



FRAGRANCE CREATORS
ASSOCIATION™

January 17, 2023

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Office of Pollution Prevention & Toxics
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC. 20460-0001
Docket No. EPA-HQ-OPPT-2020-0493

Submitted via www.regulations.gov

Re: Comments on Re-proposed Fees for the Administration of the Toxic
Substances Control Act

Dear OPPT Staff:

Fragrance Creators Association (Fragrance Creators)¹ and its members appreciate this opportunity to provide input to EPA regarding its proposed fees for administration of the Toxic Substances Control Act (TSCA) during Fiscal Years 2023-2025.² Our members are dedicated to the effective implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. We offer these comments to underscore priorities for the fragrance value chain, including the advancement of green chemistry, new chemicals, and U.S. innovation.

Fragrance Creators is the trade association representing the U.S. fragrance industry at large. The organization's 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 support the Research Institute of Fragrance Materials,³ a nonprofit, scientific organization that supports the global fragrance industry in the safe use of fragrance materials, conducts comprehensive science

¹ Learn more about Fragrance Creators at www.fragrancecreators.org.

² 87 Fed. Reg. 68647 (Nov. 16, 2022).

³ www.RIFM.org.

programs covering all relevant human health and 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.⁴

In brief, these comments address four principal points:

1. *The proposed fees are more than is reasonably necessary to defray the costs of the covered TSCA programs.* They will impose unreasonably cumulative burdens on companies, particularly small businesses.
2. *EPA could refund some percentage of the fee for every month that the review continues beyond the applicable review period thus incentivizing speedy reviews.* This would not apply to when EPA is awaiting information from the submitter.
3. *EPA Should Not Increase Fees on New Chemicals Submissions.* The proposed fees for Section 5 submissions will add an additional obstacle to the already costly and arduous process of introducing new fragrance ingredients into U.S. commerce. They exacerbate a bias toward existing chemistry and away from innovation and Green Chemistry. They also disadvantage U.S. commerce vis-à-vis Canada and the European Union (EU).
4. *Fragrance Creators Largely Supports EPA's Proposed Exemptions From, and Procedures for Allocating, Risk Evaluation Fees.* EPA's proposed exemptions will significantly simplify the job of determining the applicability of fees for existing chemical risk evaluations. Those exemptions, and EPA's proposed procedures for allocating risk evaluation fees, will also substantially alleviate the inequities of the current approach.
5. *Fragrance Creators supports applying the proposed Section 6 exemptions to test rules and orders.*

I. EPA's Proposed Fees Are Unreasonably High and Burdensome

Amended TSCA provides that fees cannot be "more than reasonably necessary to defray the cost" of the Section 4, 5, 6 and 14 programs.⁵ Fragrance Creators is concerned that rapid and unchecked growth in the cost of those programs renders EPA's newly-proposed fees unreasonable.

EPA's estimates of fee-supported TSCA program costs have more than doubled in less than two years, from \$87.5 million to \$181.9 million.⁶ Part of that growth likely reflects the Agency's surprising inability to adhere to the statute's temporal limits on covered EPA activities – in particular, requirements that the agency conclude new chemical

⁴ More information about Fragrance Creators is available at www.fragrancecreators.org.

⁵ 15 U.S.C. § 2625(b)(1).

⁶ 87 Fed. Reg. 68651.

reviews in 180 days⁷ (or else refund applicable fees⁸), and conclude existing chemical risk evaluations in 3.5 years.⁹ In setting such precise and demanding dates, Congress necessarily must have envisioned that EPA could conduct the required work within those time frames. But the Agency in the last two years has implemented an increasingly expansive interpretation of what the statute's substantive mandates require, spawning complex and massive reviews and documentation that push well beyond the level of effort that Congress intended.¹⁰ And the Agency is further bulking up its cost estimates by adding costs that should fairly be attributed to a wider range of Agency activities (e.g., the Office of Research & Development's work to develop new approach methodologies to characterizing the toxicity of chemicals, which has application across the Agency). Added to costs likely to be imposed by the nascent Tiered Data Reporting Rule and the PFAS reporting rule, the result is steadily growing regulatory costs for TSCA-regulated businesses – especially small businesses, which make up approximately 75% of Fragrance Creators' membership. Growing TRI compliance costs¹¹ only add to this cumulative burden.

As just noted, one of the temporal requirements of the 2016 amendments is that the Agency provide a full refund of a new chemicals fee whenever the Agency fails to act on the submission within the applicable review period.¹² So far as Fragrance Creators is aware, the Agency has never provided anyone with such a refund, despite failing in all or virtually all cases to act on new chemical submissions within that period. The Agency simply obtains the submitter's "voluntary" suspension of the deadline. We offer a compromise that should expedite reviews but have less draconian consequences for EPA: EPA could offer to refund some percentage of the fee for every month that the review continues beyond the applicable review period. This obligation would be tolled any time the Agency is waiting on the submitter to supply EPA with additional requested information.¹³ Such a refund regime would incentivize speedy reviews and yet avoid the binary, all or nothing refund choice that the statute establishes.

II. EPA Should Not Increase Fees on New Chemicals Submissions

In 2021, Fragrance Creators strongly supported EPA's proposal not to increase the current fees for new chemical notices and exemption requests, expressing appreciation

⁷ 15 U.S.C. § 2604(a)(1)(B)(i); § (c).

⁸ *Id.* § 2604(a)(4)(A).

⁹ *Id.* § 2605(b)(4)(G).

¹⁰ Consider for example EPA's expanded approach to assessing ambient air and water exposures.

¹¹ EPA recently classified HHCB as a chemical of special concern, meaning that fragrance companies will be unable to rely on the *de minimis* exemption in determining whether they manufacture, process or otherwise use 100 lbs/year of this common fragrance ingredient. See 87 Fed. Reg. 73475 (Nov. 30, 2022).

¹² See 15 U.S.C. § 2604(a)(4)(A).

¹³ We note that EPA's tracking of new chemical reviews should make for easy and transparent accounting of the time EPA is waiting on submitter information.

for EPA's explanation that it "does not want to stifle economic development in the chemical industry."¹⁴ Unfortunately, EPA's administration of the new chemicals program since 2016 has already accomplished this result, at least in the fragrance industry. The Agency has approved very few new fragrance ingredients without a consent order and/or a follow-on significant new use rule (SNUR) since the Lautenberg amendments to TSCA were adopted. Unfortunately, that remains true today. Because fragrance ingredients are overwhelmingly used in commercial and consumer products, a SNUR can severely limit the economic value of a fragrance ingredient. Further, affected fragrance companies have effectively lost years of research and millions of dollars invested in the development of innovative new chemicals. This state of affairs also further disadvantages U.S. commerce, as both Canada and the EU – but not the United States – provide exemptions from new chemical reviews for *de minimis* quantities of chemicals.

Rather than ameliorate this situation, the current proposal would worsen it greatly. EPA would more than double fees for pre-manufacture notices (PMNs) and exemption notices, adding yet another impediment to the business case for developing a new fragrance chemical.

An unintended consequence of the new chemicals program post-Lautenberg is that approval of safer and greener chemicals has been delayed, meaning that the marketplace continues to rely upon older chemicals that lack such properties. Our downstream members frankly admit that they have been reduced to "mining" the Inventory of existing chemicals as they formulate new products. They are being forced to accept lower performance and higher risk profiles than they would expect from using a new molecule because it has become so difficult to get new chemistries approved under Section 5. The proposed increases in new chemicals fees would pose an additional obstacle to creating greener fragrance ingredients.

Fragrance Creators does support EPA's proposal not to impose fees for notices of commencement (NOCs), as this idea has a double-dipping quality. Our members have already paid for EPA's reviews via the fees they have paid for PMNs. EPA incurs no significant additional cost by receiving an NOC.

Fragrance Creators also supports EPA's proposal to offer a refund of 20% of the fee for a Section 5 submission 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, at the conclusion of that process, 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

¹⁴ 86 Fed. Reg. 1890, 1902 (Jan. 11, 2021).

20% of the fee they paid, and the Agency will have that many fewer chemicals on which to conduct risk management.

In conclusion, the TSCA program ought to exhibit a bias toward new chemicals, and so it is entirely appropriate for fees on existing chemicals (which Fragrance Creators all use) to continue to subsidize new chemicals reviews.

III. Fragrance Creators Largely Supports EPA's Proposed Exemptions From, and Procedures for Allocating, Risk Evaluation Fees

A. Exemptions

The costs imposed by EPA's fees for risk evaluations do not just consist of the fee itself. Many companies in 2020 also had to expend significant staff resources to determine whether those companies in fact manufactured or imported a relevant chemical in some small quantity, or as a tiny percentage of some other product, during the previous five years. EPA's 2020 enforcement policy greatly reduced the number of companies liable for these fees, thus illustrating how many companies were being swept into the program by inadvertent manufacture. It would also have been highly inequitable for such companies then to be on the hook to pay fees comparable to those paid by more substantial manufacturers. Fragrance Creators thus has supported all of EPA's proposed exemptions – i.e., those for:

- manufacture as a byproduct that is not later used for commercial purposes or distributed for commercial use;
- manufacture or import as an impurity;
- importation in an article;
- manufacture as a non-isolated intermediate;
- manufacture or import below 2,500 lbs/year; and
- manufacture or import for research and development purposes.

All these exemptions would significantly simplify the job of determining the applicability of fees for risk evaluations. EPA's proposed exemption for R&D would also support chemical innovation and green chemistry, two important chemical policy goals.

Fragrance Creators is, however, opposed to EPA's continued proposal to condition eligibility for any of these exemptions on both (i) having met the exemption for the five prior years *and* (ii) a commitment to continue meeting the exemption for the next five years. This requirement combines the conditions applicable to both the "no manufacture" and "cessation of manufacture" exemptions and is thus more demanding than either. Having met an exemption in previous years is most analogous to not having manufactured or imported the chemical, rather than ceasing to manufacture it prior to

notice of prioritization. Tracking compliance with one of the exemptions in the future would also be burdensome. Companies should not have to make commitments regarding future manufacture in order to qualify for any of the proposed exemptions.

B. Allocation Procedures

As just noted, the lack of exemptions initially posed significant inequities in the allocation of risk evaluation fees, particularly given EPA's per capita formula for allocating those fees. EPA's proposal to allocate risk evaluation fees on a volumetric basis will substantially alleviate the inequities of the current process, and Fragrance Creators strongly supported it in 2021. We support the concept again now. We also support EPA's new proposal to base its allocation on the average annual production volume from the three, rather than four, prior calendar years of commercial activity. Finally, we support the concept of having the top 20% of production pay for 80% of the cost of risk evaluation fees.

But Fragrance Creators strongly opposes EPA's proposal to determine who falls into which category by simply ranking companies in order of production volume. This rank order approach will in many cases result in significant unfairness. This can most easily be seen by comparing the cases where five companies versus six companies are responsible for fees. In the case of five, the top 20% of production would be exactly one company. But if there were six companies, the top two companies would automatically be deemed the top 20%, even if only one company was actually responsible for the lion's share of production. In at least two cases among the first 30 chemicals on which EPA has initiated risk evaluation, only one company manufactured the chemical domestically or globally. Given the infinite ways that manufacture and import volumes can vary, it would be far more fair to determine who falls into the top 20% of production based on actual production volumes. EPA certainly should be able to protect those figures from public disclosure when they are confidential business information.

IV. Section 4 Fees

Fragrance Creators supports EPA's proposal to extend the exemptions proposed for Section 6 so that they also apply to Section 4 rules and orders. We agree that the same fairness considerations applicable under Section 6 are applicable, albeit at a lower level of intensity, to Section 4.

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Fragrance Creators appreciates the opportunity to submit these comments on the proposed fees for TSCA administration during Fiscal Years 2023-2025. If you have any

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questions, please do not hesitate to contact me at dferrer@fragrancecreators.org or 571-317-1505.

Sincerely,

A handwritten signature in cursive script that reads "Darci Ferrer".

Darci Ferrer, Chief Scientist
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