Consultation Questions for the Information Collection Request (ICR) for TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances

(1) Publicly Available Data

A. Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

TSCA Existing Chemicals (TSCA §4), EPA may issue a rule, order, or consent agreement and mandate the submission of health effects data, environmental effects, fate and transport, physical/chemical properties, occupational and general population exposure. TSCA Pre-Manufacturing (PMN), (TSCA §5), submissions are required to provide physical and chemical properties, environmental fate, human health effects, environmental effects, and exposure and release.

Safety and exposure data for existing fragrance materials are publicly available through the Research Institute of Fragrance Materials (RIFM) on Elsevier and through government-initiated reviews for product safety including Canada Chemical Management Program (CMP), Australia Industrial Chemicals Introduction Scheme (formerly NICNAS), and EU Scientific Committee on Cosmetic Safety (SCCS).

Safety data on new fragrance materials are publicly available in international company registrations including REACH regulation (EC) No 1907/2006. These registrations often include physical/chemical data, toxicological profiles, and exposure assessments.

There are also commercial sources from third parties available to the public on a subscription or fee basis.

In addition, some relevant data may already be held within EPA databases or accessible through other federal agency programs, such as the National Toxicology Program (NTP) or the Agency for Tosic Substances and Disease Registry (ATSDR).

Fragrance Creators Association supports the use of existing data to the maximum extent possible, particularly for lower risk, lower exposure, lower tonnage, safe and sustainable materials such as fragrance materials. This approach aligns with TSCA's intent to reduce unnecessary testing where adequate data already exists.

B. If yes, where can you find the data?
(Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they do not meet our data needs very well?)

These sources are widely used by government agencies and regulatory bodies, because they provide peer-reviewed data, adhere to good laboratory practices (GLP), and/or meet the highest international scientific standards. Fragrance data is publicly available on

platforms such as Elsevier, and through the European Chemicals Agency (ECHA), EU's Scientific Committee on Cosmetic Safety (SCCS), Health Canada, and Australia.

(2) Clarity of Instructions

The ICR covers the requirement under the PBT rule for respondents to maintain records.

A. Based on the instructions (regulations, FR Notices, etc.), is it clear what you are required to do? If not, what suggestions do you have to clarify the instructions?

Under Section 6(h) of the Toxic Substances Control Act (TSCA), the U.S. Environmental Protection Agency (EPA) finalized a rule in January 2021 concerning Persistent, Bioaccumulative, and Toxic (PBT) chemicals. This rule includes recordkeeping requirements for entities that manufacture, process, or distribute certain PBT chemicals. Companies are required to maintain documentation demonstrating compliance, including any prohibitions, restrictions, and exemptions. This documentation must include chemical identification, quantities manufactured, processed, and distributed, and relevant dates, and it must be retained for a period of 3 years.

The current order includes 5 PBT chemicals: decabromodiphenyl ether (DecaBDE), Phenol, Isopropylated Phosphate (3:1) [PIP (3:1)], 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP), hexachlorobutadiene (HCBD), and pentachlorothiophenol (PCTP).

The instructions provided in the rule and accompanying notices are clear and understandable. It is important to note that these PBT chemicals are not used in the fragrance sector.

Fragrance Creators Association supports proper documentation and recordkeeping as required under the current PBT chemicals rule.

B. Do you understand that you are required to maintain records? Yes.

(3) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet.

A. What do you think about electronic alternatives to paper-based records and data submissions? Would you be interested in pursuing keeping records electronically?

The Government Paperwork Elimination Act provides the option for companies to use electronic transactions. Our concerns are aligned with those expressed previously regarding data security, particularly considering that the fragrance sector relies heavily on Confidential Business Information (CBI) and trade secret protections. Additionally,

technology neutrality is important for the fragrance sector considering there is no single electronic system currently used consistently across the fragrance value chain.

Fragrance Creators Association supports an efficient, secure, and cost-effective chemical information submission process, including secure electronic submission options. We welcome continued dialogue to develop modern electronic submission systems that uphold CBI protections while allowing flexibility for businesses that rely on established paper-based IP protections.

B. Are you keeping your records electronically? If yes, in what format?

Chemical information management systems are varied through the fragrance value chain. These include third party systems, internally-developed (home built) systems, which are very common, hybrid systems that combine electronic and paper records, and stand-alone paper repositories.

Many documents are already maintained in electronic format (e.g., scanned files, PDFs, structured forms) and are transmitted through secure channels. However, because of the highly sensitive natures of CBI communications in the fragrance industry, certain critical documents/reports are maintained exclusively in paper form only and are not digitized.

---

(4) Burden and Costs

A. Are the labor rates accurate?

TSCA labor rates per the 2020 rate used in TSCA §8(a)/§8(d) ICRs include: $139.11/hr for managerial staff, $111.38/hr for technical staff, $54.00/hr for clerical staff. Publicly available data from the Bureau of Labor Statistics, Salary.com, Comparably, and other sources indicate that fully loaded hourly rates for the chemical sector currently range from $90-120 for senior managers, $120-160 for director-level personnel. The hourly rates therefore are within the publicly available bands.

Fragrance Creators Association recommends the use of hourly rate ranges rather than fixed single-point rates for better estimation of PMN-related costs and burden.

B. The Agency assumes there is no capital cost associated with this activity. Is that correct?

Yes. Capital costs and planning typically occur during product commercialization, following PMN approval. As such, capital costs are not relevant to the paperwork burden associated with the PMN process itself.

C. Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR (*e.g.*, the ICR does not include estimated burden hours and costs for conducting studies) are the estimated burden hours

and labor rates accurate? If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.

We understand that EPA estimates the burden based on approximately 95 hours per PMN, with a cost per submission of $10,000 to $13,000, based on 300-400 annual submissions, resulting in a total industry cost of $3 to $5 million per year.

However, for sectors and submitters, such as fragrance materials, that often provide extensive toxicological testing, characterization, and safety data, the burden is significantly higher. Based on industry experience, the typical investment averages around 275 hours per PMN. This includes time for literature searches for published data and data curation, identification and compilation of internal data, coordination with third-party laboratories (and associated legal and compliance requirements). As a result, the estimated cost per PMN can range from approximately $10,000 to $26,000.

D. Are there other costs that should be accounted for that may have been missed?

Yes. There are additional paperwork costs associated with maintaining records of studies/testing, correspondence, and compliance documentation. These costs are ongoing and directly tied to the information collection burden, even though they are not part of the initial submission process.

Consultation Questions for the Information Collection Request (ICR) for TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances

(1) Publicly Available Data

A. Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

Yes, there may be publicly available data satisfying some of the Agency's needs.

B. If yes, where can you find the data?
(Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they do not meet our data needs very well?)

In some cases, data on the chemical substance itself may be publicly available, for example, the public part of a REACH dossier hosted by the European Chemicals Agency (ECHA) or Cosmetic Ingredient Review (CIR) reports. There may also be situations in which the data exists for an analogue to a case under submission, but our members report that there was an inconsistent usage of identified analogues and subsequent incorporation into the Agency's assessment despite concerted efforts to collect, identify, and provide the information to the Agency.

In addition, if there are methodological deficiencies in a test report or the data needs do not align well, the information is generally not considered, even in situations where it is more likely that an imperfect test report will provide more reliable data than a modeled result. Our members report that a general impression is that modeling and a generic set of analogues are given preference over specific analogues and publicly available data.

These efforts likely increase the burden on submitters and the Agency both during the initial review, but also if the submitter attempts to rebut an Agency determination.

(2) Clarity of Instructions

The ICR covers the requirement under the PBT rule for respondents to maintain records.

A. Based on the instructions (regulations, FR Notices, etc.), is it clear what you are required to do? If not, what suggestions do you have to clarify the instructions?

N/A

B. Do you understand that you are required to maintain records?

N/A

---

(3) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet.

A. What do you think about electronic alternatives to paper-based records and data submissions? Would you be interested in pursuing keeping records electronically?

Yes, many records are collected and stored electronically.

B. Are you keeping your records electronically? If yes, in what format?

This is highly variable and depends on the type of data being generated/stored. Many records are stored as PDFs, Word, or Excel documents, but may also be stored in secure databases.

---

(4) Burden and Costs

A. Are the labor rates accurate?

The labor rates are reasonably accurate.

B. The Agency assumes there is no capital cost associated with this activity. Is that correct?

If there is a change in data needs by the Agency, there will likely be a capital cost by submitters to develop new systems or modify existing systems.

C. Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR (*e.g.*, the ICR does not include estimated burden hours and costs for conducting studies) are the estimated burden hours and labor rates accurate? If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.

In our member's experience, the burden estimate of 250 hours is no longer reflective of the efforts necessary for a PMN submission. Submitters must put in substantially additional effort to collect further information, discuss the case with the case workers, and resubmit the data for consideration. In addition, due to the prevalence of Significant New Use Rules (SNURs) and their impracticality in the marketplace, there have been significant additional efforts to develop strategies to minimize the likelihood of a SNUR.

Our best estimate is that these efforts add approximately 100-125 hours of additional burden to a PMN submission.

We note that the estimates for number of PMNs, SNUNs, and so forth per year are based on data from fiscal year (FY) 2016-2017. As EPA has implemented the amendments to TSCA included in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, passed in 2016, there have been several procedural changes at EPA that have impacted the number of submissions received. For example, the number of PMN submissions received has dropped by approximately 40% for FY 23 and 24. EPA is also issuing far more SNURs, which may result in a higher number of SNUN applications per year than the 9 included in EPA's estimate for the ICR. We suggest updating the number of annual responses to be based on post-Lautenberg data given the substantive changes.[1]

D. Are there other costs that should be accounted for that may have been missed?

As noted under 1B, it is not clear if the burden associated with rebuttals or resubmissions is adequately captured. For example, in order to provide a meaningful rebuttal or resubmission, a submitter may request and review the engineering reports that EPA developed as part of the risk assessment for the new chemical, then develop additional reports for EPA accordingly. Submitters may also go through multiple rounds of resubmission if the first or second set of information provided is not specific enough to meet EPA's needs. EPA has previously observed that submissions can be reworked anywhere from 1-5 times, and approximately 30% of all submissions are reworked. The burden estimate will vary widely depending on the amount of rework needed but given that a significant number of submissions are impacted, we recommend considering how to account for this in the ICR.

[1] Relies upon information in Analysis of Engineering Information Submitted for TSCA Section 5 New Chemicals Submissions at https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf