECHA, and other relevant European, Asian and international chemical regulatory agencies." Regarding the REACH dossiers, two commenters requested that it would be more efficient if industry overall could submit one set of study reports and IUCLID files per chemical rather than making every company with a study in its possession submit. They claim that the latter approach would lead to much duplication of submitted information. Finally, one commenter states that "EPA should consult already available data sources and identify the actual data gaps for risk evaluation for these substances and tailor mechanisms to seek that information." They add that the proposed rule "would cast a broad net, requiring companies to search for information that is unlikely to be useful for EPA's TSCA section 6 activities."

Sources: 0016-A1, 0027-A1, 0029-A1, 0035-A1.

Response: EPA acknowledges and values international data sources such as ECHA's REACH database. While EPA does use these international data sources when appropriate under TSCA, direct submissions of health and safety studies are required under TSCA section 8(d). This ensures that EPA has access to the most relevant and current data specific to U.S. regulatory needs.

With regards to the commenter's suggestion for a single industry wide submission of REACH dossiers and IUCLID files, EPA acknowledges your concern about potential duplication effort with every entity if every company with relevant study data is required to submit it individually. The suggestion to allow for a consolidated submission of study reports and IUCLID files per chemical is noted. However, the current TSCA Section 8(d) rule requires each manufacturer or importer to submit the health and safety studies in their possession to ensure a comprehensive collection of all relevant data. This approach is designed to provide a complete dataset and prevent information gaps that are critical for risk evaluation.

EPA also appreciates the recommendation to consult existing data sources and identify specific data gaps for risk evaluation. The EPA continuously reviews available data and assesses where additional information is needed. The data collection mandated by this rule aims to capture all potentially relevant information to support robust risk assessments under TSCA Section 6.

In response to concerns about duplicative submissions, particularly when trade associations and individual companies both report similar health and safety studies under TSCA section 8(d), trade associations, pursuant to 40 CFR 716.30(a)(10), may report for members, and other entities, by providing a list of studies that includes relevant chemical names, CAS numbers, and a cover letter with the submitting officials' information, and details about the manufacturing or processing establishment. The cover letter should also confirm that the submission fulfills TSCA reporting requirements and note any known impurities or additives, unless already mentioned in the studies. Section 716.20(a)(1) provides that individual companies are not required to resubmit studies already submitted by trade associations, thereby streamlining the reporting process and preventing unnecessary duplication of effort while maintaining comprehensive data collection.

Finally, EPA believes some of the commenters' concerns are addressed through the 8(d) framework rule's study exemptions. Studies that have been published in scientific literature (including international journals) are not required under this rule.

8. Relationship Between this Rule and the Tiered Data Reporting (TDR) Rule

Summary: Two commenters do not think that the proposed rule aligns with EPA's plans for the Tiered Data Reporting (TDR) rule. They stated that "this proposed rule does not collect information to add to a standardized data set, is not fit to a specific need or purpose, and is not tiered. Its broad scope is antithetical to the tiered and tailored approach that would be envisioned for a sound TDR framework." Both commenters also requested that EPA explain how the proposed rule fits into TDR, "including whether it should be viewed as a model or precursor for any aspect of the TDR."

One commenter stated that EPA should repropose the rule after conducting a Small Business Advocacy Review Panel for the TDR rule and subsequent rulemaking. They also stated that if EPA does move forward with the proposed rule, they should "focus the rule on the five chemical substances that have been chosen for prioritization. As EPA aims to finalize the TDR scheme in 2024, the Agency should use

the TDR framework to collect information for the remaining 11 chemical substances which have not started prioritization, if EPA identifies data gaps for any of them."

Sources: 0020-A1, 0029-A1.

Response: EPA appreciates the support for the future TDR framework rule, which is expected to encompass information reportable under TSCA 8(a), 8(c), and 8(d). The type of study information collected under this 8(d) rule might therefore be a subset of the information collected under the future TDR framework rule. However, the TDR proposed rule is still under development, and therefore any collection of TDR data is further in the future. EPA is not reproposing this rule or delaying the study collection for any of the chemicals based on TDR, as that would not satisfy the data needs for chemicals currently under prioritization or pre-prioritization activities.

9. Economic Impacts of the Proposed Rule

9.a) Economic Analysis is Inappropriately Based on CDR Reporting Requirements

Summary: Three commenters said that, for the proposed rule, EPA based the number of potentially affected firms and sites on counts of reporters in the 2020 CDR. They remark that the differences between reporting thresholds and exemptions between CDR reporting requirements and the proposed rule led to incorrect estimates of potential reporters. One commenter added that their members "will be reporting import or manufacture of de minimis by-products and impurities or any amount in mixtures" and therefore "the number of affected businesses and related costs are significantly higher than EPA's estimates." Two of the commenters stated that EPA should either revise the economic analysis for the proposed rule to reflect the differences between the two potential reporting universes and application of exemptions or align the proposed rule with CDR conditions of reporting.

Sources: 0029-A1, 0034-A1, 0038-A1.

Response*:* EPA acknowledges that the number of firms affected by this rule may not perfectly overlap with the universe of firms that meet the threshold for CDR reporting. Meaning, there may be some firms may not be captured in CDR (e.g., due to manufacturing the chemical below CDR reporting thresholds or being otherwise exempt as a small manufacturer) that are manufacturing a chemical covered by this rule. While this is a known limitation of CDR, CDR provides the best source for estimating the universe of firms potentially impacted by this rule. Small businesses, especially those which have not previously reported under CDR or other TSCA section 8(d) rules, may not have the same resources that are available to large companies. These small businesses may not have the resources to conduct health and safety studies and therefore EPA assumes the majority of non-CDR reporters may not be significantly affected by this rule. Small businesses nevertheless may have studies that they've conducted or may have studies or information on studies for chemical substances subject to this rule; however, the Agency does not have information, nor does it anticipate, that such small businesses would have much such information and thus any burden associated with their reporting would be minimal.

Conversely, there may be firms that report to CDR for these chemicals but are not required to submit studies to this 8(d) rule. For example, this 8(d) rule is limited to manufacturers in certain NAICS codes, whereas CDR does not stipulate reporting requirements on the basis of NAICS codes.

For the final rule, EPA has incorporated additional burden and cost estimates for reporting on impurities and a lack of de minimis. The number of businesses impacted has not increased as a result of this information, as the universe of available importers and manufacturers of the 16 chemical substances has not changed. However, the associated burden and costs involved in searching for health and safety studies with impurities or lacking a de minimis level have been incorporated. Input from one commenter (EPA-HQ-OPPT-2023-0360-00350035) was used to develop estimates for the increased burden associated with searching for health and safety studies with impurities and the increased number of reports due to the exclusion of a de minimis level.

9.b) Burden/Costs

Summary: One commenter disagreed with EPA's statement that the proposed rule does not impose any new reporting burden under the Paperwork Reduction Act (PRA). Further, they stated that the current TSCA section 8(d) ICR does not include the additional burden posed by the rule and it should therefore be revised and submitted to OMB for review. Another commenter expressed their concern regarding submission of studies that are considered confidential. These "studies will be available to competitors that have not participated in the funding of those studies and allow them a competitive advantage in reaching markets outside the United States." A third commenter stated that EPA's economic analysis did not address the costs that firms may incur to purchase studies already in their possession in order to avoid legal restrictions on the use of the studies. The commenter added that "EPA did not, however, quantify the potential burden to submitters of having to re-negotiate access to studies for use in responding to the TSCA Section 8(d) rule. Submitters may have obtained a letter of access to responsive studies but would be subject to use restrictions, whereby the submitters compensated the data owners for a letter of access to the studies for the sole purpose of registration under REACH."

Sources: 0009, 0029-A1, 0033-A1, 0034-A1.

The Office of Management and Budget has determined this rule is non-significant under Executive Order (EO) 12866 and waived review. For the final rule, EPA has incorporated additional burden and cost estimates to account for reporting on impurities and a lack of de minimis.

TSCA has from its inception provided EPA with the authority to require submission of health and safety studies, limiting confidentiality protection for such submissions. As discussed in the proposed rule and in this Response to Comments, the data collected under this rule would help EPA carry out the requirements of the statute and make accurate assessments of the risks of the chemical substances that are the subjects of the studies required to be submitted.

EPA is clarifying that the scope of information to be submitted are health and safety studies already in the submitter's possession or control. Thus, a reporter would not necessarily be required to repurchase studies, however entities may face challenges or costs associated with existing legal agreements or confidentiality restrictions. EPA has included burden and cost estimates associated with CBI legal review and substantiation in the EA.

9.b.i) Time Estimates are Too Low

Summary: Two commenters stated that the overall burden and costs estimated in EPA's economic analysis for the proposed rule are too low. One of these commenters indicated that it would take them approximately 5,000 hours to comply at a cost of $500,000. They explained that the effort would include

"searching our databases, reviewing reports, pulling compositions, and comparing those compositions to test substances reviewing and redacting for CBI, preparing IUCLID templates, and uploading into CDX both CBI and non-CBI reports." The commenter estimated that they would submit between 600-1,000 reports. The other commenter said EPA's estimated costs of compliance were too low because EPA made several incorrect assumptions including: "that submission of completed templates will be voluntary and that only studies of listed substances at 90% purity or greater will be subject to the rule. In addition, several of the listed substances are very well characterized in studies, in many cases more so than those in previous TSCA Section 8(d) rules. Therefore, more time will be needed to locate and report all relevant information, especially if that requires the input of older data into harmonized templates."

One commentor disagreed with EPA's reporting burden estimates for two activities – searching files for studies and performing TSCA CBI review. Specifically, the commenter said that EPA's estimate of 4.88 hours per company to search their files for studies is too low adding that "this estimate may be accurate if file searches were limited to studies that were intentionally performed on the listed chemical substances. The estimate does not, however, consider the burden of performing an in-depth search of all studies performed by all manufacturers and importers and cross-referencing to identify studies that may have evaluated a test article that included one or more of the listed chemical substances at any level, whether present as an impurity or not." Regarding CBI review, the commenter questions EPA's estimated one hour per study for performing a TSCA CBI review in situations where the submitter is "searching for responsive studies and ensuring that the compositional details do not reveal TSCA confidential business information (CBI) about the manufacturing process of chemistries that may contain a listed chemical substance in trace quantities."

One commenter said that current TSCA Section 8(d) ICR estimates of firms and burden hours are much lower than the number of firms and burden hours estimated in the proposed rule. Therefore, the commenter disagrees with EPA's statement that the action doesn't impose any new information collection burden under the Paperwork Reduction Act (PRA).

Sources: 0034-A1, 0035-A1, 0036-A1.

Response: For the final rule, EPA described burden and cost estimates for reporting on impurities, lack of a de minimis level for reporting, and for costs associated with submitting CBI substantiated studies using the OECD harmonized templates via the IUCLID6 software

EPA breaks down the burden and costs associated with various activity stages in complying with the rule in the Economic Analysis (EA). In the executive summary of the EA, EPA details the various stages considered: "Firms who manufacture(d) or import(ed) any of the listed chemicals will review the rule, identify sites that may have relevant studies and then search for studies responsive to this proposed rule at those sites. Among those firms subject to the proposed rule, a subset will have studies to submit to EPA in response to this proposed rule. Those firms will submit reports and, in doing so, will provide study title lists, review studies for CBI, and prepare information to substantiate any claims for confidentiality. Among those firms that submit a report, some may voluntarily develop and submit robust summaries of the studies included in their submission. Firms that submit a report will undertake activities to facilitate submission of an electronic report, which include CDX registration and submission of an electronic signature agreement. Lastly, any firm that has ongoing or newly initiated studies during the reporting period will be required to provide a copy of those studies once they are completed."

EPA has incorporated the feedback from commenter EPA-HQ-OPPT-2023-0360-00350035 into developing updated estimates for the burden associated with searching for health and safety studies with impurities and the increased number of reports due to the exclusion of a de minimis level. For the final rule, EPA is providing greater clarity on the requirements around submitting studies using the OECD harmonized templates and submitting in the IUCLID6 software. The submission of studies using the OECD harmonized templates will only be required for CBI substantiated studies. Additionally, the EA will include updated burden and cost estimates to correspond to an increased expected level of reporting due to impurities and a lack of de minimis level.

EPA has incorporated the feedback into both the rule and the accompanying final Economic Analysis. For the rule, EPA is clarifying that the submission of OECD harmonized templates will be limited to CBI substantiated studies. For the EA, EPA has developed new burden and costs estimates for a separate activity related to the search for studies that include impurities and the exclusion of a de minimis level.

Table 4-10 of the draft EA included a breakdown of burden and costs associated with multiple stages of activity involved with searching and providing health and safety studies to EPA. This table shows that EPA assumes 9 burden hours per firm for reviewing studies for possible CBI in the draft EA. After further review EPA finds that this number was lower than what should have been estimated at that point in time, given that the draft EA assumed each firm would submit 40 studies, the burden should have been 40 hours per firm. The final EA will reflect a correction to this, and the burden hours associated with CBI review will reflect the correct number of studies estimated per firm.

EPA acknowledges that the ICR estimate of burden hours are smaller than the estimated burden numbers in the EA. The ICR figures represent an estimate. These unit burden estimates are average values. Large multi-divisional, multi-departmental firms may require more than the average time to comply. However, there are smaller firms that are less complicated, and these firms may have a simpler process that requires less time.

9.b.ii) Estimated Time to Fill Out OECD Template is Too Low

Summary: Two commenters stated that EPA's burden estimate of 12 hours to convert a single study to the OECD template is too low. Reasons for why this estimate is inappropriate include variety of studies that would need to be abstracted, companies lack familiarity with the template and IUCLID6 software and time to educate themselves about both, uncertainty about how CBI requirements would apply to the template, and potential need to hire consultants to help them with filling out the template. One of these commenters added that they did not agree with EPA's assumption that only six percent of studies would need to be submitted with robust summaries. They believe that the proposed rule will require 100 percent of the studies to be submitted with robust summaries. Further, the commenter said that EPA's high-end estimate (in the sensitivity analysis) also does not incorporate this assumption. Another commenter disagreed with EPA's assumption that reporters will be familiar with and routinely use IUCLID6. Adding that "Many U.S. companies do not use IUCLID6. If a U.S. company has an affiliate in the European Union (EU), the EU professionals use IUCLID6. For U.S. companies without an EU affiliate and do have Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) registrations, those companies use an Only Representative (OR). It is the OR, not the potential respondent that has experience using IUCLID6." Finally, two commenters stated that the existing TSCA section 8(d) ICR doesn't include burden and costs for preparing OECD templates and should be updated.

Sources: 00027-A1, 0034-A1, 0036-A1.

Response: EPA is only requiring firms that submit studies with CBI substantiation to use the OECD templates and IUCLID software. EPA has updated the industry costs in the EA to account for the increased burden associated with converting studies to the OECD templates and submissions to the IUCLID6 software. There are four template groups for which the firms will submit the CBI substantiated health and safety studies, each with varying burden hours per chemical: physicochemical properties (21 hours), environmental fate and behavior (21 hours), effects on biotic systems (108 hours), and health effects (108 hours). Based on historic rates of TSCA 8d rule submissions, EPA expects on average 14.3% of studies to be CBI substantiated per firm with an average of 1.54 chemicals per firm using the OECD templates and IUCLID software.

Robust summaries are mentioned under TSCA, but submission of robust summaries is voluntary. EPA reviewed the most recent set of TSCA section 8(d) submissions and found six percent of studies were submitted with robust summaries. As a result, the analysis assumes that six percent of non-CBI studies will be submitted with robust summaries and includes additional burden estimates for those studies.

9.c) Benefits

Summary: Two commenters indicated that the benefit of the proposed rule is that the information collected supports preventative healthcare which could help to minimize treatment costs associated with "chemical-related health problems."

Sources: 0005, 0014.

Response: EPA agrees that one of the key advantages of collecting detailed information under the rule is its potential to support preventative healthcare. By providing a more comprehensive understanding of chemical-related health risks, the data collected contribute to informing options to protect human health and the environment. This proactive approach not only helps in identifying and, as applicable, addressing potential health issues before they become more serious. EPA appreciates the commenter's recognition of these benefits and remains committed to enhancing our regulatory efforts to protect public health and reduce associated costs effectively.

9.d) Small Business Impacts

Summary: Two commenters addressed the potential impacts of the proposed rule to small businesses. One commenter generally expressed concern that the proposed rule would disproportionately impact small businesses. The other commenter stated that "EPA has not adequately estimated costs to small businesses when concluding that only 44 small businesses will be affected and only 1 small business is estimated to incur annualized cost impact of more than 1% of revenue."

Sources: 0009, 0038-A1.

Response: EPA has considered the cost of the rule, including the costs to small businesses. For the final rule EPA has taken comments into account to adjust estimates for costs associated with searching for health and safety studies with impurities and a lack of de minimis, as well as costs related to submitting CBI substantiated studies using OECD templates in the IUCLID6 software. EPA has updated the EA to incorporate the latest industry data and revenue estimates into its small entity impact analysis. EPA reviews importers and manufacturers involved in the production of any of the 16 chemical substances and reviews their financials for small business status. Therefore, EPA respectfully disagrees with these comments.

10. Central Data Exchange (CDX)

Summary: Two commenters indicated that using CDX can be cumbersome and time consuming. One stated that contacting the help desk can result in long waits that do not lead to prompt answers. The other commenter added that use of CDX can be particularly time consuming for first time users who also need to familiarize themselves with the interface. Two commenters requested that EPA allow for manual submission in addition to electronic uploads, suggesting that "a paper submittal option will alleviate burdens on both the electronic filing system and the filer."

Two commenters stated that the proposed reporting period for the rule will lead to a log jam of CDX submissions just prior to the reporting period, particularly if the reporting deadline overlaps with other reporting requirements such as CDR and the TSCA PFAS reporting rule. These commenters request an extension to the deadline, with one saying it should be at least 6 months. Finally, one commenter indicated that CDX does not allow for the submission of lists of studies even though the rule calls for manufacturers to "to submit "lists" of known studies not possessed by them (or underway but incomplete)." Instead, reporters must complete a "an extended data-field-by-data-field entry of study related information for each study, which is not a list and not an inconsequential effort." The commenter also states that EPA has not acknowledged the reporting burden associated with submitting such lists in its TSCA Section 8(d) Information Collection Request. The commenter goes on to request that EPA modify the CDX interface to allow for the upload of lists of studies.

Sources: 0016-A1, 0021-A1, 0029-A1, 0036-A1, 0038-A1, 0027-A1.

Response: EPA is aware of the concerns noted by the commenter regarding the use of the CDX system. The application for 8(d) submissions is a simpler application than that which is used for other TSCA reporting requirements. To that end, EPA does not anticipate notable issues or complications with manufacturing providing information via the 8(d) application. The application is designed to handle many concurrent users and submissions largely take the form of PDF attachments. EPA is amenable for feedback on how to improve the application, which it will endeavor, as resources and priorities allow, to incorporate into the application for any future 8(d) reporting requirements.

EPA appreciates feedback from commenters regarding manual data submission; however, EPA will not be permitting manual submission with electronic uploads for this rule. All submissions are required to be submitted via the CDX. This will ensure consistency in the data collection process and ensure that EPA is able to review all 8(d) studies from a single location. Additionally, allow manual data submissions would significantly increase the administrative burden associated with managing and processing data. Data submission via the CDX is designed to streamline data handling and reduce processing errors and allows for the submission of CBI claims and substantiations, if applicable.

11. Request for TSCA 8(a) Rulemaking for Subject Chemicals

Summary: One commenter suggested that EPA should gather additional information on 6PPD and 6PPD-q by initiating a rulemaking for these chemicals using their authority under TSCA 8(a). This action would allow the Agency to collect "the full suite of information that EPA has authority to require under that provision, including "[t]he categories or proposed categories of use" for 6PPD and 6PPD-Q; the quantities of 6PPD and 6PPD-Q manufactured or processed for each category of use; "[a] description of the byproducts resulting from the manufacture, processing, use, or disposal" of 6PPD and 6PPD-Q; and information about environmental and health effects, occupational exposures, and disposal methods."

This information would be particularly useful in the risk management process for 6PPD in tires as well as for other products and processes.

Sources: 0032-A1.

Response: EPA appreciates the commenters' interest in gathering additional information on 6PPD and 6PPD-q via other regulatory authorities, such as TSCA section 8(a). However, this rulemaking is focused on TSCA section 8(d), and considerations of section 8(a) are outside of the scope of the rulemaking.

However, EPA notes that it has several ongoing actions for these chemicals. One significant action is the EPA's commitment to publishing an Advance Notice of Proposed Rulemaking (ANPRM) for 6PPD and 6PPD-q under TSCA section 6(a), which will publish prior to this rule. An ANPRM is a preliminary notice that allows EPA to solicit and collect information from the public that will help inform EPA's future determinations and regulatory actions regarding the potential risks of 6PPD and 6PPD-q to human health and the environment. For more detailed information on the list of additional key actions related to 6PPD and 6PPD-q, please visit 6PPD-quinone | US EPA.

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. For assistance in locating these other documents, please consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

1. U.S. Environmental Protection Agency. TSCA Section 8(d): Economic Impact Analysis for the Addition of Sixteen Chemicals to the Health and Reporting Data Rule. (October 2024).

2. U.S. Environmental Protection Agency. Petition ID No. 001845: Toxic Substances Control Act Section 21 Petition Regarding N-(1,3- Dimethylbutyl)-N'-phenyl-p-phenylenediamine (CASRN 793-24-8, aka 6PPD) in Tires - Final EPA Response to Petition. signed.PET-001845_TSCA-21_Petition_6PPD_Decision_Letter.pdf (epa.gov). November 2, 2023

3. U.S. Environmental Protection Agency. TSCA Work Plan for Chemical Assessments: 2014 Update. TSCA Work Plan for Chemical Assessments 2014 Update (epa.gov).October 2014.

4. U.S. Environmental Protection Agency. Framework for Human Health Risk Assessment to Inform Decision-Making. April 5, 2014.

5. U.S Environmental Protection Agency. Guidelines for Carcinogen Risk Assessment. March 2005