August 8, 2023

Tyler Lloyd
New Chemicals Division (7405M)
Office of Pollution Prevention and Toxics (OPPT)
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, NW
Washington, DC 20460–0001

Submitted via regulations.gov

RE: Proposed Rule, Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA), EPA-HQ-OPPT-2022-0902-0001

Dear Mr. Lloyd:

SOCMA appreciates the opportunity to provide comments on EPA's proposed rule entitled "Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)" [1] (hereinafter referred to as the "proposed rule" or "proposal").

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture new and innovative chemistries used in a wide range of commercial, industrial, and consumer products. SOCMA maintains a strong record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote industry stewardship. SOCMA's members also implement ChemStewards®, an EHS&S performance improvement program that is a mandatory component of membership.

SOCMA members rely on the TSCA Section 5 review process to bring new chemicals to market, and since innovation is the life blood of the specialty chemical industry, it is of top concern that the EPA program meet statutory review deadlines. Additionally, the process must be transparent, efficient, predictable, and consistent with TSCA statutory authority. EPA states that the intent of the proposed rule is to align the new chemicals regulations with the Frank R. Lautenberg Chemical Safety for the 21st Century Act amendments ("Lautenberg Amendments")[2] to TSCA Section 5, incorporate EPA's existing policies, increase the quality of the information initially submitted in new chemicals notices, improve EPA's processes for completion of the risk assessment and the new chemicals review, and make certain substances ineligible for Section 5 exemptions. SOCMA appreciates EPA's efforts to improve the efficiency of the new chemicals review process, however, the proposed amendments fall far short of making much-needed improvements to the program. In fact, some of EPA's proposed changes are likely to increase the length of time of new chemicals reviews.

[1] 88 Fed. Reg. 34100 (May 26, 2023).
[2] Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 112-182 (June 22, 2016).

Presently, pre-manufacture notices (PMNs) take multiple years rather than only 90 days to be approved. These delays make it very difficult for companies to make critical business decisions and plans for new products. EPA's existing process is unpredictable, lacks transparency and consistency, and typically relies on conservative defaults instead of using data provided by submitters. PMN submitters are perpetually stuck in a cycle of having to approve suspensions of the statutory review period (often without a legitimate reason or explanation from EPA) or withdraw the submission. These same challenges exist with low volume exemptions (LVEs). An overwhelming majority of the approved PMNs come with consent orders and follow-on significant new use rules (SNURs), which can limit the desirability of the chemistries to downstream customers who use the substances in consumer or commercial products. Small businesses, which make up a substantial portion of SOCMA membership are disproportionately impacted by these circumstances.

As it stands, the new chemicals program post-Lautenberg Amendments is so delayed that submitters are effectively discouraged from trying to bring safer and more innovative chemistries to market in the US. Companies are forced to rely on older chemistries that may have lower performance and higher risk profiles than newer chemicals simply because EPA is unable to review and process new chemicals submissions in a timely manner consistent with using best available science. These issues coupled with EPA's recent proposal to double TSCA Section 5 fees[3] will further stifle innovation for years to come.

Consistent with the intent and purpose of TSCA, EPA should use its authority "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."[4]

SOCMA's comments address the following points:

- **Use of best available science**- EPA must incorporate TSCA Section 26 science standards into the proposed rule instead of relying on conservative defaults.

- **New upfront data requirements**- If EPA is going to codify data requirements, it must be required to use PMN submitter data and not apply conservative assumptions or use modeling unless EPA can show that its data is more scientifically accurate. Further, EPA must provide the opportunity for submitters to explain why a specific data requirement is not applicable to a submission.

- **Reasonably foreseen uses**- Consistent with TSCA, EPA must modify its approach to reviewing intended, known, or reasonably foreseen conditions of use. Additionally, TSCA does not require EPA to review reasonably foreseen uses at the same time as the intended and known uses identified by a submitter. SOCMA strongly recommends that EPA bifurcate the review process and review the submitter intended uses and separately review the reasonably foreseeable uses.

- **Refunds**- To encourage accountability with statutory timelines, EPA should issue refunds to PMN submitters if EPA asks the submitter to suspend the review period for reasons other than legitimate scientific reasons.

[3] 87 Fed. Reg. 68647 (November 16, 2022).
[4] 15 U.S.C. § 2601(b)(3).

- **Extensions of the review period**- EPA should not extend its ability to request suspensions of the review period from 15 days to 30 days, as this would result in more delays and uncertainty in the program. Specifically, EPA should justify extension requests.

- **Pre-submission meetings**- EPA should codify procedures for pre-submission meetings with PMN submitters and ensure that appropriate experts, including an EPA human health risk assessor, attend.

- **Potentially exposed or susceptible subpopulations (PESS)**- EPA should align the proposed definition with the TSCA statutory definition for PESS.

- **Restarting "90-day clock" if submitter later provides information that EPA believes was "known to or reasonably ascertainable by" the company**- SOCMA urges EPA not to finalize this requirement because this will result in even longer new chemicals reviews, and, in practice, submitters provide such data to EPA typically after EPA unnecessarily applies its own conservative assumptions, causing the submitter to have to provide more information to rebut EPA's assumptions.

- **Perfluoroalkyl and polyfluoroalkyl substance (PFAS) and persistent, bioaccumulative, and toxic (PCB) exclusion from LVEs and Low Releases and Exposure Exemptions (LoREXs)**- EPA should not categorically classify large groups of substances as ineligible for LVEs or LoREXs. EPA already has authority to deny LVE or LoREX applications if it is unable to find that manufacture, processing, distribution in commerce, use, and disposal of the exempted substance will not present an unreasonable risk of injury to human health or the environment. Further, EPA needs scientific evidence and input to formalize this type of ban and it should not be included in a "procedural" rulemaking but requires a standalone rulemaking.

- **Transparency**- EPA should provide more information to submitters about the status of their new chemical notices.

- **Review of EPA determinations**- EPA should provide submitters with the opportunity to administratively challenge an EPA determination on a new chemical notice rather than having to resort to federal court action.

- **Sector-specific approaches**- EPA should clarify procedures for and consideration of sector-specific approaches to new chemicals reviews if requested by a specific industry sector or based on other scientifically valid criteria.

- **Use of check boxes in the PMN form**- EPA should not modify the PMN form to require check boxes on every screen.

- **EPA must implement a risk, not hazard based approach for new chemical reviews**- TSCA requires that EPA evaluate new chemicals to ensure they do not present an unreasonable ***risk*** of injury to health or the environment under the conditions of use. EPA should not make hazard-based determinations on new chemicals.

I. EPA Must Incorporate TSCA Section 26 Science Standards into the Proposed Rule

TSCA requires, in Section 26(h), that in administering Sections 4, 5, and 6 of TSCA, to the extent EPA makes a decision based on science, it must use "scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."[5] EPA must consider:

> (1) the extent to which 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;
>
> (2) the extent to which the information is relevant for EPA's use in making a decision about a chemical substance or mixture;
>
> (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
>
> (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
>
> (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.[6]

EPA codified these statutory "best available science" requirements in its procedural rule for risk evaluations;[7] however, it has not done so for new chemicals reviews. In fact, the preamble of the proposed rule does not even mention the TSCA Section 26(h) standards. EPA must include TSCA Section 26(h) "best available science" provisions in the final rule so that there is confidence that, when EPA reviews notices under Section 5, it will make decisions based on the best available science. Unfortunately, that has not been the case with EPA's current practices in the new chemicals program.

EPA acknowledges this in the preamble to this proposed rule. Multiple times, EPA explains that, when a Section 5 notice lacks detail, EPA "typically uses conservative assumptions and default values."[8] EPA states that "a submitter may not know or be able to reasonably ascertain certain details about the chemical substance that is the subject of the notice, such as details about manufacturing, processing, or use sites out of the submitter's control. In those situations, EPA would make conservative assumptions and use conservative default values…."[9] And EPA admits "[i]f a field [on the PMN form] is left blank, EPA would make conservative assumptions and use conservative default values when assessing risk, which could result in more stringent risk management requirements."[10]

This practice is contrary to TSCA's mandate that EPA make decisions based on the best available science. In fact, TSCA, including the Lautenberg Amendments, makes no mention of applying "conservative

[5] 15 U.S.C. § 2625(h).
[6] *Id*.
[7] 40 C.F.R. § 702.33 and § 702.41
[8] 88 Fed. Reg. at 34106.
[9] *Id*.
[10] *Id*. at 34109.

assumptions" or "default values." The best available science does not mean taking a highly precautionary approach with worst-case, conservative assumptions that are unrealistic or impractical in the new chemical's real-world application. For example, SOCMA has often heard from member companies that EPA requests 90-day inhalation studies when the new chemical does not have inhalation exposure, or that EPA makes unjustified assumptions for particle size (that all particles are respirable unless the submitter can demonstrate they are not). And, even when industry provides studies and data or suggests relevant analogs to use, EPA has disregarded this data and information and instead has chosen different analogs that are less relevant to the chemistry being reviewed.

EPA should not rely on its own modeling or analog data when the submitter has provided data to support its new chemical. EPA should commit to using submitter data. In the case that EPA does not believe the submitter modeling is accurate or the analog is not appropriate, EPA should be transparent with the submitter and work jointly to use the best data and analog.

Further, even if EPA views a notice as lacking detail or seeks to fill in gaps of information, it should not default to applying worst-case, conservative assumptions; rather, EPA should consult public literature and other existing data sources that meet the TSCA Section 26 criteria for best available science.

Finally, EPA should also clarify in the regulations that the best available science also means consideration of the substitution benefits of a particular chemistry. This means that, if the new chemical is lower risk than the existing chemical in commerce it is intended to replace, EPA should consider this benefit in its analysis.

In the final rule, EPA should codify the Section 26(h) science requirements and clearly state that EPA will apply these principles in assessing new chemicals going forward, as is required by the Lautenberg Amendments.

II. EPA's Proposed New Data Requirements Should Come with a Commitment by EPA To Use Submitted Data, and EPA Must Provide Stakeholders with Additional Certainty Regarding How These Data Will Be Used

EPA proposes that submitters provide significantly more data upfront with Section 5 notices, including information on articles that incorporate the new chemical, consumer and commercial information, site information, physical and chemical properties, and environmental fate. In current practice, SOCMA understands that a substantial amount of time is spent corresponding and negotiating with EPA as to what data are necessary for a new chemical under review, and often the submitter is surprised or not made aware of what exactly EPA believes it needs until much later in the review process. This creates uncertainty, unpredictability, and delays in new chemicals reviews.

With several caveats, SOCMA could support EPA's efforts to clarify what information it needs up front to review Section 5 notices so that submitters do not spend time, waiting for months on their applications, only to be told that EPA does not have sufficient information on the new chemical to make a decision. However, as written in this rule, SOCMA does not have confidence these data sets, or upfront data, will inform risk-based evaluations nor that it will help EPA meet the LCSA statutory review deadlines.

First, if EPA is going to require more data submitted upfront with new chemical notices, it should include in the regulations a requirement that it must utilize the submitter generated data and provided data rather than its own conservative assumptions or modeling. It would be frivolous and lacking practical

utility to require that submitters incur significant expenses and time developing and providing data that is either not necessary or even applicable for the particular chemistry, or that will not be used by EPA to inform the risk assessment for the new chemical. Submitters are more likely to support additional upfront data requirements if they have certainty that their data will be relied upon by EPA to make more expeditious, risk-based, and scientifically sound decisions on their notices.

Second, EPA should not require a laundry list of data or tests for every Section 5 notice. Each data element must be justified for and pertinent to the specific application. Therefore, data requirements should be tailored to the type of application, similar to the data requirements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[11] The level of data required should be commensurate with the level of risk expected with the new chemistry. For example, higher production volume substances can fall under a higher "band" and require more data than lower volume substances. Additionally, EPA should provide in the regulations an opportunity for submitters to explain or identify when a particular data element is not applicable or not necessary to their application, similar to how FIFRA permits registrants to submit waiver requests from data requirements.

Third, if EPA is going to prescribe more data be provided upfront, it should specify in the regulations the appropriate test methods, test criteria, and laboratory requirements, similar to how data requirements are prescribed under FIFRA, so that submitters have certainty that the data will be acceptable and used by the agency. Submitters should be also able to satisfy a data element by citing to appropriate public literature or other credible data sources in lieu of new testing if they choose. This is important because, other global authoritative bodies do not allow the generation of data tested on animals including fish. EPA itself has made a commitment to stop conducting or funding studies on animals by 2035. Not all tests currently have alternatives approved; therefore, mandating these studies would be counter to that commitment and detrimental to chemicals used across different industries.

Fourth, SOCMA understands from our members that EPA's proposal to require environmental fate information will be particularly challenging to generate up front. Bioaccumulation is impossible to accurately test. Biodegradation studies often take six months to complete due to backlogs at testing facilities that are GLP certified.

III. Consistent with TSCA, EPA Must Modify its Approach to Reviewing Intended, Known, or Reasonably Foreseen Conditions of Use

EPA is required to make a determination of whether the new substance presents an unreasonable risk of injury to health or the environment "*under the conditions of use*."[12] TSCA defines "conditions of use" to mean "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, used, or disposed of."[13] Unfortunately, EPA's current practice in reviewing "reasonably foreseen" uses of new chemicals has been a source of many delays in the new chemicals review process.

EPA has provided guidance on the meaning of "reasonably foreseen" uses:

[11] See 40 C.F.R. Part 158.
[12] 15 U.S.C. § 2604(a)(3)(A)(emphasis added).
[13] 15 U.S.C. § 2602(4).

> The Agency is committed to exercising its discretion to determine the conditions of use in a reasonable manner and will not base this determination upon hypotheticals or conjecture. The identification of "reasonably foreseen" conditions of use will necessarily be a case-by-case determination and will be highly fact-specific. Sources of facts to support such determinations may include known activities associated with similar chemicals, knowledge of a chemical's properties that may allow it to replace a function currently being performed by non-chemical means, or information on research and development activities applying a chemical substance to a particular new use. It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible but, over time under proper conditions, probable.[14]
>
> Reasonably foreseen conditions of use are future circumstances under which the Administrator might expect the new chemical substance to be manufactured, processed, distributed, used, or disposed of. Reasonably foreseen conditions of use are separate from and in addition to a submitter's intended conditions of use. The identification of reasonably foreseen conditions of use is necessarily a case-by-case determination and highly fact-specific, necessitating that EPA apply its professional judgment, experience, and discretion. The sources EPA uses to identify reasonably foreseen conditions of use may include, but are not limited to, searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, patent abstracts in the Chemical Abstract Service STN platform, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), other information in the Chemical Abstract Service STN Platform, REACH Dossiers, and technical encyclopedias (e.g., Kirk-Othmer and Ullmann).[15]

EPA should codify these parameters in the new chemical's regulations. EPA is not required under TSCA to eliminate *all* potential, hypothetical risks for a chemical for all uses under the sun. Rather, TSCA requires that EPA address *unreasonable* risks based on the known, intended, and reasonably foreseen conditions of use. EPA should not evaluate *unreasonably* foreseen conditions of use and, on that basis, impose unreasonable and unnecessary restrictions (typically through a SNUR) on a new chemical based on these unreasonably foreseen uses. EPA should also not assume that noncompliance with labeling, PPE, or other OSHA or EPA requirements is "reasonably foreseen."

Additionally, TSCA does not require EPA to evaluate all conditions of use at the same time. If a submitter provides EPA with information about known and intended uses, other uses which are not intended do not need to be part of the review process. EPA's desire to review all conditions of use at once, including hypothetical conditions of use which are not intended by the submitter, is causing new chemicals reviews to take longer than necessary, certainly more than 90 days, and is bogging down the program with hypothetical uses.

EPA has the authority to first make determinations that chemicals, under known and intended conditions of use are "not likely" to present unreasonable risk. EPA should make these known and intended conditions of use a priority. If EPA identifies other circumstances which it believes could occur in the future, even if they are not reasonably foreseen, EPA could identify these uses as significant new

[14] 82 Fed. Reg. 33726, 33730-1 (July 20, 2017).
[15] EPA's Draft New Chemicals Working Approach (December 2019): https://www.epa.gov/sites/default/files/2021-04/documents/new_chems_working_approach_-_12.20.19_final_with_disclaimer.pdf.

uses. This approach, which EPA has a long history of using, would then require notification to EPA if someone wanted to commence use of the new chemical for these reasonably foreseen uses.

IV. EPA Should Issue Refunds When Submission Is Unreasonably Delayed

Congress included a requirement in the Lautenberg Amendments that, if EPA failed to make a determination on a new chemical under Section 5 by the end of the 90-day review period, EPA must refund the TSCA fees charged to the submitter, except when the submitter has failed to provide information required by EPA or has otherwise unduly delayed the process.[16] However, in practice, SOCMA is not aware that EPA has ever issued a refund under this provision of TSCA, even though new chemical notices are routinely and significantly delayed long past the 90-day statutory review period. The "workaround" EPA uses to avoid issuing a refund is that it repeatedly requests the submitter to voluntarily suspend the review period, otherwise the submitter is forced to withdraw the application.

By specifically including a provision for refunds, Congress intended that EPA continue to meet its statutory deadlines and efficiently review new chemicals. Congress certainly did not intend for this provision to be rendered toothless through EPA's current practice of suspending the review period continuously, resulting in reviews taking years to complete without any consequence to EPA. In order to encourage accountability with statutory timelines, EPA should include in the new chemicals regulations a requirement (in addition to the statutory requirements) that submitters are entitled to at least a partial refund if EPA asks the submitter to suspend the review period for reasons other than legitimate scientific reasons (for example, if the notice has just been sitting on a supervisor's desk and has not been looked at yet).

Further, SOCMA supports a 20 percent refund of TSCA fees if a new chemical submission is voluntarily withdrawn after EPA has concluded risk assessment but before it has begun work on risk management. Given the conservatism of the Agency's Section 5 risk assessment practices, submitters may well determine that a chemical is simply not going to be viable given the risk management that the Agency is likely to impose. Such submitters will welcome the chance at least to recoup 20 percent of the fee they paid by withdrawing the submission, and the Agency will have that many fewer chemicals on which to conduct risk management.

V. EPA Should Not Allow 30-Day Extensions of the Review Period

EPA should not extend its ability to request suspensions of the new chemical review period from 15 days to 30 days using informal oral or email processes. EPA's justification is that this would reduce the need for repeated requests for 15-day suspensions.[17] However, to allow EPA to suspend the review period for double the amount of time will likely result in less frequent communication from EPA with the submitter and more delays and uncertainty for submitters. This is contrary to EPA's stated intent of the proposed rule, which is to improve the efficiency of the new chemicals review process.

VI. EPA Should Include Procedures for Pre-Submission Meetings

EPA should codify in the regulations its procedures for submitters to voluntarily request, and for EPA to conduct, pre-submission meetings. As EPA acknowledges, pre-submission meetings are valuable

[16] 15 U.S.C. § 2604(a)(4)(A).
[17] 88 Fed. Reg. at 34102.

opportunities for EPA and submitters to clarify what needs to be included in submissions and what the submitter can expect.[18] The new chemicals regulations should clarify how submitters should submit requests for a pre-submission meeting and, more importantly, what EPA is obligated to do in these meetings. EPA should require that the meetings be an exchange of information from the submitter to EPA, and that EPA provide feedback to the extent it is able on how the submitter can submit a complete application (rather than listening sessions) similar to FIFRA pre-application meetings. For example, a pre-submission meeting must have an EPA human health risk assessor present in the meeting in order to appropriately inform the submitter what data it could or is likely going to be expected to provide. If EPA is not committed to having technical experts participate in the pre-submission meetings, these meetings will lack the utility that is needed for them to be valuable to submitters or improve the quality of new chemical submissions.

VII. EPA Must Align the Proposed Definition of PESS with the TSCA Statutory Definition and Not Unreasonably Expand the Scope of New Chemicals Reviews

EPA is required to make a determination on whether the new substance "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation [PESS] identified as relevant by the Administrator under the conditions of use."[19] TSCA states PESS "means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."[20]

EPA proposes to incorporate this statutory definition of PESS in the proposed rule, for the most part. However, EPA also adds "overburdened communities" into the definition of PESS so that "overburdened communities" will need to be specifically evaluated by EPA when assessing the unreasonable risks of a new chemical under the conditions of use. EPA explains that this addition will assist EPA in determining potential exposures, hazards, and risks to overburdened communities associated with new chemicals and enable EPA to design "appropriate future risk management actions" affecting communities with environmental justice concerns.[21] Unfortunately, EPA provides no definition for what is meant by "overburdened communities" and provides no justification for why it is necessary to amend the definition of PESS that was provided by bipartisan lawmakers in the Lautenberg Amendments.

EPA's allegedly "procedural"[22] revision to the statutory definition of PESS could significantly expand the scope of new chemicals reviews to include evaluations of exposures to *all* communities that border not only the submitter's facilities that will be producing the new chemical, but also any facility EPA "reasonably foresees" will produce the chemical. And the lack of clarity as to the definition of an "overburdened community" can be interpreted to include communities that may be downstream users of the new chemical substance (in certain consumer products, for example). This could potentially mean

[18] See EPA website "Filing a Pre-manufacture Notice with EPA" at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa#:~:text=Companies%20are%20encouraged%20to%20contact,new%20chemicals%20for%20potential%20risks.
[19] 15 U.S.C. § 2604(a)(3)(A).
[20] 15 U.S.C. § 2602(12).
[21] 88 Fed. Reg. at 34118.
[22] EPA characterizes this addition to the statutory definition of PESS as an action that is "procedural in nature." 88 Fed. Reg. at 34118.

thousands of communities and individuals throughout the country. EPA already struggles with serious resource constraints to review new chemicals in a timely fashion. This revision to the statutory definition of PESS could have the unintended consequence of delaying and complicating the new chemicals program even more. EPA's consideration of fenceline communities and environmental justice concerns would be better served through other policies rather than through regulations mandating EPA's review of undefined "overburdened communities" for every new chemical notice.

Consistent with EPA's intent to align the new chemicals procedural rules with the Lautenberg Amendments, EPA should finalize a PESS definition that is consistent with the statute. Had Congress felt a broader definition was necessary, they would have provided it in 2016. EPA's proposal moves EPA further from, not closer to, alignment with the Lautenberg Amendments and has the potential to significantly increase EPA's workload, making it even more difficult for EPA to meet the 90-day statutory deadlines required by Congress.

VIII. EPA Should Not Restart the "90-Day Clock" if a Submitter Later Provides Information EPA Believes Was "Known to or Reasonably Ascertainable by" the Submitter

SOCMA urges EPA not to finalize the proposed requirement that EPA "re-start" the 90-day review period if a submitter provides information that EPA believes was "known to or reasonably ascertainable by" the submitter in the beginning but was not submitted. This proposed requirement will result in even longer new chemicals reviews. In practice, submitters are providing this kind of information at a later stage of the new chemicals review process in response to EPA's application of unexpected and unnecessary conservative assumptions. The information submitters provide is intended to rebut EPA's approach. When the submitter is surprised to see the results of EPA's application of conservative assumptions, or when EPA requests more specific usage detail that the submitter did not anticipate, the onus is on the submitter to go back and find information that more accurately represents the real-world application of the new chemical. Submitters should not be penalized with further delays when they provide information to help clarify or supplement data EPA is requesting from the submitter.

IX. EPA Should Withdraw its Proposal To Categorically Classify PFAS and PBTs as Ineligible for LVEs and LoREXs

EPA proposes to make PFAS and certain PBT substances categorically ineligible for LVEs and LoREXs in order to codify this Administration's current policies for PFAS[23] and EPA's 1999 PBT policy. EPA should not finalize this provision.

Under Section 5 of TSCA, EPA is authorized to "exempt the manufacturer of any new chemical substance from all or part of the requirements of [the PMN requirements] if [EPA] determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation

[23] In April of 2021, EPA announced a new policy that it will no longer accept any LVE requests for PFAS due to the "scientific complexities associated with assessing PFAS" and the potential hazards associated with various sub-classes of PFAS. See EPA Announcement "EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market": https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-prevent-unsafe-new-pfas-entering-market.

identified by the Administrator under the conditions of use."[24] In its rulemaking creating LVEs and LoREXs,[25] EPA already fully evaluated and determined that substances that meet the volume, release, and exposure criteria are categorically eligible for an exemption from PMN requirements: "EPA has made a finding that new chemical substances eligible for the [LVE and LoREX] exemptions will not present an unreasonable risk of injury to human health or the environment when manufactured, processed, used, distributed in commerce, or disposed of under the terms of the exemptions."[26]

EPA also makes clear that it is not required under TSCA to determine that LVE and LoREX substances carry "no risk" at all; rather, EPA believes that the "risks are not likely to be any greater than if the full PMN process were completed," and that, on balance with the benefits, an exemption is warranted:

> EPA's determination that manufacture, processing, use, distribution in commerce, and disposal of these two categories of substances under the terms of these exemptions will not present an unreasonable risk of injury to human health or the environment is based on consideration of (i) the limitations on risk that would result from the safeguards built into the rule, including Agency review; (ii) the limitations on risk resulting from the restriction of the exemptions to the chemical substances manufactured at volumes of 10,000 kg/yr or less and to low release/low exposure chemical substances; (iii) the benefits to industry and the public provided by new chemical substances manufactured under the exemption; and (iv) the benefits to the public and the Agency from the Agency's enhanced ability to utilize its limited resources on reviewing new chemical substances and uses of higher risk and concern.
>
> EPA recognizes that, even with the safeguards imposed by this rule, it is not ensuring that there will be no risk from new chemical substances manufactured under the exemption. The statute does not require zero risk. Rather, it defines unreasonable risk as a balancing of risk and benefit. Because of the safeguards in the amended regulation, the requirement that the provisions of the approved exemption are binding on the submitter, and the restricted nature of the exemption categories, EPA believes that risks are not likely to be any greater than if the full PMN process were completed. Furthermore, the new chemical substances provide benefits to industry and to the public. These benefits are an important element in the finding that these substances will not present an unreasonable risk.[27]

The current exclusions in the regulations from the LVE and LoREX exemptions are substances EPA determines may cause 1) serious acute (lethal or sublethal) effects, 2) serious chronic effects, or 3) serious environmental effects.[28] These criteria directly go to EPA's assessment of unreasonable risk. EPA cannot render an entire class of thousands of chemicals ineligible for LVEs or LoREXs without any data to support that each of the substances no longer meets the unreasonable risk safety standard under Section 5(h) for exemptions. Yet, this is what EPA has proposed.

---

[24] 15 U.S.C. § 2604(h).
[25] 40 C.F.R. § 723.50.
[26] 60 Fed. Reg. 16351, 16345 (Mar. 29, 1995).
[27] *Id*.
[28] 40 C.F.R. § 723.50(d).

While EPA has proposed to take actions on certain PFAS it has deemed to present risks, there are thousands of PFAS in existence,[29] and EPA has only completed evaluations for only a small subset of PFAS.[30] Additionally, as EPA is aware, PFAS substances are chemically diverse, and EPA is conducting research to inform how these diverse structures could be grouped and prioritized.[31]

If EPA is concerned about PFAS or PBT exemption notices, it already has authority under TSCA Section 5 to deny (or conditionally approve) LVE or LoREX requests if it is unable to affirmatively find that manufacture, processing, distribution in commerce, use, and disposal of the exempted substance will not present an unreasonable risk of injury to human health or the environment. At a minimum, EPA should withdraw these proposed actions and conduct a separate rulemaking because these proposed changes are significant changes to the substance of the LVE and LoREX regulations and are not "procedural" in nature.

X. EPA Should Allow Submitters To More Easily Track the Progress of Their Section 5 Notices

As part of the new chemicals procedures, EPA should permit submitters to request from EPA information about where their Section 5 notices stand in the "queue" of notices. This would enable submitters to have a better idea about the progress of their notices and the completed review steps. This information would help submitters understand the expected timing for their new chemical review and, if there are significant delays, which steps in the process are contributing to such delays.

XI. EPA Should Provide for Administrative Review of its New Chemical Determinations

EPA must make one of the following determinations on a new chemical notice within the applicable review period:[32]

- The chemical substance presents an unreasonable risk of injury to health or the environment, as set forth in Section 5(a)(3)(A) of the Act. If EPA makes this determination, it must issue a Section 5(f) order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance to the extent necessary to protect against an unreasonable risk of injury to health or the environment.

- For the following three determinations, EPA will issue a Section 5(e) order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, to the extent necessary to protect against an unreasonable risk of injury to health or the environment (which may entail testing):

[29] "There are thousands of PFAS chemicals, and they are found in many different consumer, commercial, and industrial products. This makes it challenging to study and assess the potential human health and environmental risks." EPA website "PFAS Explained": https://www.epa.gov/pfas/pfas-explained.
[30] EPA has completed hazard assessments for only a few PFAS, including PFOA, PFOS, HFPO-DA, PFHxA, PFBA, and PFBS.
[31] See EPA's ongoing research described at: https://www.epa.gov/sciencematters/epa-and-partners-describe-chemical-category-prioritization-approach-select-75-pfas.
[32] 88 Fed. Reg. at 34123.

- Information available to EPA is insufficient to permit a reasoned evaluation of the health and the environmental effects of the relevant chemical substance, as set forth in Section 5(a)(3)(B)(i) of the Act.

- In the absence of sufficient information to permit EPA to make such an evaluation, the chemical substance may present an unreasonable risk of injury to health or the environment, as set forth in Section 5(a)(3)(B)(ii)(I) of the Act.

- The chemical substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant or substantial human exposure to the substance, as set forth in Section 5(a)(3)(B)(ii)(II) of the Act.

- The chemical substance is not likely to present an unreasonable risk of injury to health or the environment, as set forth in Section 5(a)(3)(C) of the Act. In this case, EPA will issue a findings document describing that determination for publication in the *Federal Register*, and the submitter may commence the manufacture of the chemical substance.

Under current law, there is no administrative-level recourse if a submitter disagrees with an EPA determination that the substance requires a Section 5(e) or 5(f) order. Rather, the submitter would have to wait until EPA issues a Section 5(e) or 5(f) order and then file a petition for judicial review in federal court.[33] SOCMA strongly recommends EPA include in the regulations a procedure for a submitter to challenge an EPA determination earlier in the process (at the administrative level) and the opportunity to have EPA's decision reviewed.

XII. EPA Should Clarify Criteria for Consideration of "Sector-Specific Approaches" to New Chemical Reviews

EPA has dedicated resources to implement streamlined and efficient processes under the new chemicals program to expedite reviews for certain types of new chemistries that EPA has determined are a priority or otherwise appropriate for a sector-specific approach. For example, in early 2022, EPA announced an integrated approach for consistent and efficient reviews of biofuel PMNs.[34] And, in October 2022, EPA implemented an approach to review mixed metal oxides (including modified cathode active materials or CAMs) used in numerous electrical applications in batteries, electric vehicles, semiconductors, and renewable energy generation.[35] These two examples were due to the current Administration's prioritization of chemistries that are intended to address the climate crisis.[36] EPA has also publicly encouraged stakeholders to come to EPA with ideas for more sector-specific approaches regardless of whether they relate to the Administration's climate change goals.

SOCMA appreciates the concept of EPA considering replacement value new chemicals reviews though there can be challenges with taking a sector-specific approach. In order to ensure this opportunity

[33] 15 U.S.C. § 2618(a).
[34] EPA website "Integrated Approach for Biofuel Premanufacture Notices": https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/integrated-approach-biofuel.
[35] See EPA Announcement "EPA Announces Innovative Effort to Bring New Chemicals Used in Electric Vehicle, Semiconductor, Clean Energy Sectors to Market," https://www.epa.gov/newsreleases/epa-announces-innovative-effort-bring-new-chemicals-used-electric-vehicle.
[36] *Id*.

remains viable for future administrations, SOCMA recommends EPA commit to providing criteria and procedures for EPA evaluating replacement values in new chemicals reviews. An efficient program will help alleviate burdens for EPA's new chemicals program staff and will therefore help improve the timeliness of new chemicals reviews.

XIII. EPA Should Not Modify the PMN Form To Include Check Boxes

The proposed rule discusses that EPA is considering adding statements with accompanying check boxes to certain screens of the electronic PMN form that would required submitters to indicate that, for fields of the form left blank, the submitter attests that the information is not known or reasonably ascertainable.[37] As an alternative, EPA also considered adding automatic checks to CDX that would make certain fields mandatory before advancing further in the PMN form submission. Both of these options are flawed and would increase submitter burden. Additionally, EPA suggests that, if information is not provided during the PMN submission process but is later provided, EPA may declare the original submission incomplete, thus impacting the timeline for review. EPA also suggests that, if information is not provided, EPA would make "conservative assumptions" and use "conservative defaults." As discussed previously in these comments, such an approach is not consistent with EPA's requirement to use the best available science.

Modification of the PMN form to make it more burdensome for submitters is not the approach EPA should be using to encourage the submission of known or reasonably ascertainable data. Instead, EPA should provide stakeholders with a predictable and transparent framework that describes EPA's commitment to using submitted information to inform and expedite the new chemicals review process in lieu of conservative default assumptions.

XIV. EPA Must Incorporate a Risk-Based Process into New Chemicals Reviews

Section 5 of TSCA requires that EPA evaluate new chemicals to ensure they do not present an unreasonable ***risk*** of injury health or the environment under the conditions of use.[38] EPA should not be making hazard-based determinations. Far too frequently, SOCMA members' new chemicals reviews are bogged down by EPA's sole consideration of hazard, without due consideration of known and intended exposures. This is particularly disconcerting when EPA has been provided with all the necessary exposure information but simply does not consider it.

The word "hazard" does not occur in Section 5 of the statute, and there is no language in the Lautenberg Amendments that suggests EPA should be evaluating toxicity in isolation. Exposure information is a critical piece of a risk-based review, and EPA must give due consideration to this important information. EPA should consider modifications to its review process such that reviews are not delayed, and new data are not requested, until EPA completes a full risk-based evaluation that takes the provided exposure information into account.

[37] 88 Fed. Reg. at 34109.
[38] 15 U.S.C. § 2604.

XV. Conclusion

Thank you for the opportunity to provide these comments. While there are many suggested reforms for how regulated entities can assist EPA to improve the process for new chemicals reviews, SOCMA encourages EPA to also evaluate what concrete steps it can and should take now to ensure that reviews are completed in 90 days as required. For instance, EPA should commit to training new staff or providing guidance and policies for staff and stakeholders that would provide much needed consistency and predictability in the program. EPA should also prioritize funding and resources to continuing to hire new staff to reduce the backlog of notices.

Please contact me at rhelminiak@socma.org if you have any questions.

Regards,

Robert F. Helminiak