FRAGRANCE CREATORS ASSOCIATION®

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:

The Fragrance Creators Association (Fragrance Creators) 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"). Below, we list several reforms that we believe would improve the process for new chemicals reviews, with special emphasis on **consideration of the scope of "reasonably foreseen use" within fragrance** and the **development of a risk-based sector-specific approach for the fragrance industry**.

Fragrance Creators is the principal trade association representing the U.S. fragrance industry.[2] The organization's diverse 60+ member companies create and manufacture fragrances and scents for home care, personal care, fine fragrance, and industrial and institutional products. Fragrance Creators also represents companies that market finished products containing fragrance, as well as those that supply fragrance ingredients, including natural extracts and other raw materials, that are used in perfumery and fragrance mixtures. Fragrance Creators' members also rely on the Research Institute for Fragrance Materials ("RIFM"), a nonprofit, scientific organization that supports the global fragrance industry in the safe use of fragrance materials, conducts comprehensive scientific programs covering all relevant human health and

[1] 88 Fed. Reg. 34100 (May 26, 2023).
[2] More information on Fragrance Creators can be found at https://www.fragrancecreators.org/.

environmental endpoints, maintains the world's largest and most complete database on fragrance materials, and offers education and guidance on scientific and safety issues that are relevant to the fragrance industry.[3]

For Fragrance Creators, ensuring that the TSCA Section 5 (Pre-Manufacturing Notification application) review and approval process is transparent, efficient, predictable, and consistent with TSCA statutory authority is of the highest importance to our members. We appreciate EPA's efforts to improve the efficiency of the new chemicals review process and EPA's recent efforts to bring more resources and staff to the new chemicals program. However, these comments mark Fragrance Creators' sixth submission to the Agency in seven years regarding the need to improve the New Chemicals Program. We have also met with senior Agency staff on these issues many times over the same period. Although we appreciate the Agency's willingness to meet and to discuss these issues, concrete progress has been lacking.

Unfortunately, Fragrance Creators' members are strongly affected by the lack of clarity or transparency in the logistics and timelines of the review process, finding themselves forced to approve suspensions of the statutory review period (often without a reason or explanation provided from EPA); otherwise, their PMNs are withdrawn. These challenges limit the desirability of the chemistries to downstream customers who use the substances in consumer or commercial products. Small businesses, which make up 75% of Fragrance Creators' membership, are disproportionately impacted by these circumstances.

Importantly, EPA should encourage submitters to try to bring greener, safer, and more innovative chemistries to market in the US. However, because EPA is unable to review and process new chemicals submissions in a timely and scientifically judicious manner, companies are forced to rely on older chemistries that may have lower performance, higher carbon footprints, and higher hazard profiles than newer chemicals.

Our comments address the following points:

- **Reasonably foreseen uses**- EPA should modify its approach to reviewing intended, known, or reasonably foreseen conditions of use. This is particularly important for fragrance because the cost and purpose of these chemistries stringently limit reasonably foreseen use.

- **Risk-based, 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 be

[3] More information on RIFM can be found at https://www.rifm.org/.

making hazard-based determinations on new chemicals. This is particularly important for fragrance because the exposure levels to fragrance materials are typically very low.

- **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. Fragrance is an excellent candidate for a sector-specific approach due to its abundance of resources and commitment to innovating greener, more sustainable chemistries.

- **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 codifies data requirements, it should be required to use PMN submitter data and not apply conservative assumptions or use modeling, unless EPA can show that its data are more scientifically accurate.

- **Voluntary Pre-submission Meetings**- EPA should establish clear and consistent procedures for voluntary pre-submission meetings with PMN submitters and ensure that appropriate experts from EPA attend.

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

- **Restarting "90-day clock" if submitter later provides information that EPA believes was "known to or reasonably ascertainable by" the company**- We urge EPA not to finalize this requirement because this will result in even longer new chemicals reviews.

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

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

COMMENTS

I. EPA's Review of Intended, Known, or Reasonably Foreseen Conditions of Use is Particularly Critical for Fragrances, which have a Narrow Scope of Use and are Solely Used to Impart Scent.

EPA should codify its parameters on "reasonably foreseen" uses in the new chemicals regulations. EPA is not required under TSCA to eliminate *all* potential, hypothetical risks for a chemical for all uses. 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." EPA's desire to review all conditions of use at once, including hypothetical conditions of use that are not important to the submitter, is causing new chemicals reviews to take longer than necessary.

Fragrance ingredients are not used for any non-fragrance purposes, specifically because they have a strong scent. That is the essence of fragrance ingredients: a very small amount can impart a very distinctive fragrance to a product. Inclusion of a fragrance ingredient in any product formulation at even very small concentrations would give that product a very strong scent. For example, some of the most aromatic fragrance materials are present in finished consumer products at < 1 ppm, yet still provide a valuable contribution to the aroma of the product. Almost any use of a fragrance ingredient is thus going to be a de facto fragrance use, even if it had some other purpose as well. The very high cost of fragrance ingredients is another major practical obstacle to using fragrance ingredients for non-fragrance purposes.

For olfactory and economic reasons, therefore, it is not reasonable to foresee a product that incorporates a fragrance ingredient for a non-fragrance use being commercially viable. Consistent with this characteristic fact about fragrance ingredients, many Fragrance Creators member companies, including large multi-national houses, have never sold a fragrance ingredient for a non-fragrance use. Such uses are not reasonably foreseeable, and EPA should not base a SNUR on unforeseeable uses. However, the industry is open to the possibility of EPA assigning SNURs on fragrance materials for any use that is not a fragrance use, so that their use is legally limited to that of fragrance only.

II. EPA's Consideration of Exposure Data, which Demonstrate that Fragrance Material Exposures are Typically Very Low, is Essential for a Risk-Based Process in New Chemicals

Section 5 of 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.[4] EPA should not be making hazard-based determinations. 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. Far too frequently, our 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. Exposure information is a critical piece of a risk-based review, and EPA must give due consideration to this important information.

[4] 15 U.S.C. § 2604.

Fragrance material exposures are typically very low because humans can smell odors in low quantities –as low as in the parts per trillion range in some cases. Furthermore, the concentrations of different fragrance ingredients may vary by factors exceeding 1000-fold, depending on the odor intensity of the material. The low volume and high impact nature of fragrance means it has a lower carbon footprint because it can "do more with less" (e.g., less transport, less processing). Thus, exposure is critical when evaluating fragrance ingredients rather than only hazards.

III. EPA Should Consider a "Sector-Specific Approach" for Fragrance due to its Abundance of Data and Resources, Relatively Low Chemical Exposure Levels, and Industry-Wide Teams of Innovators Dedicated to Greener, More Sustainable Chemistries

Within the past two years, 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. 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. We commend EPA's efforts to streamline new chemicals reviews with its sector-specific approach initiative. To ensure this opportunity remains viable for future administrations, we recommend that in the final rule EPA commit to providing criteria and procedures for EPA consideration of sector-specific approaches to new chemicals reviews. An efficient sector-specific program will help alleviate burdens for EPA's new chemicals program staff and will therefore help improve the timeliness of new chemicals reviews.

A sector specific approach for fragrance could use sound science to streamline the review of more environmentally friendly chemicals while progressing the Administration's climate goals and protecting human health and the environment—new fragrance molecules are often greener, safer, and more sustainable. There are several unique traits about fragrance that make it a perfect candidate for a sector-specific approach: (1) Many resources are available through engagement with the Research Institute for Fragrance Materials (RIFM). Through RIFM, over 6000 ingredients have been categorized and clustered; information on these chemicals is available to inform read-across in safety assessments. (2) Fragrance materials lack "foreseeable uses" beyond perfume applications, typically have low exposure levels, and have defaults (e.g., regarding drum residue) that are specific to the industry. (3) There is a dedicated team of reviewers identifying similarities across the industry that would drive efficiency, predictability, and green, sustainable innovation. Importantly, however, this approach should remain nuanced, and not handle all fragrances in the exact same manner (i.e. applying generic SNURs to all fragrance ingredients). Members of the industry can serve as valuable tools for input and consultation for building a scientifically judicious approach, and are happy to work with EPA. Fragrance Creators is committed to advancing these priorities with Congress and the White House and is hopeful about producing results—through a sector-specific approach for fragrance—during President Biden's current term.

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

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. Section 26(h) of TSCA requires 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 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.

In fact, the preamble of the proposed rule does not mention the TSCA Section 26(h) standards at all. EPA acknowledges the omission of the best available science in the preamble several times, explaining that when a Section 5 notice lacks detail, EPA "typically uses conservative assumptions and default values."[6] 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…."[7] 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 assumptions" or "default values." The best available science does not mean taking a highly precautionary approach with worst-case, conservative assumptions that are unrealistic in the new chemical's real-world application.

If data, studies, or relevant analogs provided by submitters are based on the best available science, then EPA should commit to using the provided information. EPA should not rely on its own modeling or analog data when the submitter has provided data to support its new chemical. This would encourage submitters to provide this information upfront and, as a result, EPA will have more accurate and applicable data for a given Section 5 notice.

V. 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 Considered

We generally support EPA's efforts to clarify what information it needs upfront to review Section 5 notices. However, we face a lack of clarity on whether or how EPA intends to use these data

[5] 15 U.S.C. § 2625(h).
[6] 88 Fed. Reg. at 34106.
[7] *Id*.

to inform risk-based evaluations. Currently, 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.

First, if EPA is going to require more data to be submitted upfront with new chemical notices, it should include a requirement that it must consider all data generated or provided by the submitter rather than simply its own conservative assumptions or modeling. It is impractical to require that submitters incur significant expenses and time developing and providing data 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 scientifically sound decisions on their notices.

Second, data requirements should follow similar protocols to those under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[8] Each data element required by EPA for Section 5 notices should be justified for and pertinent to the specific application (or type of application). 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, like how FIFRA permits registrants to submit waiver requests from data requirements. Furthermore, similar to how data requirements are prescribed under FIFRA, EPA should specify the appropriate test methods, test criteria, and laboratory requirements, 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 appropriate public literature or other credible data sources in lieu of new testing if they choose. This is important because for certain substances, other authoritative bodies do not allow the generation of data using animal models.

VI. EPA Should Include Procedures for Pre-Submission Meetings

EPA should establish clear and consistent procedures for voluntary pre-submission meetings (how submitters can request, how EPA will conduct). As EPA acknowledges, pre-submission meetings are valuable opportunities for EPA and submitters to clarify what needs to be included in submissions and what the submitter can expect.[9] 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, similar to FIFRA pre-application

[8] See 40 C.F.R. Part 158.

[9] 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.

meetings. For example, a pre-submission meeting must have an EPA human health risk assessor present in the meeting to appropriately inform the submitter what data it could or is likely going to be expected to provide. Having technical experts participate in the pre-submission meetings provides the necessary utility for such meetings to be valuable to submitters or improve the quality of new chemical submissions. Likewise, transparent, focused, and cooperative planning between EPA and the submitter prior to PMN submission should make the review process easier for EPA.

VII. 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 information from EPA on 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.

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

We urge EPA not to finalize the proposed requirement that EPA "restart" 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. Experienced PMN submitters within our membership have felt surprised by both the scope and quantity of information they were asked for, as well as the number of times they were required to provide additional data. 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 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.[10] 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. However, 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.

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

EPA proposes to incorporate TSCA's 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. 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 "procedural"[11] 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. 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 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 fence-line 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. If Congress had felt a broader definition was necessary, they would have provided it in 2016. EPA's proposal moves its definition of PESS further from 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.

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[10] 88 Fed. Reg. at 34109.

[11] EPA characterizes this addition to the statutory definition of PESS as an action that is "procedural in nature." 88 Fed. Reg. at 34118.

XI. Conclusion

Thank you for the opportunity to provide these comments. Although there are many suggested reforms for how regulated entities can assist EPA to improve the process for new chemicals reviews, we would especially appreciate your **consideration of the scope of "reasonably foreseen use" within fragrance** and the **development of a risk-based sector-specific approach for the fragrance industry**. We look forward to the opportunity to continue to engage with the Agency as it advances the goals of the New Chemicals Program.

Please do not hesitate to contact me at dselechnik@fragrancecreators.org if you have any questions or if there is any additional information we can provide.

Sincerely,

Dan Selechnik, Ph.D.
Director, Regulatory Science
Fragrance Creators Association