PROCEDURES FOR CHEMICAL RISK EVALUATION UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

Office of Pollution Prevention and Toxics
United States Environmental Protection Agency

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS COMMENTS

Attention: EPA–HQ–OPPT–2023–0496; FRL–8529–01–OCSPP

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I. Introduction

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits these comments on the Environmental Protection Agency's ("EPA" or "the Agency") Federal Register notice titled, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)" ("Proposed Framework" or "Proposal"). EPA proposes to significantly depart from risk evaluation approaches used by the Agency for decades to a new, overly complicated, and burdensome approach.[1] AFPM's comments highlight the following concerns that the Proposed Rule:

- Will cast aside its long-established and proven risk assessment processes and practices used throughout the world,
- Moves TSCA from a risk-based approach companies have relied upon for decades to a hazard-based, academic approach that amounts to molecule-tracking,[2]
- Disproportionally weighs unlikely and unpredictable exposure scenarios,
- Pulls impurities and byproducts into risk management even though they do not contribute appreciably to overall risk; and,
- Utilizes a "whole chemical" approach that will result in unreasonable risk findings for just about every chemical that EPA determines is a high priority.[3]

EPA should withdraw the Proposed Framework and, if the Agency feels changes are necessary, repropose a more realistic process for conducting risk evaluations.

II. AFPM Interest in the Proposed Framework

AFPM is the leading trade association representing the manufacturers of the fuels that keep America moving and base petrochemicals that are the essential building blocks for organic chemistry, including plastic products that improve the health, safety, and living conditions of humankind and make modern life possible. AFPM members are committed to sustainably manufacturing safe, high-performing fuels and the petrochemicals and derivatives that growing global populations and economies need to thrive.

AFPM member companies are regulated under TSCA, and their products have been and will continue to be subject to TSCA risk evaluations. If properly implemented, TSCA can be a critical statute to ensure sound chemical management. Unfortunately, EPA has recently departed from the aspects of the law that are grounded in sound science and balance the need for risk-

[1] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023.
[2] Molecule-tracking in this context describes a regulatory program that attempts to account for every bit of a chemical substance that could possibly be in commerce, including unintentional byproducts and impurities.
[3] Historically, EPA made separate unreasonable risk determinations for every condition of use of a chemical. EPA has recently decided to modify this approach when conducting risk assessments under TCSA. Per the EPA "[f]or the first 10 chemicals under TSCA and for any similar chemical that presents significant risks across many uses, EPA will continue to assess and analyze each condition of use, but then the agency plans to make the determination of unreasonable risk just once for the whole chemical when it is clear the majority of the conditions of use warrant one determination." EPA is referring to this as the "whole chemical approach" *See* also, https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

based evaluations with the need to promote innovation. As a result, the program has slowed to a crawl without any material difference to risk, a trend that will only continue if EPA finalizes the Proposed Framework.

III. History of EPA Risk Evaluation under TSCA

Over the course of decades, EPA built a risk evaluation framework that relied on tiered, targeted, and risk-based methods to develop a workable regulatory approach to chemical safety. EPA is now trying to turn the risk evaluation process into an academic exercise that demands perfect information for decision-making. The risk evaluation is only supposed to be geared for decision-making in risk management. For example, EPA's most recent decision to ban all uses in its proposed risk management rule for asbestos, even when asbestos is totally encapsulated or otherwise contained, will result in an increased risk to human health because respirable fibers (the main exposure pathway) will be generated during abatement. This is but one example of why the Proposed Framework must be developed in the context of overall risk management.

Most of the Agency's experience has come from reviewing the lifecycle of thousands of new chemical substances under the Agency's New Chemical Program.[4] EPA had little experience reviewing and regulating existing chemicals under TSCA Sec. 6; however, the Agency's reviews of Premanufacture Notices ("PMNs") under TSCA Sec. 5 have provided the Agency with plenty of relevant experience in evaluating risk in the absence of perfect information.

Between 1979, when TSCA was enacted, and 2016, when the Frank R. Lautenberg Chemical Safety Act for the 21st Century ("Lautenberg Chemical Safety Act"[5] or "LCSA") was enacted, the Agency reviewed 40,151 PMNs and 13,267 Low Volume Exemption (LVE) notices.[6] EPA recognized that TSCA was a regulatory program that had to be built from scratch and developed processes and procedures that were tiered and targeted, refining them over decades. Agency scientists realized early on that EPA could not afford to wait for perfect information when making decisions on whether new chemicals presented an unreasonable risk within the statutory deadline. EPA has put forth no evidence that the risk evaluation processes utilized for decades under the new chemicals program have allowed unsafe chemicals to enter commerce. A comparison of TSCA Sec. 8(e) notices and Notices of Commencement to manufacture would provide an indication as to whether unsafe chemicals have escaped EPA's scrutiny.[7]

EPA developed the PMN form and its information requirements and over the years refined it to capture information on the entire lifecycle of new chemical substances. PMN submissions rarely had robust data sets, especially for chronic toxicological properties and measured exposure monitoring. Many did, however, provide physical and chemical properties, acute toxicity profiles, and other data from which the Agency could compare and contrast

[4] *See* EPA's TSCA New Chemical Program for information on how EPA conducts risk evaluations under Sec. 5.
[5] 15 U.S.C. §2601 et seq.
[6] See EPA's New Chemical Statistics Prior to June 22, 2016.
[7] TSCA Sec. 8(e) requires companies to report to EPA when they obtain "information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment."

information among a wide range of different chemical classes. Through negotiated consent agreements, EPA was able to collect tiered and targeted information on toxicological properties for many substances, including chemicals on the confidential portion of the TSCA Inventory.[8]

EPA has taken the data it has collected under the new chemicals program, as well as data collected from other programs such as the High Production Volume Chemical Challenge and Organization for Economic Cooperation and Development Screening Information and Data Set Programme ("OECD SIDS") and constructed and validated predictive software that can estimate ranges of hazards just based on the chemical's molecular structure. EPA has also developed predictive software for environmental effects that can estimate ranges for aquatic toxicity to fish and plants. Because EPA did not possess much measured exposure data, it developed exposure models using conservative default assumptions and has been able to estimate the potential for exposures among a wide range of different use scenarios. While these advancements could have greatly improved TSCA implementation, over the past few years EPA has adjusted the default values in the models to the point that the exposure scenarios no longer reflect real-world conditions of use and are not supported by sound science.

EPA has not been alone in developing processes and models to conduct timely risk evaluations; most countries with chemical safety laws have faced similar challenges. Not wanting to rely on its own guidance in a vacuum, EPA has worked with regulators and scientists from all over the world to develop consistent and reliable methods for hazard assessment, exposure assessment, and risk evaluation under the OECD Environment Directorate. In addition, EPA has worked specifically with Canada and Mexico under the Commission for Environmental Cooperation ("CEC"), which originated as part of the North American Free Trade Agreement.[9] Chemical companies, many of which are global, have come to rely on those approaches and risk evaluation methodologies to construct coherent business models and make significant investments for new manufacturing facilities. These investment decisions last for decades, create thousands of jobs, and cost billions of dollars.

With this Proposed Framework, those well-established, regulatory chemical risk management approaches used throughout the world, that companies have relied on for decades, are being cast aside in the pursuit of perfect information in the form of molecule-tracking and other academic approaches that do not provide demonstrable safety benefits.

IV. EPA Reasoning for Changes to the Risk Evaluation Framework

EPA claims the Proposed Framework is designed to "better align with applicable court decisions and the statutory text, to reflect the Agency's experience implementing the risk evaluation program following enactment of the 2016 TSCA amendments, and to allow for consideration of future scientific advances in the risk evaluation process."[10]

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[8] The TSCA Inventory is a list of all chemicals known to be in commerce in commercial quantities (i.e., produced at 25,000 lbs. per year or more).

[9] The CEC is now under the United States of America, the United Mexican States, and Canada Agreement (the USMCA).

[10] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74292.

While EPA may be correct that it should not exclude conditions of use, the court decision does not justify the Agency's attempt to broaden the definition of "conditions of use" from normal use scenarios to unlikely and unpredictable scenarios that cannot be quantified using validated chemical risk assessment methods. Furthermore, EPA must approach each condition of use from a scientifically sound perspective. For example, if an occupational exposure to a chemical could cause an injury, and an OSHA regulation requires PPE for handling that chemical, then EPA should evaluate the risk of exposure to the chemical while wearing PPE, which is what the Agency did in the original perchloroethylene risk evaluation.[11] An assumption that no PPE is worn is not scientifically sound.

EPA has a long-established track record with successfully applying a risk-based framework, developed over the course of many decades. There has been no material change in the science of risk assessment that requires a wholesale change in how EPA approaches its risk evaluations.

To support its implication that the sciences supporting risk evaluation have significantly evolved or will evolve in the near future, EPA at a minimum must put forth evidence from professional societies that specialize in chemical risk assessment, such as the Society of Toxicology ("SOT") and Society of Environmental Toxicology and Chemistry ("SETAC"), or from international scientific bodies like the Environment Directorate at OECD, reflecting any paradigm shift. The Agency should specifically explain how any past or future changes in toxicology, industrial hygiene, chemistry, and other key disciplines have affected or will affect the outcomes of risk evaluations. The fact of the matter is that EPA has very limited experience conducting risk evaluations on existing chemicals. The only real experience the Agency has had using its Sec. 6 authority was a proposed risk management rule for asbestos.[12] The vast majority of its experience is rooted in the decades prior to 2016, during which EPA evaluated thousands of chemicals for risk.

V. Overarching Changes to the Risk Evaluation Framework

EPA proposes a dramatic overhaul of how the Agency conducts risk evaluations. While the LCSA changed the requirements for the Agency's administration of TSCA, it did not change the nature of risk assessment or its supporting sciences. EPA's Proposed Framework goes way beyond what Congress envisioned when crafting the LCSA. AFPM briefly highlights major concerns in this section, with more detailed discussions for some in response to specific comment requests.

[11] See *Draft Risk Evaluation for Perchloroethylene (ethene, 1,1,2,2-tetrachloro)*, EPA Document # 740-R1-8011. Published December 2020. pp. 211-216.
[12] See Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

1. **EPA proposes to significantly expand the scope of all future risk evaluations, using unsubstantiated assumptions based on speculation.**

EPA proposes to mandate the scope of risk evaluations such that it "will not exclude any 'conditions of use'."[13] AFPM supports EPA's consideration of all known conditions of use if those conditions are directly related to the scenarios under which a chemical is normally used. Conditions of use should not include scenarios based on unsubstantiated stakeholder conjecture, accidental spills or leaks, future climate effects, or other situations that are not likely to occur or are unpredictable.

EPA's interpretation of "conditions of use" is overly broad and goes well beyond what Congress intended when creating the LCSA.[14] For example, if "a circumstance is reasonably foreseen to occur in the future, EPA will determine that circumstance to be a condition of use and include it within the scope of the risk evaluation, even where that condition of use may not contribute significantly to the Agency's ultimate conclusions on risk."[15] There are no criteria offered in the proposed framework by which to judge what is "reasonably foreseen." Furthermore, TSCA Sec. 6(b)(4)(F) lists the requirements of risk evaluations and item (iv) explicitly requires EPA to "take into account, where relevant, the **likely** (emphasis added) duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." The word "likely" is a probabilistic term; therefore, Congress clearly did not intend for EPA to consider **unlikely** or unpredictable scenarios in TSCA risk valuations, such as future climate-related events, accidental releases, or other events outside normal conditions of use.

The key word in the phrase "reasonably foreseen" is "reasonably" and should be taken in the context of the Congressional requirement for EPA to consider the **likely** circumstances of conditions of use with respect to potential exposures. AFPM disputes EPA's claim that accidents are reasonably foreseeable because the Agency does not put forth any evidence of accident history or substantiate patterns of frequency, duration, and magnitude of exposure. EPA provides no evidence whatsoever in the Proposed Framework to demonstrate the foreseeability of accidental releases or resulting exposures. Furthermore, the default assumptions and values in the models the Agency uses to estimate exposures in the workplace, which often assume leaks and spills occur whenever a chemical is used, are without any type of scientific or evidence-based foundation and do not even come close to meeting the science standards in TSCA Sec. 26(h).

EPA claims that "known, intended, and reasonably foreseen production of a chemical as a byproduct or the known presence of a chemical as an impurity or within an article, for example, are squarely 'conditions of use' that generally must be included within the scope of risk

[13] See *88 Fed. Reg. 74292,* "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74296.
[14] The LCSA defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, use, or disposed of." See 15 U.S. Code § 2602.
[15] *Id*. at 74298.

evaluations."[16] This is a significant departure from EPA's long history of exempting *de minimis* concentrations of byproducts and impurities.

Chemists and engineers continually look for ways to take what would otherwise be waste products from chemical processes and turn them into value-added products. Those products inherently contain impurities because of the complexity of certain chemistries, especially those involving substances of unknown or variable composition, complex reaction products or of biological materials (UVCBs), aka Class 2 substances. There is no commercial intent for an impurity or byproduct at low concentrations. Furthermore, EPA has never documented that the risk to human health or the environment from such miniscule concentrations is appreciable, let alone unreasonable. That is why, until now, EPA has always provided exemptions for *de minimis* concentrations of byproducts, impurities, and releasable concentrations in articles.

To demonstrate the absurdity of EPA's proposed process, the agency intends to consider "certain exposures associated with a spill or leak" if there are "regular or predictable exposures."[17] Risk is a function of inherent hazard and the probability of someone or something being adversely affected by that hazard. The probability of a spill or leak that results in exposure to a particular chemical is quite small. The only world in which spills and leaks occur with regular or predictable frequency is in EPA's unrealistic modeling scenarios that have been driving the Agency's risk evaluations. Unrealistic modeling scenarios that ignore actual use frequency and duration data are not the "best available science."

In the Proposed Framework, the Agency says it does not expect to include "exposures from releases of a chemical substance that are unsubstantiated, speculative or otherwise not likely to occur."[18] In its risk evaluations so far, however, EPA has done exactly that.[19] In its exposure assessments for the first high-priority chemicals, the Agency uses unsubstantiated and speculative default assumptions for accidental leaks during transfers from transport containers to storage tanks, assumes that the workplace is not following OSHA regulations, assumes workers do not wear PPE and get the chemical on their skin, and assumes exposed workers just leave it on there for 8 hours.[20] Now the Agency proposes to codify those misguided approaches in the Proposed Framework. Accidental spills and leaks are not likely to occur with any predictable frequency, nor are they common. EPA may claim otherwise, but the Agency has never substantiated its modeling assumptions with accident data from poison control centers, OSHA, or the National Response Center, nor has it made an attempt to justify those assumptions in any of the risk evaluation rules. Those modeling assumptions are little more than speculation by people unfamiliar with a modern, tightly regulated workplace.

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[16] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74298.
[17] *Id.*
[18] *Id.*
[19] EPA decided unilaterally to reopen a number of the original risk evaluations for the first 10 chemicals and use the assumption of accidental releases, no PPE, etc., with the result of unreasonable risk in all cases.
[20] See *Draft Risk Evaluation for Perchloroethylene (ethene, 1,1,2,2-tetrachloro)*, EPA Document # 740-R1-8011. Published December 2020. pp. 166 – 168, *87 Fed. Reg. 76481*, "Perchloroethylene (PCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability." EPA–HQ–OPPT–2016–0732; FRL–9942–02–OCSPP, published December 14, 2022; AFPM comments on the original draft risk evaluation; and, AFPM and API comments on the revised risk evaluation.

For instance, when EPA modeled potential exposures to perchloroethylene at petroleum refineries in its risk evaluation, the Agency assumed that an accidental spill or leak occurred 250 times per year during transfers from transport containers to storage units, and that the exposed person wore no PPE and just left the substance on his or her skin. The reality is that product transfers of perchloroethylene at petroleum refineries occur only 10 to 35 times per year from tote bins or 2 to 12 times per year from trucks.[21] In the real world, the transfer pipes, hoses, and fittings create a closed system, so the only way a spill could occur is through system failure or human error, both of which are unlikely because they are very infrequent. Personnel conducting the transfer wear PPE and follow all applicable OSHA and DOT regulations. EPA puts forth no evidence or data to demonstrate any kind of spill or leak frequency or likelihood, nor has the Agency ever substantiated its assumption that workers at petroleum refineries do not wear PPE. Yet somehow it concludes that these are "regular or predictable."

As further evidence of these extreme assumptions, EPA intends to consider events from "rising sea levels or extreme temperatures made worse by climate change" as relevant to a substance's conditions of use.[22] There is absolutely no way that EPA can predict weather events, let alone quantify or attribute them to a particular cause. There is no mention of climate in the statute, so Congress did not intend for EPA to consider climate effects in TSCA risk evaluations.

2. In cases where even one use of a chemical is found to present an unreasonable risk, EPA will determine that the "whole chemical" presents a risk, even if there are conditions of use that do not present an unreasonable risk.

EPA claims its mandate from Congress is to prioritize chemicals and "evaluate their risks, holistically," yet there is no mention of the word "holistic" or "holistically" in the statute.[23] Throughout the proposed rule, EPA seems fixated on TSCA Sec. 6(b)(4)(A), which is a general statement about the objective of a risk evaluation under Section 6, to justify its interpretation that it must determine whether the "chemical itself" (whole chemical) presents an unreasonable risk, versus each condition of use. Sec. 6(b)(4)(F) sets out the actual statutory requirements for a risk evaluation. Nowhere in the statutory text does Congress direct EPA to determine a single risk for the whole chemical; rather, the text in Sec. 6(b)(4)(F)(i) requires EPA to "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance" and Sec. 6(b)(4)(F)(iv) directs the Agency to consider "the likely duration, intensity, frequency, and number of exposures under the conditions of use."[24]

EPA is also taking TSCA Sec. 6(b)(4)(A) out of context when it states, "if a specific use of a chemical—in isolation—presented an unreasonable risk under TSCA, that chemical itself would necessarily present an unreasonable risk irrespective of risks posed by other uses."[25] That

[21] See AFPM comments on "Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA)."
[22] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74298.
[23] *Id*. at 74296.
[24] See Sec. 6 risk evaluation requirements for the exact language in its full context.
[25] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74301.

is akin to saying because a peanut can cause an allergic reaction in a sensitive subpopulation, peanuts present an unreasonable risk to everyone.

Under its misinterpretation of TSCA Sec. 6(a), EPA "suggests that the chemical substance presents the unreasonable risk, and not specific conditions of use."[26] A "whole chemical" or a "chemical itself" does not present an unreasonable risk unless the chemical can cause harm during its use (i.e., the conditions of use). EPA's hazard-based rationale simply defies logic because exposure is the only variable in the risk equation, and exposure is driven by the conditions under which a chemical is used.

For example, Chemical X is used as a catalyst in a closed system, which reduces the operating temperature and pressure, enhancing process safety and reducing carbon dioxide emissions, and reduces waste by promoting the formation of desirable products. Chemical X also happens to be toxic by skin absorption. Because it is used in a closed system with process controls, Chemical X does not present an unreasonable risk under these conditions of use. Chemical X is also used as an ingredient in a formulated consumer product. While the label clearly states that rubber gloves should be worn, consumers may not follow those directions. Chemical X may present an unreasonable risk in this case because there are no controls in place to prevent exposure and it is likely that some people do not read the instructions on the label or follow the recommendations for gloves. Under the Proposed Framework, EPA would assume that the "whole chemical" presents an unreasonable risk and implement a broad ban, even for the use as a catalyst in a closed system.

EPA goes on to discuss Sec. 6(i)(1) and (2), which set out criteria to determine final agency actions.[27] The Agency claims that because "[n]either provision mentions the conditions of use" it must mean that Congress intended for EPA to determine risk for the chemical as a "whole."[28] The provisions of Sec. 6(i) assume that the risk evaluation has been completed and/or risk management measures have been proposed. Congress did not feel the need to state the obvious when it did not explicitly reference "conditions of use" in those provisions.

EPA finds that the word "determination" in TSCA Sec. 6(i)(1) "is singular, suggesting Congress did not envision multiple determinations" of risk.[29] The determination was envisioned to be a document that reflects multiple uses of a single chemical, some of which may present an unreasonable risk and some that do not. Congress did not intend or direct EPA to create a separate rule for each condition of use. Again, a chemical substance does not pose any kind of risk unless someone or something is exposed to the substance. For instance, if a substance is contained in a storage container, reaction vessel, or other closed system, it does not pose a risk. Only when that substance is removed from the closed system does it raise the potential that someone or something could be exposed.

[26] *Id.* at 74302.
[27] EPA publishing a finding of no unreasonable risk is considered a final agency action, as is the publication of a final risk management rule.
[28] *Id.*
[29] *Id.*

EPA claims that because preemption applies to the "chemical substance," it suggests "that Congress did not envision that TSCA section 6(a) risk management rules would address only risks presented by individual uses or some subset of a chemical's uses, but rather unreasonable risk presented by the chemical as a whole."[30] Preemption is based on the conditions of use identified in the scope, regardless of the outcome of the evaluation. According to EPA's logic, all of the conditions of use the Agency considered as part of the "whole chemical" should be subject to the exact same risk management measures. The risk management rules thus far, however, even using EPA's "whole chemical" approach, address the individual risks under each condition of use. For example, in its proposed risk management rule for perchloroethylene, EPA has proposed to allow for certain uses while banning others.[31] It appears even EPA has difficulty following this "whole chemical" approach.

EPA stretches its rationale further when it claims the Agency can find unreasonable risk "based on risk associated with even a single condition of use."[32] This hazard-based approach ignores the exposure side of the risk equation for all other uses and, therefore, does not comport with the approach required for risk management actions or the sound science provisions in Sec. 26(h). EPA is required to publish its risk findings, capturing all conditions of use identified within the scope, and to propose risk management actions to control the unreasonable risk(s). Again, these take the form of a single document because it would not make sense to publish a separate rule for each condition of use. EPA's interpretation is wrong, and its conclusions are subsequently unfounded.

TSCA requires EPA to assess the risk for each of the chemical's conditions of use. Where one use poses an unreasonable risk, that risk should be managed to the extent the risk is no longer unreasonable; however, other uses that do not pose an unreasonable risk should continue without Agency intervention. Under EPA's proposed approach, all uses of the chemical would be tainted by the one use that poses unreasonable risk. If Congress had intended to create a "whole chemical" approach, it would have directed EPA to stop the risk evaluation as soon as it found an unreasonable risk under that one condition of use. Congress would have explicitly directed the Agency to broadly apply the same risk management measures for the "whole chemical."

EPA also defies its own logic because it asserts that the statute requires the Agency to consider all conditions of use; however, if EPA finds only one condition of use presents an unreasonable risk, it will ignore all the other conditions of use and assume the "whole chemical" poses an unreasonable risk.

EPA creates even more uncertainty and seems to question its own logic when it back-peddles on using the term "whole chemical" and states the following:

> "Although the Agency has previously referred to this as a 'whole chemical' approach, this descriptor may have created some

[30] *Id.*
[31] See EPA's proposed risk management rule for perchloroethylene.
[32] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74302.

> confusion regarding the Agency's intent and purpose. EPA believes that a more accurate description of the approach is simply one where the Agency makes its risk determination for the chemical substance. A determination that a chemical substance presents an unreasonable risk does not mean that the entirety or whole of that chemical's uses—or even a majority of uses—presents an unreasonable risk. Rather, EPA may determine that a chemical substance presents an unreasonable risk based on risk associated with even a single condition of use."[33]

EPA says that certain stakeholders have "expressed concern that EPA will use a singular risk determination to regulate in an overly broad manner."[34] AFPM is one of those stakeholders. These concerns have already come to fruition. For the chemicals the Agency has determined to present an unreasonable risk as a "whole chemical," which is all of the high-priority chemicals so far, EPA has proposed broad bans and overly prescriptive and duplicative risk management actions that encroach on OSHA's statutory authority. Additionally, EPA is attempting to supplant OSHA's workplace exposure thresholds with a largely made-up threshold it is calling the Existing Chemical Exposure Limit ("ECEL"). See Section VIII.6 of these comments for further discussion of ECELs.

The Agency believes that "in exercising EPA's authority under TSCA section 6(a) to ensure that 'the chemical substance . . . no longer presents such risk,' EPA may regulate conditions of use that do not themselves contribute to unreasonable risk for a given chemical."[35] This is a clear abuse of regulatory authority because there are no provisions in TSCA that authorize EPA to regulate substances or conditions of use that do not present an unreasonable risk. The phrase "no longer presents such risk" indicates that risk management measures should only apply to the conditions of use that present the unreasonable risk. That is all that Congress authorized, nothing more.

In cases where EPA determines that a downstream use presents an unreasonable risk, it feels it has the authority to regulate "the chemical's upstream manufacture, processing or distribution in commerce—even where the upstream activity itself does not directly result in the exposures that present the unreasonable risk."[36] TSCA does not delegate this type of authority to EPA. Moreover, this type of approach ignores any benefits society derives from other uses and displays a complete lack of understanding of manufacturing and how the supply chain works.

In cases where there is "a known, imminent and unreasonable risk of serious or widespread injury to health or the environment (i.e., imminent hazard) associated with a use or chemical," EPA says it can take action under Section 7.[37] While AFPM agrees that EPA has the authority to control the risk, this statement conflates hazard and risk, which is the basis of many misinterpretations in this hazard-based proposed rule. EPA seems to lose the fact that exposure is

[33] *Id.*
[34] *Id.* at 74303.
[35] *Id.*
[36] *Id.*
[37] *Id.*

a key component of the risk equation and is the only variable. Hazardous chemicals are used safely every day, and the Proposed Framework ignores that fact.

This proposed approach will result in "presents an unreasonable risk" for virtually every chemical substance that EPA evaluates, because high-priority chemicals for risk evaluation usually exhibit some sort of hazard. This misinterpretation has played out, with EPA finding all of the chemicals it evaluated (100%) thus far to present an unreasonable risk. In addition, it appears that any exceedance of the ECEL will also be seen by EPA as an unreasonable risk. The Agency's Proposed Framework turns its back on longstanding, peer-reviewed, risk assessment methodologies and replaces it with a *de facto* hazard-based approach. It does not seem to matter to EPA that a chemical may have conditions of use that are safe. EPA completely ignores the exposure side of the equation in its determination for a "whole" chemical. With its proposed expansion of the term "conditions of use" and disregard of the exposure side of risk, any chemical with a hazard will be found to present an unreasonable risk because EPA will find a scenario, likely or not, where the chemical presents such risk.

3. EPA departs from the sound science provisions in TSCA Sec. 26(h).

EPA's risk evaluation approaches, including its consideration of data, must be consistent with the scientific standards set forth in TSCA Section 26(h) (15 U.S.C. 2625(h)). EPA seeks to eliminate the definitions of "best available science" and "weight of the evidence," claiming the definitions will take away its discretion and need to be changed as the science evolves. EPA does not explain or offer any example as to how these definitions would affect its discretion or why they would need to be changed in response to evolving science. "Best available science" and "weight of the evidence" are foundational elements to be considered in all aspects of TSCA, especially in the risk evaluation process. This is why they are explicitly called for in the statutory language.[38] To exclude them from the Risk Evaluation Framework is directly contrary to the plain text and purposes of TSCA Sec. 26(h).

EPA should not rely solely on guidance documents to define "best available science" and "weight of the evidence" because most of those documents were developed internally, often reflect administrative policy rather than science, and have rarely been subject to notice and comment, stakeholder involvement, or robust scientific scrutiny. See VIII.3 of these comments for an in-depth discussion.

4. EPA states that risk evaluations must be fit-for-purpose.

EPA talks about flexibility in the level of detail it considers for each condition of use, saying that for "TSCA implementation efforts to be sustainable, risk evaluations must be fit-for-purpose."[39] AFPM generally agrees with the fit-for-purpose concept and the rationale the Agency puts forth to support it. Further, AFPM firmly believes that all of TSCA should be fit-for-purpose. The rest of the Proposed Framework, unfortunately, is the opposite of fit-for-purpose and will leave the Agency little discretion when conducting risk evaluations, which will result in poor implementation, inconsistent rulemaking, and lack of regulatory certainty.

[38] See 15 U.S. Code §2625.
[39] *Id*. at 74300.

5. The Proposed Framework demonstrates clear mission-creep and encroaches on OSHA's regulatory authority.

In the Proposed Framework, EPA says, "the Agency will strive for consistency with existing OSHA requirements" when promulgating risk management rules.[40] EPA must not simply "strive for" consistency; rather, the Agency must ensure that stakeholders will not be faced with duplicative or inconsistent regulatory requirements. There is no justifiable reason to have redundant regulations with another federal agency. Redundancies will confuse the regulated community, especially if there are conflicting standards or regulations. There is no way to discern which federal agency takes precedence. Congress delegated to OSHA the specific authority to set exposure limits in the workplace and manage those exposures. Congress knew of OSHA's longstanding approach to managing chemical exposure in the workplace and would not have remained silent if it intended for EPA to displace or otherwise contradict OSHA's role in this area.

EPA asserts that since there could be cases of workers not wearing PPE, the Agency must assume that no workers are wearing PPE.[41] Furthermore, the Agency will assume that "subpopulations of workers are exposed due to absence or ineffective use of personal protective equipment" by relying on "reasonably available information" on "known and reasonably foreseen circumstances."[42] These are absurd assumptions that would result in most chemicals already regulated by OSHA to be deemed unreasonable risks under TSCA. Clearly, Congress would not have remained silent on that issue when the LCSA was enacted. Moreover, EPA has put forth zero evidence or specific examples of workplaces not following OSHA regulations in this Proposed Framework or any of the risk evaluations. The assumption appears to be based solely on comments received by certain, unidentified stakeholders. There is no way to verify the accuracy of the assumption because EPA does not provide or point to any corroborating evidence.

EPA says it will only consider PPE in cases where companies provide "information demonstrating that performance of a condition of use is impossible in the absence of PPE."[43] AFPM sees no way to demonstrate or verify that the lack of PPE would make a task "impossible" without putting a worker in danger. This is an irresponsible standard at best.

Aside from fallacious logic, EPA's assumption that workers do not wear PPE completely ignores the requirements in Sec. 26(h) to use the best available science. The outputs of EPA models used in TSCA risk evaluations are subject to the same sound science provisions as all other data used to make risk determinations. If those models assume that workers get exposed to chemicals and do not wear PPE at a petroleum refinery or petrochemical plant, then those models are wrong. AFPM has conveyed to EPA in comments on the problem formulation, risk

[40] *Id.* at 74304.
[41] *Id.*
[42] *Id.* at 74305.
[43] *Id.*

evaluation, and risk management rules for perchloroethylene that its default assumptions in its exposure models are wrong, as is the assumption that workers do not wear PPE.[44,45,46]

EPA also claims that "workers may be highly exposed" because their workplaces are not covered by OSHA or are breaking the law by not following OSHA regulations.[47] Nowhere in this Proposed Framework or any of the published risk evaluations has EPA quantified how often workplace PPE violations are committed, nor has the Agency quantified workplaces that are somehow exempt from OSHA regulations. Moreover, it is well-settled law that regulations will be followed. Risk evaluations under TSCA must not assume that people are breaking the law because those circumstances are unlikely and not reasonably foreseeable. Furthermore, if EPA claims those circumstances are "known," then the Agency must provide evidence and quantify those circumstances and not rely solely on hearsay from unidentified stakeholders. Even then such situations would be subject to and under the purview of OSHA enforcement action, not EPA regulation.

EPA is proposing an entirely new workplace exposure limit that is intended to supplant the current exposure limits established by other agencies. EPA says the reason it needs to establish new thresholds (ECELs) is because many of OSHA's limits were developed in the 1970s.[48] While this may be true, the inherent hazards (the basis of the thresholds) have not changed and will never change. EPA insists that "the science" has enlightened the Agency and that new thresholds are warranted, yet the evidence put forth thus far in the risk management rules is specious and does not represent the best available science. EPA must stay in its lane. If it has reason to believe that a particular OSHA Permissible Exposure Limit ("PEL") requires revision, it should provide the data needed and allow OSHA to conduct its own revision.

EPA says its risk evaluations "are subject to statutory science standards, an explicit requirement to consider risks to potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk factors when determining whether a chemical presents an unreasonable risk that warrants regulatory actions," but "those factors do not apply to development of OSHA regulations."[49] Here, EPA conflates risk evaluation and risk management. The development of OSHA regulations is risk management, just like development of ECELs is risk management. Neither are subject to those listed factors, except that Sec. 26(h) of TSCA applies to the entirety of TSCA and not just Sec. 6 risk evaluations. EPA goes on to say that it may find an unreasonable risk even if there are OSHA regulations in place to manage that risk. As stated at the beginning of this section, EPA will strive for consistency with OSHA

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[44] See AFPM comments on "Problem Formulations for the Risk Evaluations To Be Conducted for the First Chemical Substances Under the Toxic Substances Control Act, and Application of Systematic Review in TSCA Risk Evaluations; Extension of Comment Period; Tetrachloroethylene (also known as perchloroethylene)." *82 Fed. Reg. 12589*. EPA-HQ-OPPT-2016-0732-0108.

[45] See AFPM comments on "Perchloroethylene; Draft Toxic Substances Control Act (TSCA) Risk Evaluation and TSCA Science Advisory Committee on Chemicals (SACC) Meetings; Notice of Availability, Public Meetings, and Request for Comment" *85 Fed. Reg. 26464*. EPA–HQ–OPPT–2019–0502.

[46] See AFPM comments on EPA's "Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA)." *88 Fed. Reg. 39652*, EPAHQ-OPPT-2020-0720.

[47] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74302.

[48] *Id.* at 74304.

[49] *Id.*

regulations. For some reason EPA believes that promulgating duplicative and redundant regulations will somehow result in more effective risk management.

Thus far, proposed ECELs have been based on epidemiology studies that do not control for confounding factors but are given the same weight as controlled laboratory experiments. This is inappropriate and a departure from established weight-of-the-evidence protocols. OSHA, the National Institute for Occupational Safety and Health ("NIOSH"), the American Conference of Government Industrial Hygienists ("ACGIH") are the regulatory and standards-setting bodies for establishing workplace thresholds. The normal approach for reviewing and establishing workplace thresholds, utilized by these organizations for decades, is a multistakeholder and multidisciplinary approach. EPA developed its own thresholds, in-house, with no opportunity for public participation.

AFPM does not support the development or establishment of ECELs. None of the proposed ECELs were developed in conjunction with OSHA, NIOSH, or ACGIH, or even through consensus among scientific experts, such as toxicologists and industrial hygienists, nor were they subject to notice and comment.

6. Cumulative Risk Assessment ("CRA") is not appropriate for TSCA risk evaluations because methods are still undergoing scientific evaluation most have yet to be validated.

EPA is seeking how it "could incorporate provisions for cumulative risk assessment into [its] risk evaluation procedures in a way that would accommodate future advancements in the science."[50] EPA claims that TSCA "provides authority to consider non-chemical as well as chemical stressors when identifying" sensitive subpopulations; however, the word "stressor" does not appear anywhere in the statute.[51] In fact, the term "cumulative risk" does not even appear in the statute. In TSCA Sec. 6, Congress only authorizes EPA to consider chemicals and their conditions of use when conducting risk evaluations.

In February 2023, EPA released a draft of its principles for consideration of CRA in TSCA risk evaluations.[52] The proposed draft is useful for providing a high-level review of available CRA guidance developed by regulators up to this point, but the draft does not specify how EPA would use and apply the proposed principles in a chemical risk evaluation. The principles do not even describe data thresholds that would justify the development of a CRA for a risk evaluation. In its Proposal EPA says it will consider weight-of-the-evidence but there is no mention or description of any established, systematic process to ensure that the evaluation process is sufficiently transparent.

The Agency says that the principles document is not guidance but also indicates that the draft document will be relied upon to determine if CRAs should be part of chemical risk evaluations. These statements are contradictory. The draft principles document raises more

[50] *Id.* at 74306.
[51] *Id.*
[52] See *88 Fed. Reg. 12354*, "Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act." EPA-HQ-OPPT-2022-0918. Published February 27, 2023.

questions than answers because it fails to communicate the scientific and policy details necessary to understand when and how CRAs will be developed going forward.

AFPM does not support the inclusion of CRA in the Risk Evaluation Framework at this time. Most of the science behind the CRA methods is still being evaluated and is not even ready for validation. Nobody knows what the future of CRAs will look like, so it is premature to include consideration of CRAs in the Risk Evaluation Framework. More importantly, in TSCA Sec. 6, Congress only authorizes EPA to consider chemicals and their conditions of use when conducting risk evaluations.

7. EPA is trying to include social injustices in chemical risk evaluations.

EPA talks about "potentially exposed or susceptible subpopulations" and intends to add "overburdened communities" to the definition.[53] The Agency states that "vulnerability may be attributable to an accumulation of negative or lack of positive environmental, health, economic, or social conditions within these populations or places."[54] Congress did not create TSCA to be a social justice statute. EPA is trying to force-fit these considerations into the TSCA framework; however, executive orders cannot supplant Congressional authority. These kinds of considerations, while important, have never been part of the chemical risk assessment process and should be left to other government agencies with expertise in the social justice arena. Trying to incorporate all of these undefined considerations into the risk evaluation process will result in paralysis by analysis. EPA is already far behind in its work and adding more considerations will only place the Agency further behind.

8. EPA stretches its discretion on peer review and the Agency's definition is not consistent with traditional and widely accepted definitions.

EPA asserts that "there are circumstances when the additional peer review of influential products that have had adequate prior peer review may not be necessary" and that "there may be situations when repeated peer review is not warranted."[55] EPA uses the case of 1,4-dioxane as an example of where the Agency "determined that additional peer review was not warranted."[56] In essence, EPA asserts it can take parts of peer-reviewed documents, even if they were created for a different purpose, put them together in a fit-for-purpose evaluation, and bypass peer review for the risk evaluation as a whole. EPA should commit to a peer review of the entire risk evaluation to ensure that the Agency's assumptions and conclusions are in fact fit-for-purpose and follow the sound science provisions under Sec. 26(h).

EPA uses the term "peer review" liberally throughout the Proposed Framework and in its risk evaluations. EPA's process for reviewing draft risk evaluations is more akin to a consultation than the traditional peer review used by technical journals and professional societies. The Agency uses the term "peer consultation" in most other toxicological and risk

[53] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74306.
[54] *Id.*
[55] *Id.* at 74307 – 74308.
[56] *Id.* at 74308.

assessment programs, so OPPT should be consistent and use the same term for its work under TSCA to avoid confusion.

In the context of scientific studies to support risk evaluations, the term "peer review" has been coopted over time and the approaches used by "science" publications often do not follow the traditional approaches used by technical journals published by scientific professional societies. In many "peer reviewed" publications, replication means little anymore, as does controlling for confounding factors and other fundamentals. Additionally, there seems to be more concern over funding sources than the study itself. There are existing mechanisms to check for bias and those should be employed.

EPA can no longer just rely on whether a study was subject to "peer review" or who funded the work when applying weight to judge the quality of the study. EPA must also consider the approach used by the peer review group, including judgement criteria, makeup of the peer group, reproducibility of the study results, and other factors historically used to judge the quality of scientific work. That is why it is so important to retain the current definitions of "weight-of-the-scientific-evidence" and "best available science" in the Risk Evaluation Framework.

9. EPA has abandoned interagency review.

EPA provides no documentation of its meetings with other agencies when it comes to TSCA implementation. The coordination with other agencies is a statutory requirement; therefore, it is incumbent upon EPA to at least list the agencies with whom it has met, and the subjects discussed, so that stakeholders can gauge the involvement and interest of others in the federal government.

VI. EPA Requests for Comment

1. *EPA requests comment on how the Agency could consider potential climate-related risks in a risk evaluation.*

Consideration of potential climate-related risks is not and should never be part of a risk evaluation under TSCA Sec. 6. To have practical utility, TSCA risk evaluations must consider normal conditions of use and not try to predict the future. To be considered reasonably foreseen or likely, the risk equation would have to include a validated probability factor for anything outside normal conditions of use, which is not an expectation expressed anywhere in TSCA. Congress did not authorize EPA to speculate on future climate considerations in the context of TSCA risk evaluations. EPA has been granted authorities under other statutes to address climate considerations.

Sec. 6(b)(4)(F) lists the requirements of risk evaluations and item (iv) explicitly mandates EPA to "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." The word "likely" is a probabilistic term. The potential effects from climate change are unpredictable and the attempt of EPA to tie climate change to potential chemical exposures in the future is equally unpredictable. Chemical risk assessment practices concern potential exposures under predictable and likely

scenarios. There is no example of a credible chemical risk assessment method that considers potential climate effects.

2. *EPA requests comment on the proposed approach of publishing a draft scope during the prioritization process when it is clear that the chemical undergoing the prioritization process will be designated as a high-priority chemical.*

TSCA Sec. 6(b)(4)(D) states that EPA must publish the scope "after the initiation of a risk evaluation" and "ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation." Congress clearly intended for EPA to publish the scope after initiation of the risk evaluation.

Under TSCA Sec. 6(b)(1)(A), Congress requires EPA to "establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations." Congress uses Sec. 6(b)(4)(B) to direct EPA to develop the risk evaluation process, which is clearly separate from the prioritization process. EPA would have to amend the rule established under the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* to make changes to the prioritization process.[57]

3. *EPA requests public comment on the proposed elimination of the definitions of best available science and weight of scientific evidence, the need for such definitions, and the utility of definitions as the state of science evolves.*

EPA is proposing to eliminate the definitions for "best available science" and "weight of the scientific evidence" because the Agency is concerned that definitions will somehow take away its discretion and need to be changed as the science evolves. The Agency proposes to rely on "long-established Agency guidance documents to guide weight of scientific evidence analyses" for TSCA risk evaluations.[58] EPA does not explain or offer any example as to how these definitions would affect its discretion, other than the fact that they are statutory requirements, or why they would need to be changed in response to evolving science. EPA should not rely solely on guidance documents to define "best available science" and "weight of the evidence" because most of those documents were developed internally and were not subject to notice and comment or stakeholder involvement.

The current Risk Evaluation Framework defines "best available science" as "science that is reliable and unbiased…involving the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."[59] This definition is consistent with the Safe Drinking Water Act ("SDWA") and it does not appear to have affected EPA's ability to implement SDWA regulations as the science has evolved. Further,

[57] *See* 82 *Fed. Reg.* 4825, "Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act." EPA-HQ-OPPT-2016-0636-0074; FRL–9957–74 OCSPP, published January 17, 2017.
[58] *Id.* at 74308-74309.
[59] *Id.* at 74309.

the White House Office of Management and Budget ("OMB") views the SDWA standard as precedent-setting and includes it in the OMB Information Quality Guidelines.

Other factors in the current definition include:

- The scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

- The information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

- The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

- The variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

- There is independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

These factors also do not change with evolving science; in fact, they are core sound-science tenets found in Sec. 26(h) of TSCA. EPA needs to clarify how the current definition would necessitate a change with evolving science. The Agency offers no examples of how the current definition "could limit the Agency's ability, flexibility, and mandate to incorporate the best available science into TSCA risk evaluations."[60] Even EPA admits "the SDWA definition of 'best available science and the associated guidelines and policies are all aligned with the science requirements enumerated in TSCA section 26(h)."[61]

The current definition for "weight of the evidence" is:

> ''a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."[62]

EPA says, "this definition is problematic and inconsistent with typical risk assessment practice," and attempts to offer an explanation from the National Academies of Science,

[60] *Id.*
[61] *Id.*
[62] *Id.* at 74310.

Engineering and Medicine ("NASEM") review of EPA's guidance document *Application of Systematic Review in TSCA Risk Evaluations* (EPA 2018a).[63,64]

In its Proposed Framework, EPA uses a quote from NASEM regarding weight-of-evidence ("WOE"): "this definition of WOE seems to say that the TSCA systematic review is itself a WOE evaluation."[65] EPA has taken this quote out of context and claims that NASEM reviewers were referring to the definition in the Risk Evaluation Rule at 40 Code of Federal Regulations ("CFR") Part 702, while in fact, NASEM reviewers were referring to the EPA 2018a systematic review guidance document and several risk evaluations. NASEM points to the definition in 40 CFR that says weight-of-the-evidence "is a systematic review method" not that systematic review is a weight-of-the-evidence method.

EPA further discusses how the NASEM report finds conflation of the terms "weight of evidence" and "systematic review."[66] Again, the Agency is taking NASEM's conclusions and recommendations out of context. The conflation is in the context of the guidance document and two risk evaluations. In those documents, NASEM found that EPA repeatedly confuses the two terms and uses them interchangeably.[67] In the proposed rule, EPA conveniently leaves out that NASEM "suggests that OPPT adopt a different specific term to be used during the evidence integration step, such as "strength of evidence" or "certainty of evidence" as utilized in the Grading of Recommendations Assessment, Development and Evaluation process" because of the difficulty in changing the definition by rule.[68]

As a minimum, EPA needs to clarify how these definitions affect its discretion and how changes in science would necessitate changes to the definitions before seeking comment. Additionally, EPA needs to strengthen its case for changing the definitions in 40 CFR Part 702 that is just as strong as the case made to create those definitions. If the Agency cannot make a case for change, then the definitions should not be changed.

4. *EPA requests comments on the proposed changes to the process of a manufacturer requested risk evaluation ("MRRE"). In regards to cost, while the costs to EPA would be reflected in the final invoice to the requesting manufacturer, EPA is seeking comment on, to the extent that test orders are issued to support a MRRE, whether the entire test order fee should also be directed to the requesting manufacturer, even where the order is also issued to another entity. Additionally, EPA requests specific comment on the burden estimate of a manufacturer requested risk evaluation, including the assumptions used in estimating the burden (e.g., number of requests EPA expects).*

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[63] *Id.*
[64] National Academies of Science, Engineering, and Medicine. *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations*. 2021.
[65] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74311.
[66] *Id.*
[67] National Academies of Science, Engineering, and Medicine. *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations*. 2021. p.47.
[68] *Id.* at p.7.

TSCA allows a manufacturer of a chemical substance to request an EPA-conducted risk evaluation on the chemical substance for conditions of use of interest to the manufacturer, also known as an MRRE. EPA proposes drastic changes to these MRREs that will likely result in no further requests.[69] The Agency will use a "whole chemical" approach and include all conditions of use (with the expanded scope) in its risk evaluation, even if the manufacturer is only requesting evaluation of a specific condition of use. There are no provisions in the LCSA authorizing EPA to expand the scope of the MRRE beyond what the manufacturer is requesting. To go beyond what is requested by a manufacturer, EPA would need to initiate a risk evaluation by categorizing the chemical as a high priority and following the procedures set forth in TSCA Sec. 6(b).

For instance, Company A requests a risk evaluation for Chemical X under the conditions associated with its use as an industrial processing aid in a closed system; however, Chemical X is also used by another company in a product formulation. Company A has no control over the use of Chemical X in a product formulation and may not even know of that use. Company A should in no way bear the responsibility for another company's decision, nor should Company A be expected to provide information that is not related to its intended conditions of use as an industrial processing aid. The conditions of use as a processing aid in a closed system are totally different than the conditions of use as an ingredient in a product formulation.

To further complicate the process for MRREs, EPA proposes to put the onus on Company A "to request EPA use its information collection authorities under TSCA" to compel other companies to provide EPA with information on Chemical X.[70] EPA already has authority to promulgate test rules and orders, require submission of existing data, and inspect facilities to carry out risk evaluations under Sec. 6, but obviously not for conditions of use beyond that requested by Company A. By including this in the proposed Risk Evaluation Framework, EPA realizes it does not have the authority to collect information for conditions of use beyond what Company A requests. Here, EPA is trying to force Company A into requesting a risk evaluation beyond its intended conditions of use. If Company A does not, then under the Proposal EPA can deem the request as incomplete and reject it.

EPA says that requests "otherwise not well-supported will be rejected and returned to the submitter" and that the Agency may "make an initial judgment as to the quality or quantity of information provided" and if determined to be insufficient, EPA will reject the request.[71] These are very subjective terms that go beyond the simple language found in TSCA Sec. 6(b)(4)(C)(ii), which says EPA must conduct a risk evaluation on a chemical "that a manufacturer of the chemical substance has requested."

EPA uses the term "sufficient information" repeatedly when referring to MRREs, but Congress did not authorize a minimum data set. EPA must use its testing authority under Sec. 4 and its information collection authority under Sec. 8 to fill data gaps, and that only applies to the

[69] See *88 Fed. Reg. 74292*, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP, published October 30, 2023. p.74312-74316.
[70] *Id.* at 74313.
[71] *Id.* at 74314.

requesting manufacturer's conditions of use. To go beyond the scope of the request, EPA would have to issue different test or information collection rules and subject other manufacturers.

Under the proposed approach for MRREs, EPA gives itself unfettered authority over all aspects and can at any time start and stop the clock and demand more information. The submitting company has only three options for response: (1) provide the necessary information to EPA, (2) if the risk evaluation has not yet been initiated, withdraw the MRRE request, or (3) request that EPA obtain the information using authorities under TSCA sections 4, 8, or 11.[72]

In its proposed approach, EPA says that it can require more information at any time during the MRRE process and that "MRRE requests cannot be withdrawn by the requesting manufacturer once EPA has initiated the risk evaluation." This provision would allow EPA to keep any fees paid. In cases where a MRRE submitter finds the Agency's demands for more information unreasonable, it would have no recourse but to pursue a remedy in the courts or forego what could be several million dollars.

EPA is seeking specific comment on whether it should charge the fees associated with Sec. 4 actions to the MRRE submitter even in cases where the test order pertains to another company.[73] EPA has no authority to compel a company to take financial responsibility for another company. The Agency's statutory authority for testing and financial obligations of manufacturers are found in TSCA Sec. 4(c) and must be followed. The statute only addresses monetary obligations in cases where a company requests an exemption from testing, or a company intends to manufacture (or import) that chemical after testing was conducted. Congress did not provide EPA authority to specify who owes what in a consortium. EPA cannot use the CFR to change the provisions of TSCA Sec. 4.

5. *EPA requests comment on general approaches or best practices for improving engagement with small entities. Early engagement with and feedback from all those who manufacture, process, distribute, use or dispose of a chemical is critical for the Agency to be able to accurately identify and characterize that chemical's conditions of use for consideration in the risk evaluation, EPA is seeking comment on how to improve its outreach to the stakeholder community, including education on the TSCA risk evaluation process for small entities.*

EPA should contact potentially affected trade associations, with an emphasis on downstream users, early on to inform them that their members could be affected by the chemical risk evaluation and potential risk management for each high-priority chemical. EPA could develop and provide the trade associations with educational materials about the risk evaluation and risk management processes with respect to each high-priority chemical substance and request the association to distribute the materials to its members. EPA should then conduct targeted outreach to potentially affected downstream users of the high-priority chemical via video conference or regional in-person meeting and provide details of what the Agency knows about the chemical's conditions of use. In addition, EPA should use the outreach venue as a means to collect information that it does not know.

[72] *Id.* at 74315.
[73] *Id.*

6. *EPA requests public comment on how the Agency can provide a transparent and detailed basis for the proposed unreasonable risk determination and existing chemical exposure limits ("ECELs") derived from the risk evaluation process.*

EPA should adhere to the provisions in TSCA Sections 6 and 26 for guidance on transparency, scientific rigor, and communications for its *Federal Register* notices. The proposed risk evaluations published thus far have not been as robust in transparency as directed by the statute. The supporting scientific information is often left out of the *Federal Register* notice. Data to justify EPA's claims and assumptions for the Risk Evaluation Framework is also lacking. The Agency should ensure that its claims are well-supported with data, especially for significant changes to policies and procedures.

AFPM does not support the development or use of ECELs because the whole concept is duplicative and contradictive of existing federal standards and regulations. EPA created the concept and the first round of ECELs in a vacuum and did not include stakeholder scientists who are experts in toxicology and/or industrial hygiene. The unreasonably low threshold values proposed in the risk management rules so far are orders of magnitude below existing thresholds used throughout the world. The ECELs are so low that they challenge the levels of analytical detection, which makes verification next to impossible.

If EPA moves forward with its own threshold, it will likely confuse the regulated community as to which threshold should be followed. Instead, EPA should form a multistakeholder group of qualified scientists from the disciplines of toxicology and industrial hygiene, in conjunction with OSHA and NIOSH, to review existing workplace exposure limits and determine if and how existing limits should change. Changes should be made according to established standards-setting approaches at OSHA and NIOSH.

To demonstrate the unworkability of ECELs, EPA is proposing an entirely new workplace exposure limit for perchloroethylene that is intended to supplant the current exposure limits established by other federal and state agencies. In the proposed risk management rule for perchloroethylene, EPA discusses workplace exposure thresholds established by OSHA, NIOSH, ACGIH, and the California Division of Occupational Safety and Health, all of which, with the exception of OSHA, recommend a 25 parts per million ("ppm") workplace exposure threshold.[74] OSHA's standard is 100-ppm. The 25-ppm threshold established by the other agencies incorporates the standard 4-fold margin of safety employed by every agency except EPA. The Agency dismisses the use of the 4-fold threshold standard because it does not conform to EPA's own guidance (developed by EPA, of course), which uses anywhere from a 30-fold to 100-fold margin of safety.[75] EPA is proposing an ECEL of 0.14 ppm, which is 700-fold below OSHA's workplace exposure limit and almost 200-fold lower than the other established standards that already incorporate a margin of safety.[76]

[74] See *88 Fed. Reg.* 39652. "Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-0720; FRL-8329-02-OCSPP, published June 16, 2023. p. 39660.
[75] *Id.*
[76] *Id.* at 39672.

EPA states that the ECEL for perchloroethylene (0.14 ppm) is based primarily on two studies, Cavalerri et al., 1994, and Echeverria et al., 1995, both of which are epidemiological studies with very small sample sizes and subjective endpoints, such as "color confusion, impaired pattern recognition, and reaction time in pattern memory."[77] Neither study quantified the actual level of PCE in the study subjects; rather, both used air sampling to guess at what the dose values could be. There are myriad toxicological studies on PCE of varying quality. EPA did not adequately compare the study designs or weight the studies to provide an indication of why the Agency chose those two as the primary drivers for such a dramatic shift in workplace exposure thresholds. Weight-of-the-evidence analysis and robust documentation of data and assumptions are required by Congress in TSCA Sec. 26(h).[78]

AFPM did not support the proposed ECEL for perchloroethylene because it did not include a variety of stakeholder scientists who are experts in toxicology or industrial hygiene. AFPM recommended that EPA adopt the 25-ppm threshold used by all other agencies, as those thresholds were established through normal scientific review bodies. AFPM conveyed that if EPA insists on its own threshold, it likely will confuse the regulated community as to which threshold should be followed. Instead, EPA should form a multistakeholder group of qualified scientists from the disciplines of toxicology and industrial hygiene, in conjunction with OSHA and NIOSH, to establish a workplace exposure limit that is based on the best available science and not rely on two epidemiological studies with very small sample sizes.

VII. Conclusion

AFPM appreciates the opportunity to comment on the proposed Risk Evaluation Framework. The Proposal outlines risk evaluation processes that are beyond the statutory authority granted to EPA under TSCA and that will be impossible for EPA to implement within the statutory deadlines. EPA includes a section on fit-for-purpose but locks itself in with prescriptive requirements throughout the Proposal. The Agency is already far behind in its work, which has nothing to do with its budget; rather, it is the approaches taken by EPA, as outlined in the Proposed Framework, that have resulted in no final risk management rules even for the first ten chemicals.

The Proposal takes TSCA far off course into an academic exercise of molecule-tracking and attempts to include every conceivable scenario in which a chemical could be involved as a "condition of use." Coupled with the "whole chemical" approach, just about every chemical in commerce will present an unreasonable risk and face regulatory action. That surely is not what Congress intended with TSCA.

EPA should withdraw the Proposed Framework and, if the Agency feels changes are necessary, repropose a more realistic process for conducting risk evaluations.

[77] *Id.* at 39655 and 39659.
[78] See U.S. Code 15 § 2625(h).

Sincerely,

James Cooper
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