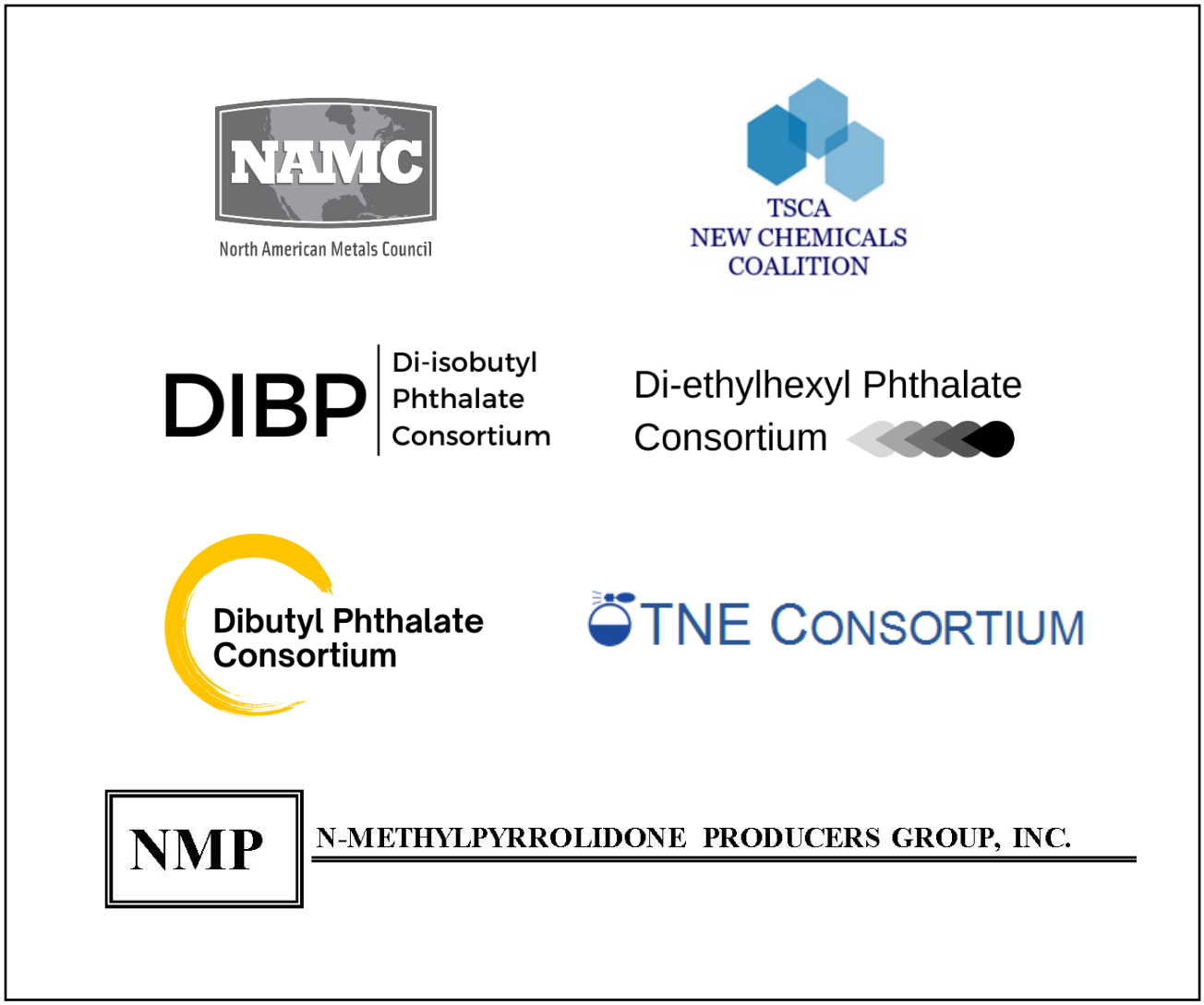

Comment Submitted in Response to Supplemental Notice of Proposed Rulemaking; Docket EPA-HQ-OPPT-2020-0493

January 17, 2023

Heather J. Blankinship
Senior Manager
B&C® Consortia Management, L.L.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, DC 20037
(202) 557-3831
hblankinship@bc-cm.com

Executive Summary

These comments reflect the views of several entities (the Coalition), including the Dibutyl Phthalate Consortium, the Di-ethylhexyl Phthalate Consortium, the Di-isobutyl Phthalate Consortium, the N-Methylpyrrolidone Producers Group, Inc., the North American Metals Council, the OTNE Consortium, and the Toxic Substances Control Act (TSCA) New Chemicals Coalition. The U.S. Environmental Protection Agency (EPA) is authorized under TSCA Section 26(b)(1) to require the payment of fees that are "sufficient and not more than reasonably necessary to defray the cost" of certain activities under TSCA and in doing so must consider the ability to pay of those entities subject to fees and EPA's costs in carrying out these activities. The Coalition acknowledges EPA's authority to seek increased fees and the Agency's need for adequate resources and funding to administer TSCA in a manner consistent with Congress's intent.

In the absence of sufficient transparency and record evidence, the Coalition questions strongly the basis for some of EPA's cost estimates and adjustments and, as a result, cannot support the proposed fee increases in all cases. The Coalition provides examples of concerns with the current implementation of TSCA and suggests approaches to address inefficiencies to enable EPA to administer TSCA in a manner consistent with Congressional intent without requiring significant increases in fees of the magnitude proposed by EPA. The Coalition summarizes its main points below:

For each of its cost estimates and adjustments to the fees for fiscal years (FY) 2023, 2024, and 2025, EPA did not provide sufficient information across Office of Pollution Prevention and Toxics (OPPT) programs to assess EPA's projected increase in the number of full-time equivalents (FTE), including partially allocated FTEs, needed to implement TSCA. EPA did not provide a transparent and sufficient basis for the justification of its requested fee increases or consider changes that would enhance efficiency that would diminish the need for significant fee increases. EPA improperly predicates its fee increases on a level of effort and resources needed to administer TSCA based on a work force size and a staffing level that will not exist for years.

In its estimates for TSCA Section 4, EPA estimates a significant increase in the number of test orders that EPA may issue in FYs 2023 through 2025, which is not justified by the supporting information provided by EPA, which instead suggests that EPA may issue 25 to 38 test orders per year. Though additional information is necessary for the Coalition to assess EPA's proposed increases, the Coalition acknowledges that fee increases may support EPA's development and administration of TSCA Section 4 test orders, test rules, and enforceable consent agreements and supports EPA's proposed fees on the basis that EPA will use its resources to implement necessary measures, such as engaging in pre-issuance discussions with potential test order recipients to increase transparency, identify and evaluate reasonably available information, and identify appropriate, practicable test protocols in adherence with scientific standards under EPA's Scientific Integrity Guidelines and TSCA Section 26.

EPA's proposed fee increases under TSCA Section 5 are not justified in the record provided by EPA, and EPA does not provide sufficient information to comment meaningfully on the proposed rule. Based on the Coalition's own estimations of the potential costs and support required to administer TSCA Section 5, the Coalition is concerned regarding EPA's significant

cost estimates and proposed fee increases. Though the Coalition recognizes EPA's intent that increasing resources allocated to activities under TSCA Section 5 may be necessary for EPA to administer efficiently and appropriately activities under TSCA Section 5 and to resolve and prevent a backlog of delayed cases, in the final rule, EPA must commit to improving its ability to meet statutory deadlines under TSCA Section 5. EPA must use its resources to implement measured improvements to the transparency, quality, and timeliness of EPA's reviews. The Coalition urges EPA to implement additional improvements to EPA's administration of TSCA Section 5 further to reduce costs and increase transparency and efficiency, including increasing communication with submitters during EPA's reviews and to cease requesting voluntary suspensions of premanufacture notice review periods.

EPA does not provide sufficient information to evaluate EPA's estimated costs and proposed fee increases under TSCA Section 6. Based on the information provided in the record, the Coalition was unable to determine how EPA derived its estimates. Furthermore, based on the information provided, EPA's estimates do not appear reasonable. The Coalition is unable to support and comment meaningfully on EPA's proposed estimates and fee increases for EPA's implementation of TSCA Section 6 in the absence of additional information from EPA.

In general, the Coalition suggests EPA ensure that its fee allocation methodology for manufacturers subject to risk evaluation is equitable. The Coalition supports a tonnage band approach for determining a fee share that is proportionate to companies' respective volumes. The Coalition furthermore supports EPA's proposed exemptions to risk evaluation fees, and other actions to facilitate the payment of fees, including lengthening the time before fee payments are due, to provide for the formation of consortia. The Coalition suggests that EPA consider a mechanism to reimburse fee payers to address circumstances where a company that did not pay the risk evaluation fee re-enters the market, or enters the market after fee payment to ensure the equitable allocation of fees among all manufacturers, whether or not all are members in a consortium, of a substance within a reasonable timeframe.

EPA must also consider and address the impacts of the Fiscal Year 2023 Omnibus Appropriations Bill, which increased OPPT's operating budget by 20 percent. EPA must ensure that its proposed fee increases are based on an appropriate budget baseline and must reconcile its proposed fee increases with this significant increase. Accordingly, EPA should re-evaluate its budget in light of the 20 percent increase.

Table of Contents

Introduction

These comments are submitted on the U.S. Environmental Protection Agency's (EPA) supplemental notice of proposed rulemaking titled *Fees for the Administration of the Toxic Substances Control Act (TSCA)* dated November 16, 2022.[1] The coalition of consortia (the Coalition) that has contributed to the preparation of these comments represents more than 50 entities, consisting of trade associations, chemical manufacturers, processors, and downstream users that are all key stakeholders for EPA's actions and fees under TSCA Sections 4, 5, and 6. Although separate and distinct, all of these consortia exist for the purpose of chemical advocacy that is premised on the common principle of sound science.

Commenting Entities

Dibutyl Phthalate (DBP) Consortium membership includes manufacturers and importers of DBP and was formed to serve as a platform for its members to address potential data needs and to advocate for the use of sound science in the risk evaluation for DBP.

Di-ethylhexyl Phthalate (DEHP) Consortium membership includes manufacturers and importers of DEHP and was formed to provide its members a platform to address potential data needs and to advocate for the use of sound science in the risk evaluation of DEHP.

Di-isobutyl Phthalate (DIBP) Consortium is composed of manufacturers, importers, and downstream users of DIBP. The mission of the DIBP Consortium is to serve as a platform to address scientific, regulatory, and product stewardship issues concerning the health, safety, and/or environmental aspects of DIBP, and to advocate for the use of sound science in the risk evaluation for DIBP.

N-Methylpyrrolidone (NMP) Producers Group includes domestic manufacturers, processors, and users of NMP and was formed to address efficiently and comprehensively regulatory issues pertinent to NMP within the framework of responsible chemical management.

North American Metals Council (NAMC) provides a collective voice for North American metals producers and users on science, regulatory, and policy-based issues that are unique to metals and the various stages of their life cycles -- sourcing, production, engineering, use, recycling, and recovery. NAMC members include trade associations and individual companies.

OTNE Consortium is composed of manufacturers, importers, and processors of octahydro-tetramethyl-naphthalenyl-ethanone (OTNE). The mission of the OTNE Consortium is to prepare and support an industry-requested risk evaluation of OTNE and to coordinate with EPA and other stakeholders on issues relating to risk evaluation and risk management.

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[1] 87 Fed. Reg. 68647 (Nov. 16, 2022), available at https://www.govinfo.gov/content/pkg/FR-2022-11-16/pdf/2022-24137.pdf.

TSCA New Chemicals Coalition (NCC) is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under amended TSCA and work collaboratively with EPA and other stakeholders to address them.

I. TSCA SECTION 4

Based on estimates that EPA's annual costs to implement TSCA Section 4 will increase from $3,543,000, as stated in the 2018 Fees Rule, to $7,383,300 for fiscal years 2023 through 2025, EPA has proposed significant increases to the fees relating to test rules, test orders, and enforceable consent agreements (ECA).[2] Though certain increases may be reasonable, EPA must support its assertions regarding the number of test orders that EPA intends to issue annually, which appear currently to be too high, and must commit to demonstrating that increased fees will result in improvements to EPA's administration of TSCA Section 4.

A. EPA Must Ensure the Accuracy of Its Estimated Activity Levels under TSCA Section 4 and Adjust Accordingly Its Total Cost Estimates and Proposed Fees

EPA's estimated fee increases are predicated on an estimate that EPA will substantially increase the number of test orders issued during the three-year fee cycle from 30 test orders to 225 test orders.[3] EPA states the following about its intended use of its authorities under TSCA Section 4:[4]

> The Agency believes it is reasonable to assume that approximately 75 test orders per year will be initiated between FY 2023 and FY 2025. Approximately 45 of these test orders are expected to be associated with the Agency's actions on PFAS [*i.e.*, per- and polyfluoroalkyl substances]. In addition, the EPA assumed two test rules and two ECAs between FY 2023 and FY2025.

The Coalition questions whether EPA erred in stating that it will initiate 75 test orders *per year* over three FYs (for a total of 225 test orders). EPA may have intended to state that it will initiate and possibly issue 75 test orders over those three years, or an average of 25 test orders per year. In its Technical Support Document, EPA notes that its estimation of 75 test orders per year is based on the expected issuance of test orders that may be necessary to close data gaps for an expected 20 EPA-initiated risk evaluations (for a total of 60 potential test orders), three manufacturer-requested risk evaluations (MRRE) per year (for a total of nine potential test orders), and other potential collection activities, such as the issuance of approximately 45 test orders

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2 *Id.*; 83 Fed. Reg. 52694, 52699 (Oct. 17, 2018), available at https://www.govinfo.gov/content/pkg/FR-2018-10-17/pdf/2018-22252.pdf.

3 83 Fed. Reg. at 52704; 87 Fed. Reg. at 68653.

4 87 Fed. Reg. at 68653.

associated with EPA's actions on per- and polyfluoroalkyl substances (PFAS).[5] If EPA were to implement these activities as projected, however, the total number of test orders over the next three years based on these activities would be 114 test orders total, or 38 test orders per year. It is not clear how EPA reached its estimate of 225 total test orders, unless EPA anticipated issuing multiple test orders per substance, which unreasonably increases costs to EPA and to test order recipients.

Furthermore, the Coalition estimates that 75 test orders *total* over FYs 2023-2025 would correspond to the issuance of ten orders to address EPA's ongoing risk evaluations, 20 orders to address expected prioritizations that will occur during the next three years, and EPA's expectation that it will issue 45 test orders associated with EPA's actions on PFAS.[6]

EPA must substantiate the basis for its claim that it will issue 75 test orders per year, or 225 test orders total, between FYs 2023 and 2025 and ensure that its estimated annual costs are accurate before proceeding with the proposed fee increases for TSCA Section 4.

B. EPA's Estimates of the Projected FTE Support Required to Implement TSCA over the Next Three Years Also Indicate That It Is Not Reasonable to Assume That EPA Will Issue 75 Test Orders Per Year

In estimating the total costs for TSCA Section 4 activities, including test orders, test rules, and ECAs, at approximately $7.3 million annually, EPA estimates approximately $4.8 million in payroll costs for 27.9 full-time equivalents (FTE) *i.e.*, full-time employees.[7] EPA further provides an example of the time and effort required for a test order, as follows:[8]

> [D]epending on the complexity of the chemical substance(s) or mixture(s) that is(are) the subject of a test order, EPA estimates that developing and issuing a test order generally takes a minimum six months of personnel fully allocated (assuming one to two personnel depending on the complexity of the test order and the number of recipients of the test order) and an array of technical personnel from different disciplines partially allocated to doing test order work.

EPA's estimate of one or two FTEs fully dedicated to developing and issuing a test order may be reasonable. For purposes of our analysis based on EPA's estimate, we assumed the need for 1.5 FTEs for six months per order, to deduce on an annualized basis that 1.5 FTEs can

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5 EPA, "Technical Support Document: Supplemental Notice of Proposed Rulemaking; Fees for the Administration of the Toxic Substances Control Act (TSCA)," RIN 2070-AK46, at 2, available at https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0084.

6 *Id.*

7 *Id*., at 8.

8 87 Fed. Reg. at 68652.

develop and issue two orders per year, or 0.75 FTEs per order per year. EPA estimates 27.9 FTEs to support Section 4 activities each year, including efforts to support two test rules and two ECAs in the coming three FYs. Considering support required for test orders alone, 0.75 FTEs per order per year would correspond to 37.2 test orders per year, a value that is much closer to the average of 25 orders per year over three years.

EPA's projection of 27.9 FTEs to support TSCA Section 4 activities appears reasonable based on the time and effort required to develop one test order. EPA's estimation of activities that may support the need for a test order to address data needs under TSCA Section 4 and EPA's projected FTEs, however, both indicate that it is likely and plausible for EPA to issue between 25 and 38 test orders per year. At present, EPA's underlying analysis does not support or explain the potential issuance of 75 test orders per year. As EPA's cost estimates should be based on an accurate and reasonable assessment of its activities over the next three years, the Coalition further suggests that EPA reevaluate its workload estimates to ensure that its projections are accurate and to lower its proposed fees accordingly.

Regarding contract support, however, EPA must provide additional information to address why its estimates are reasonable. EPA provides no basis for its estimate of non-payroll (extramural) funding for contract support, an element we presume is relevant. Assuming EPA issues 25 test orders per year, EPA's estimate of about $2.5 million corresponds to about $100,000 of contract support per order. At $200/hour (fully weighted), that corresponds to 500 hours of contract support per order. This value seems high, but it is difficult to evaluate why EPA estimates this level of effort as necessary, given the paucity of explanation in the record. EPA needs to provide more specific information related to the level of contract support required.

C. The Proposed Collection of Additional Fees for TSCA Section 4 Activities Must Be Justified by Improvements to Transparency, Data Quality, and Adherence to Scientific Standards

Increased resources to support the issuance of TSCA Section 4 test orders, including by means of increasing fee collections, must result in improvements to EPA's administration of TSCA Section 4. EPA must meet its statutory obligations to issue test orders with an emphasis on data needs, rather than data gaps, and not reflexively push work products "out the door" to "improve on-time performance" at the expense of transparency and quality. Concerns relating to EPA's exercise of its authority under TSCA Section 4 are not merely hypothetical, but are based upon EPA's track record to date on developing and issuing transparent and quality test orders.

Since March 2020, EPA has issued 20 TSCA Section 4 test orders on 11 existing chemical substances.[9] The issued test orders have, however, suffered from significant lapses in transparency, data quality, and scientific standards under TSCA Section 26. EPA has relied on the

[9] EPA, "List of Chemicals Subject to Section 4 Test Orders" (last updated Jan. 4, 2023), available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-chemicals-subject-section-4-test-orders.

issuance of test orders, as opposed to test rules or ECAs, which may provide for a more collaborative process, based on the assertion that test orders allow EPA to obtain information more quickly. The above-mentioned concerns, however, have resulted regrettably in litigation and frequent back-and-forth between EPA and order recipients. EPA must use any increase in resources to resolve these issues, address current inefficiencies, and increase transparency in tandem with EPA's intended expansion of the use of TSCA Section 4 activities. We provide two representative examples below.

First, we refer EPA to the first TSCA Section 4(a)(2) test order issued on *trans*-1,2-dichloroethylene (TDCE) in January 2021. EPA states "the *Final Risk Evaluation for Trichloroethylene* [the Final TCE RE] has sufficient environmental hazard information for use as analogue data for *trans*-1,2-dichloroethylene on benthic invertebrate toxicity data due to acute and chronic exposure via sediment."[10] In the second TSCA Section 4(a)(2) test order on TDCE issued in March 2022, EPA states, with no explanation for the reversal of its initial conclusion in the first TSCA Section 4(a)(2) test order, that "No toxicity data for benthic invertebrates exposed for acute or chronic durations were identified."[11] EPA's ordered testing on sediment organisms in the second TSCA Section 4(a)(2) test order on TDCE conflicted with the approaches used in the Final TCE RE, which EPA reaffirmed as "robust and upholding the standards of best available science and weight of the scientific evidence per TSCA section 26(h) and (i)."[12] In the Final TCE RE, EPA stated that "no ecotoxicity studies were available for sediment-dwelling organisms … [and instead used] aquatic invertebrates … as a surrogate species."[13] EPA did not, however, explain in the second TSCA Section 4(a)(2) test order on TDCE why surrogate species data were acceptable for assessing potential risks from TCE, but not acceptable for doing so with TDCE. Before requiring the development of new information by order under TSCA Section 4, EPA must ensure that its procedures are transparent, reasonable, and efficient, and that the basis for its decisions are reasonable, based on the weight of the scientific evidence, and the result of EPA's due diligence. EPA must take all precautions to ensure that EPA's decision to require new information is informed and complete. Proceeding this way may prevent the unnecessary issuance of multiple

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10 EPA, *Order Under Section 4(a)(2) of the Toxic Substances Control Act, Docket Identification (ID) Number: EPA-HQ-OPPT-2018-0465*, at 6, available at https://www.epa.gov/sites/default/files/2021-01/documents/tsca_section_4a2_order_for_trans-12-dichloroethylene_on_ecotoxicity_and_occupational_exposure.pdf.

11 EPA, *Order Under Section 4(a)(2) of the Toxic Substances Control Act, Chemical Name: trans-1,2-Dichloroethylene* (Aug. 5, 2022), at 9, available at https://www.epa.gov/system/files/documents/2022-06/9544-01_TestOrder%20trans1%2C2%20DCE_v2_signed.pdf.

12 87 Fed. Reg. 40520, 40523 (July 7, 2022), available at https://www.govinfo.gov/content/pkg/FR-2022-07-07/pdf/2022-14478.pdf.

13 EPA, *Risk Evaluation for Trichloroethylene*, EPA Document #740R18008 (Nov. 2020), at 297, available at https://www.epa.gov/sites/default/files/2020-11/documents/1._risk_evaluation_for_trichloroethylene_tce_casrn_79-01-6.pdf.

test orders on a chemical substance, resulting in unnecessary cost increases to EPA and to test order recipients.

Second, in the first TSCA Section 4(a)(1) test order issued on 6:2 fluorotelomer sulfonamide betaine (6:2 FTSB), EPA ordered "Particle Density" testing according to the Organization for Economic Cooperation and Development (OECD) test guideline (TG) 109 and "Hydrolysis as a Function of pH" testing according to OECD TG 111.[14] There are, however, reasonably available information on these endpoints. The registrant for 6:2 FTSB provided to the European Chemicals Agency (ECHA) test data according to OECD TGs 109 and 111 as part of its registration.[15,16] EPA estimated the following physicochemical properties for 6:2 FTSB using the Open (Quantitative) Structure-activity/property Relationship App (OPERA v2.8.2):[17]

- Vapor pressure (0.000025 mmHg);
- Water solubility (1.16 mg/L);
- Melting point (77 °C); and
- Boiling point (246 °C).

Based on these estimates, EPA concluded that "6:2 fluorotelomer sulfonamide betaine … is expected to be an insoluble solid substance and therefore may present concern for portal-of-entry effects for inhalation exposures."[18] There are, however, measured data on these endpoints in the ECHA Registered Substances Database, as shown below, that suggest otherwise:

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14 EPA, *Order Under Section 4(a)(2) [sic] of the Toxic Substances Control Act*, *Chemical Name: 6:2 Fluorotelomer sulfonamide betaine* (June 16, 2022), at 1, available at https://www.epa.gov/system/files/documents/2022-06/9829-01_testorder-6_2_Fluorotelomer_sulfonamide_betaine.pdf.

15 ECHA Registration Dossier, Carboxymethyldimethyl-3-[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulphonyl]amino]propylammonium hydroxide, Physical & Chemical Properties: Density, available at https://echa.europa.eu/da/registration-dossier/-/registered-dossier/17549/4/5/.

16 ECHA Registration Dossier, Carboxymethyldimethyl-3-[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulphonyl]amino]propylammonium hydroxide, Environmental Fate & Pathways: Hydrolysis, available at https://echa.europa.eu/da/registration-dossier/-/registered-dossier/17549/5/2/3.

17 *See supra* note 14, at 7.

18 *Id*.

- Vapor pressure (0.017 Pa at 25 °C);[19]
- Water solubility (ca. 50 mg/L at 20 °C, pH 4.4 - 7.7, "slightly soluble");[20]
- Melting point ("Test substance partially melted before decomposing at temperatures above approximately 150°C");[21] and
- Boiling point (waived because the test substance "Decomposed before a boiling point could be reached").[22]

EPA must ensure the basis for its decision is sound and that the required testing is necessary. Though EPA's test orders provide an opportunity for test order recipients to identify any existing studies or scientifically relevant information that EPA should consider, this safeguard measure does not supplant EPA's statutory obligation to complete a review of all reasonably available information prior to issuing the test order, especially considering that such an order will trigger a fee.

These illustrative examples are part of a much larger lapse in transparency and quality in the administration of TSCA Section 4. These lapses may be due in part to EPA's claimed resource and staffing limitations. An increase in the fee for test orders from $11,650 to $25,000 should theoretically enable EPA to develop timely, transparent, and quality test orders that are laser focused on data needs, not data gaps, and ensure the availability of the ordered test data to inform EPA's prioritization and risk evaluation activities.

For this reason, though, as noted above, EPA must further substantiate its projected number of TSCA Section 4 activities and adjust accordingly its projected costs. The Coalition supports EPA's proposed fee increases for Section 4 test orders, assuming EPA will *use* its

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19 ECHA Registration Dossier, Carboxymethyldimethyl-3-[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulphonyl]amino]propylammonium hydroxide, Physical & Chemical Properties: Vapour Pressure, available at https://echa.europa.eu/da/registration-dossier/-/registered-dossier/17549/4/7.

20 ECHA Registration Dossier, Carboxymethyldimethyl-3-[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulphonyl]amino]propylammonium hydroxide, Physical & Chemical Properties: Water Solubility, available at https://echa.europa.eu/da/registration-dossier/-/registered-dossier/17549/4/9.

21 ECHA Registration Dossier, Carboxymethyldimethyl-3-[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulphonyl]amino]propylammonium hydroxide, Physical & Chemical Properties: Melting Point/Freezing Point, available at https://echa.europa.eu/da/registration-dossier/-/registered-dossier/17549/4/3.

22 ECHA Registration Dossier, Carboxymethyldimethyl-3-[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)sulphonyl]amino]propylammonium hydroxide, Physical & Chemical Properties: Boiling Point, available at https://echa.europa.eu/da/registration-dossier/-/registered-dossier/17549/4/4.

resources to find reasonably available information, evaluate that information, and identify appropriate, practicable test protocols, all within EPA's Scientific Integrity Guidelines[23] and the scientific standards under TSCA Section 26,[24] and issue orders to appropriately targeted companies. We hope this presumption is correct and that increased funding will ensure that EPA will use increased resources to both expand and reform the use of its authority under TSCA Section 4.

D. EPA's Expansion of Fee Requirements for Companies Required to Submit Information under TSCA Section 4 Is Flawed

Regarding persons that EPA may require to remit fees for activities under TSCA Section 4, EPA proposes to extend fee obligations to manufacturers (including importers) that submit existing information in response to a Section 4 test order. EPA's basis for expanding the fee requirements is that "Regardless of whether a manufacturer conducts testing to comply with a test order, EPA incurs costs for developing the test order and administering the test order after it has been issued, including reviewing the data submitted by test order recipients."[25] This assertion, however, is not supported by TSCA. As proposed, the test order fee would inappropriately incentivize EPA to issue orders when testing is not needed. In contrast, the Coalition urges EPA instead to engage in pre-issuance discussions with potential test order recipients to avoid incurring the costs of developing and issuing an unnecessary test order and exercise its authority under TSCA Section 8 to identify and obtain existing data, and to ensure a robust review of existing data.

TSCA Section 26(b)(1) provides for the collection of fees "from any person required to submit information" under TSCA Section 4 but does not support EPA's proposed expansion of the fee requirements.[26] EPA has the authority under TSCA Section 4 to require persons to conduct testing and submit information to EPA with respect to a chemical substance or mixture.[27] A person is only required to submit information under TSCA Section 4 if EPA determines that there is an insufficiency of information or experience to determine unreasonable risk or that the development of new information is necessary to support certain activities under TSCA Sections 5 and 6 after EPA has considered information reasonably available to EPA. If a

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23 EPA (2012), "Scientific Integrity Policy for Transparent & Objective Science" (updated in 2020), at 2, available at https://www.epa.gov/sites/default/files/2014-02/documents/scientific_integrity_policy_2012.pdf.

24 TSCA § 26(h), 15 U.S.C. § 2625(h).

25 87 Fed. Reg. at 68659.

26 15 U.S.C. § 2625(b)(1).

27 *See*, for example, TSCA Section 4(b)(3)(A), which states that "A rule or order under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) or (C), as applicable, *to conduct tests and submit information* to the Administrator …" 15 U.S.C. § 2603(b)(3)(A) (emphasis added).

manufacturer has already developed information that satisfies EPA's data need under a test order, once the testing requirement is extinguished or the order is withdrawn, EPA no longer has the authority to collect fees under TSCA Section 26(b)(1) for the development of new information under the TSCA Section 4 test order.

Next, the Coalition disagrees with EPA using its authority under Section 4 as the primary means to compel the submission of existing data. EPA has and should exercise appropriately its authority under Section 8 to require the submission of data for substances considered for prioritization and/or subject to risk evaluation prior to incurring costs to develop and administer test orders. In doing so, existing data are identified, submitted, and evaluated by EPA in the normal course of prioritizing and evaluating high-priority substances under Section 6 and avoids unnecessarily expending resources on costly development and administration of test orders.

EPA can and should develop transparent, uniform, and efficient procedures to determine whether to exercise its authority under TSCA Section 8 *before* issuing a test order under TSCA Section 4. EPA's assertion is that because "developing test orders is a complex, time-consuming, and resource-intensive process involving many scientific and regulatory considerations," even if EPA extinguishes testing required under the order, all test order recipients should bear the costs of the test order.[28] It is not appropriate, however, for EPA to shift its burden and the costs of identifying existing information to potential test order recipients. To avoid unnecessary costs and inordinate burdens on both EPA and potential test order recipients, the Coalition suggests the following actions:

First, before issuing a TSCA Section 4 test order, EPA should also engage proactively with potential test order recipients in pre-issuance discussions (as EPA has started to do for additional PFAS test orders). This should occur, for example, as soon as EPA identifies its risk evaluation data needs for a substance. At this time, EPA should determine whether EPA should exercise its authority under TSCA Section 8, or whether the development of new information is justified under TSCA Section 4 (as EPA is contemplating with its Tiered Data Reporting rule). Even if a Section 8(d) rule does not exist that obligates the submission of such data or the data do not meet the threshold for reporting under TSCA Section 8(e), early engagement with manufacturers and processors of the chemical substance may result in the voluntary submission of existing data. This vital step would allow EPA to avoid the cost of developing and issuing a test order where there are existing data that can inform EPA's statutory requirement to consider all reasonably available information prior to issuing a test order. Furthermore, engaging in pre-issuance discussions to obtain existing information will enable EPA to address timelier its risk evaluation data needs.

Second, EPA is required to evaluate the sufficiency of existing data as a step in the process of conducting the risk evaluation under Section 6 of TSCA, and that evaluation of the data should be covered by risk evaluation fees, not test order fees. If existing data are insufficient to

[28] 87 Fed. Reg. at 68659.

address EPA's data needs, then EPA has the authority and resources to address these data needs under Section 4.

Third, engaging in pre-issuance discussions with potential test order recipients may reduce the time and resources required to develop and administer test orders by allowing for discussions regarding the testing requirements and refinement of the protocols and timelines of the test order before it is issued.

In summation, it is the Coalition's view that EPA should exercise its authority under TSCA Section 8 to identify and obtain existing data, ensure a robust review of the existing data, and engage proactively with prospective test order recipients *before* it begins the costly process of developing and issuing test orders. As proposed, the test order fee would have the adverse effect of incentivizing EPA to issue orders when testing is not needed.

II. TSCA SECTION 5

In the proposed rule, EPA estimates that its total annual costs for administering TSCA Section 5 during FYs 2023 through 2025 is $54,162,600, reflecting a significant increase in estimated annual costs since 2018.[29] Though EPA is seeking to reduce the impact of fee increases by aiming to recover approximately 18 percent, instead of 25 percent, of its estimated costs, EPA's proposed fee increases remain significant, risk stifling innovation, and are not justified sufficiently in the proposed rule. Furthermore, EPA must ensure that increased resources will result in measured improvements for EPA's implementation of TSCA Section 5, including EPA's ability to meet its deadlines for issuing determinations on TSCA Section 5 notices.

A. EPA Has Not Justified Sufficiently the Proposed Staffing Increases and Resulting Fee Increases for Implementing TSCA Section 5

EPA states the following about its estimated annual workload under TSCA Section 5:[30]

> EPA estimates that it will receive 210 premanufacture notices (PMNs), significant new use notices (SNUNs), and microbial commercial activity notices (MCANs) per year, and another 290 exemption notices and applications per year. EPA's cost estimates for administering TSCA section 5 include the costs associated with processing and retaining records related to NOC [Notice of Commencement of Manufacture or Import] submissions, as well as the costs of pre-notice consultations, processing and reviewing applications, retaining records, and related activities.

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29 *Id.* at 68654.

30 *Id.* at 68652.

EPA estimated the total costs for TSCA Section 5 activities at approximately $54 million annually.[31] The total annual cost includes approximately $32 million in payroll costs for 185.2 FTEs (*i.e.*, full-time employees).[32] As of February 2022, the total FTE count in EPA's New Chemicals Division was 72. What is not clear is how EPA arrives at its estimate of 185.2 FTEs. As EPA is aware, under the Administrative Procedures Act (APA), EPA must "make available to the public, in a form that allows for meaningful comment, the data the agency used to develop the proposed rule."[33] EPA has not provided the data and information on which it relied to develop the proposed staffing level that is necessary for the Coalition to comment meaningfully. Therefore, the Coalition attempts below to provide its own estimate based on its years of experience in reviewing and preparing Section 5 notices.

The Coalition estimates that review of a case (PMN, low volume exemption (LVE), or SNUN) should require approximately 30 hours of total time across all assessors. EPA employees do not write original reports for cases. EPA employees review reports generated by contractors. The Coalition's estimate of the effort required of EPA employees to review a case is based on the following estimates for each assessment stage:

- Prescreen: 0.5 hours
- Chemistry: 1 hour
- Ecotoxicity: 2 hours
- Engineering: 3 hours
- Fate: 2 hours
- Health hazard assessment: 3 hours
- Health risk assessment: 3 hours
- Case manager time: 6 hours
- Senior assessor quality control (QC) review: 3 hours
- Confidential business information (CBI) assessment: 1 hour
- Order development: 3 hours
- New chemicals meetings: 6 hours

Total: 33.5 hours/case

The Coalition rounded up that total to 34 hours per case. Next, in considering re-reviews of a case, the Coalition acknowledges that cases frequently need to be re-reviewed for different reasons. EPA sometimes makes errors in an assessment and correcting those errors requires re-review or a submitter omits needed information material to the review. Costs for re-reviews due to EPA's errors, however, should not be borne by submitters. Even so, in the below analysis, we assume that all cases are re-reviewed after the submitter has provided additional information not included in the original submission. Though it is rare that an entire case needs to be re-reviewed, the Coalition assumes conservatively that the entire process must be duplicated on

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31 *Id*. at 68654.

32 *Id*.

33 *Engine Mfrs Ass'n*, 20 F.3d 1177, 1181 (D.C. Cir. 1994) (citing 5 U.S.C. § 553(b)).

every submission. This means that a single submission requires a total of 68 hours. The Coalition's estimate of 68 hours per case, multiplied by EPA's estimate of 500 cases per year, yields a total of 34,000 hours of effort to review new chemicals.

In estimating the hours generated by year per FTE within the New Chemicals Division, the Coalition acknowledges that EPA's staff will have work-related obligations other than reviewing cases and the program needs FTEs in other roles to support reviews by assessors. To account for such overhead, The Coalition assumes that an average new chemical FTE spends only half their time actually reviewing cases. EPA scientists might, for example, be collaborating with the Office of Research and Development[34] to improve the Office of Pollution Prevention and Toxics' (OPPT) review of new chemicals. This estimate reflects the fact that some new chemicals staff spends most of their time on case reviews and other staff spends comparatively little of their time on case reviews (*e.g.*, a supervisor or manager). One FTE will generate 1,680 hours per year (40 hours per week over 42 weeks per year after accounting for leave and holidays). Assuming the average FTE spends half of those hours reviewing cases, that means an FTE produces 840 hours per FTE per year.

Using these estimates, if the New Chemicals Division needs 34,000 hours per year to review 500 cases, dividing that total by 840 hours per FTE per year gives a total of 40.5 FTEs (34,000 hours ÷ 840 hours per FTE) needed to review 500 cases per year. EPA's proposal is based on the estimate that 185 FTEs are needed to support TSCA Section 5 activities.[35] Given that the New Chemicals Division currently has on staff approximately 71 FTEs, it is unclear from the record why EPA believes that it needs an additional 114 FTEs to support TSCA Section 5 activities.

The record for the proposal does not include EPA's basis for its estimate of 185 FTEs. Even if the Coalition's estimate of the review time per case is underestimated by half, or if its estimate of new chemical FTEs that perform assessments (50 percent of the time) is wrong by half, the needed FTEs is 81, which is only slightly more than the current 71 FTEs count in the New Chemicals Division. EPA must provide support for its projected FTE support required for TSCA Section 5.

Further, if the Coalition assumes that EPA's estimate is meant to include resources to resolve its backlog of over 400 cases, it is not clear that attempting to expand EPA's FTE ceiling for this purpose is an effective way to achieve that goal. One alternative solution may be for EPA to add an additional 25 percent capacity to address backlog cases. This would allow EPA to review an additional 125 cases per year if it can locate, hire, and train an additional ten FTEs (25 percent of 40 FTEs). It is not a reasonable expectation for EPA to address its backlog in the short term (*e.g.*, addressing 400 cases in less than a year) by hiring more permanent staff.

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34 87 Fed. Reg. at 68651.

35 *Id.* at 68654.

This approach to staff management distorts the resourcing picture. First, as EPA must be aware, in this market, identifying, recruiting, on-boarding, and training its professionals in the timeframe outlined is unrealistic, as its own employment history demonstrates. Second, as noted above, even if EPA were somehow able to achieve its projections, it would significantly overstaff the New Chemicals Division.

It is inappropriate for EPA to propose to staff the New Chemicals Division for 900 cases per year (EPA's expected 500 new cases plus 400 backlog cases). Some modest additional capacity may be justifiable, but it is not reasonable for EPA to nearly double its current capacity in estimating its total costs and setting fee amounts under TSCA Section 5. This is especially true since much of the backlog has been the result of understaffing among EPA's health assessors, not all types of assessors. Even when considering the backlog, the record lacks any justification for EPA's estimated number of FTEs. Absent additional support in the record, EPA's stated need for 185 FTEs cannot be justified and appears to be wildly inflated.

Next, EPA wrongly uses its current case review throughput as a basis for its estimates for FYs 2023 through 2025. Given that EPA intends to provide additional support by increasing its resources, EPA's rate of making determinations in 2022 is not a reasonable basis for projections for the three years covered under the proposed rule. Based on EPA's own statements, EPA's administration of TSCA Section 5 has been hampered significantly because it lacks sufficient health assessors. EPA has recently improved its throughput by bringing on additional health assessors temporarily. EPA's projected costs estimate both increase costs to account for the resources needed to improve its administration of TSCA Section 5 *and* the application of these resources to improve EPA's timeliness and efficiencies. EPA cannot expect submitters to subsidize an inefficient process. Instead, EPA should apply its estimates on a more efficient rate of throughput that it could achieve with the appropriate number and type of risk assessors.

It is possible that EPA may be including FTEs assigned to support Safer Choice, a program related to, but not part of, the New Chemicals Division. Safer Choice and other voluntary programs are not within the scope of EPA's authority to recoup up to 25 percent of its costs under TSCA Section 5. No voluntary program is needed to carry out TSCA Section 4, 5, or 6, or for managing CBI. Those programs must be supported with appropriated funds, not fees collected under TSCA Section 26(b).

As with its FTE estimates, EPA provided no basis for its estimate of extramural (non-payroll) costs. EPA noted without explanation that $21,792,600 is needed to support EPA's review of new chemical notices. This corresponds to about $43,500 per case. If that corresponds to a fully loaded average hourly cost of $200/hour, that is over 217 hours of contractor support per case. This number is inexplicably high. If a contractor must expend twice the effort of EPA, that would correspond to 136 hours/case, or $27,200 per case at $200/hour, for a total of $13,600,000 per year.

EPA *must* recommit to increasing the quality, reliability, predictability, and transparency of its New Chemicals Division as mandated by TSCA. The Coalition recognizes that some of these criteria have unavoidably suffered with staff shortages, especially with respect to health assessors. While understandable, such deficiencies must not be allowed to persist, especially

if EPA increases fees. At present, however, EPA does not sufficiently explain or justify its projected staff increase, which contributes to the significant increase in costs and fees proposed for TSCA Section 5 activities. Furthermore, as the Coalition describes further below, EPA's estimate does not consider alternatives to permanent staffing increases that would address these concerns. EPA must more clearly commit in the final rule to improving its ability to meet existing statutory deadlines in the New Chemicals Division. Continued delays in reviewing PMNs, for example, cannot continue once fees increase.

B. EPA Does Not Sufficiently Justify Its Total Annual Costs for Administering TSCA Section 5

EPA estimated $32,370,000 total payroll for 185.2 FTEs, corresponding to an average of $174,748 per FTE. The Coalition presumes this is a fully loaded cost and not a gross salary. EPA's current new chemicals FTEs total 71, a number that most stakeholders would agree is insufficient. Although the calculations above suggest that only 40.5 FTEs are needed to review 500 cases per year, the Coalition will assume that its estimate is low by a factor of two. The Coalition calculates payroll costs of $14,154,588 per year for 81 FTEs. Using the estimate of non-payroll costs calculated above ($13,600,000), the Coalition calculates a total of $27,754,588 as the annual cost to review 500 Section 5 notices, or about $55,509 per case. If EPA chooses not to follow the rationale it has used in the past to keep new chemical fees below 25 percent of costs to avoid imposing undue impediments to innovation, EPA should set the fee at no more than $13,877 (25 percent of $55,509). This is less than the current fee of $19,020. Given that the statute requires that EPA evaluate and increase *or decrease* the fees,[36] the Coalition's view is that EPA should reduce the Section 5 new chemical fee to $14,000 per case. Using the same ratio that EPA used to propose an exemption notice fee ($45,000 ÷ /$13,230 = 3.4), the Coalition calculates an exemption notice fee of $4,116. Absent adequate detail by EPA to justify its proposed fees, the fee increases to $45,000 per PMN and $13,230 per exemption notice are not supported by the facts or record.

Another consideration is the language in TSCA Section 26(b)(4)(B)(i)(I) that states that EPA may set fees to "defray…the costs to the Administrator of carrying out sections 4, 5, and 6…" This language indicates that EPA's proposed fees depend on the costs if carrying out TSCA Sections 4, 5, and 6, rather than *possible* or *anticipated* costs to implement TSCA if EPA were to expand its capacity. As a result, it is not permissible for EPA to base its costs on a potential expanded workforce that may exist at a future date, as EPA has proposed in its estimations for TSCA Section 5.

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[36] TSCA § 26(b)(4)(F), 15 U.S.C. § 2625(b)(4)(F) (emphasis added).

C. EPA Must Ensure That the Proposed Fee Increases Will Increase Transparency, Quality, and the Timeliness of EPA's Implementation of TSCA Section 5

EPA states that the "[a]dditional funding collected through TSCA section 5 fees will help EPA reduce the backlog of delayed reviews and support additional work for new cases."[37] Presumably these monies will also provide EPA the necessary budget to modify its statements of work with its contractors, so the contractors can provide proposed justifications for the use of analogs, for example, as well as proposed refinements to the exposure metrics, when appropriate. Collectively, these improvements will allow EPA's assessors to exercise their inherently governmental function of evaluating and approving and/or modifying the contractor-derived work products to produce EPA-approved work products. This will provide more transparent and timely evaluations on novel chemistries notified to the Agency.

This level of transparency will also ensure that EPA is satisfying the requirements of its Scientific Integrity Policy, which states that "promoting a culture of scientific integrity [at EPA] is closely linked to transparency. The Agency remains committed to transparency in its interactions with all members of the public."[38] In doing so, EPA will additionally be providing risk assessments that document coherently its decision-making and how those decisions satisfy the scientific standards under TSCA Section 26. These considerations are critical for submitters, not in the sense that they must necessarily agree with EPA's risk determinations, but rather that submitters cannot address EPA's concerns and data needs (or correct errors) if EPA cannot provide adequately its reasoning. Transparency for all stakeholders should include documentation from EPA that clearly explains the rationale for its risk determinations, so stakeholders can understand the bases for EPA's decision-making.

Solely increasing the resources available to review cases will not resolve other material deficiencies and inefficiencies in EPA's reviews. Since 2016, the Coalition has observed decreased transparency in EPA's risk assessments on new chemical substances. While EPA must justify its proposed fee increases with material improvements to its administration of TSCA 5, EPA should take other measures to improve its processes and reduce costs to both EPA and submitters.

For example, EPA's risk assessments routinely include analogs that are used to read across potential hazards to new chemical substances. It is not uncommon for EPA's risk assessment to identify multiple analogs for doing so. One common issue, however, is that EPA's assessors will select a single analog among the many presented without stating the scientific basis for the selected analog. This issue also occurs when submitters identify analogues to EPA. EPA's assessors routinely dismiss the analogues as not sufficiently conservative without providing the scientific basis for doing so. These types of determinations lack transparency and invite

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37 87 Fed. Reg. at 68655.

38 *See supra* note 23 at 2.

unnecessary delays and increase the likelihood that cases must be reworked if EPA later concludes that its initial selection of an analog was inappropriate.

EPA also routinely uses the acute potential dose rate (PDR) as the exposure metric for assessing potential unreasonable risks to workers in its new chemical substance risk assessments. While this approach is acceptable as an initial screening-level assessment. it is not an acceptable approach for making unreasonable risk determinations beyond the screening-level without further refinements. For example, it is not uncommon for EPA to use a point of departure (POD) for a hazard concern that requires continued exposures over a long period of time to cause the hazard. EPA will use the PDR as the exposure metric that drives its unreasonable risk determination, rather than the average daily dose (ADD) for chronic non-cancer hazards. The latter metric is appropriate for making risk determinations based on hazard concerns that stem from continued exposures, not acute exposures that the PDR estimates. EPA is aware of this discrepancy and does appropriately use the ADD in its risk evaluations on existing chemical substances under TSCA Section 6. It is unclear why EPA is not doing so under Section 5, and EPA has provided no justification or explanation for this scientifically flawed practice. It is important as EPA considers the need for additional funding to improve the administration of TSCA Section 5 for EPA to also ensure that it improves upon the transparency of its assessments and adherence to scientific standards under TSCA.

Next, there are circumstances where EPA may improve upon its procedures and increase the timelines and efficiencies of its reviews. This includes preventing errors that require re-reviews of a case. If EPA makes a mistake during an early stage of its assessment (for example, during engineering review) and does not discover that error until after the entire assessment is complete, the cost of this error should not be borne by the submitter. If EPA does make an error, the cost of EPA's complete re-review should be EPA's burden to bear. One solution is for EPA to increase transparency and coordination with submitters during case review. EPA has routinely been unwilling to provide submitters with new chemicals reports in real time during case review. This means that there is no real-time outside quality check on EPA's assessment until EPA completes its review, allowing errors to compound. Implementing measures to update and communicate with submitters during EPA's review would enable submitters to ask questions and address potential errors that would result in a re-review, increasing efficiency and avoiding squandering of resources on both sides.

Other opportunities for increased efficiency and coordination with submitters includes Sustainable Futures assessments prepared by submitters to support PMNs. Currently, EPA will routinely ignore or dismiss such assessments without any explanation, which requires EPA to allocate resources to undertake a new assessment.

TSCA requires that EPA ensure transparency during the course of its review, that will lead to increased efficiency. In considering the costs of administering TSCA, identifying solutions to current problems that reduce costs to EPA and submitters is a necessary measure to ensure that submitters are not subsidizing an inefficient process. It is critical that EPA address inadequacies and improve its processes wherever possible, as foisting avoidable costs on the regulated community is unlawful and unacceptable. If EPA wishes to reduce its rework, EPA must,

at a minimum, share reports with submitters as the reports become available, and not wait for the assessment to be complete.

EPA is encouraged to consider formalizing the process for pre-PMN meetings to allow PMN submitters to receive important feedback before the actual submission of a PMN. This approach would reduce the number of poor-quality PMN submissions that require EPA resources to address. An improvement in the quality of submissions would reduce EPA's burden for PMN reviews and reduce the turnaround time for assessing PMNs. The added cost of the pre-PMN meetings would be supported by the increased fees for the PMN submissions and increase EPA's throughput for PMN reviews.

Last, it is vital that increases in fees are accompanied by significant improvements to the timeliness of EPA's reviews. Should EPA increase its fees under TSCA Section 5, EPA *must* commit to addressing issues with its review process and commit to meeting its 90-day statutory deadline. A significant increase in PMN fees that is not accompanied by a significant improvement in the PMN review process will continue to stifle innovation, foster further abandonment of the introduction of new chemicals to U.S. markets, and increase the barriers for industry to a transition to more sustainable chemistries.

The Coalition supports EPA's inclusion of the costs to process *Bona Fide* Intent Notices and NOCs in new chemical fees, but EPA must provide timely responses if it intends to charge fees for processing these notices. The record lacks sufficient information to estimate the cost of processing such notices, but we note that such effort is relatively small compared to the risk evaluation and risk management activities associated with new chemical notices.

D. EPA Must Cease Requesting Voluntary Suspensions of the PMN Review Period (Except in Cases Where Absolutely Necessary), As It Permits EPA to Delay Its Review in Excess of the Statutory Review Period and at a Significant Cost to Submitters

Regardless of the fee that EPA ultimately implements in its final rule, EPA must cease requesting voluntary suspensions of the review period prior to EPA completing its initial risk evaluation. Submitters are suffering interminable and unacceptable delays while EPA suffers no consequence for its inaction (other than having to make time-consuming biweekly calls to submitters requesting additional suspensions). While EPA's view may be that all suspensions are voluntary, not agreeing to a suspension places the submitter in a very prejudicial, adverse position, limiting both EPA's and the submitter's legal options. By not requesting suspensions prior to completing its initial risk evaluation, EPA leaves itself "on the clock" to complete its review timely or, if it cannot, refund the submission fee. Refunding the fee does not mean that EPA has completed its determination. It allows a submitter to decide if it wishes to withdraw its PMN without suffering the loss of the fee or to wait for EPA to complete its required actions.

III. TSCA SECTION 6

EPA's estimate of its annual costs for administering TSCA Section 6 is based on conducting at least 20 EPA-initiated chemical risk evaluations and at least three MRREs per year, prioritizing chemical substances, and performing risk management. As shown in Table 1, EPA estimated its total costs at approximately $95 million annually with approximately $51 million covering payroll for 296.6 FTEs.[39] It is unclear how EPA derived the allocated FTEs for each of the activities shown in Table 1 and estimated the total annual costs for these activities based on the provided record.

Table 1. EPA's estimated costs and FTEs for administering TSCA Section 6.			
	Total Annual Costs	Payroll	FTEs
Prioritization	$8,820,900	$6,254,000	35.9
EPA-initiated risk evaluation	$54,877,100	$28,291,100	161.40
MRREs	$7,483,200	$3,857,900	22.0
Risk management	$24,553,500	$13,536,000	77.3
Totals	$95,734,700	$51,939,000	296.6

A. EPA Does Not Sufficiently Justify Its Annual Costs and Anticipated Increases for the Prioritization Process for Risk Evaluations under TSCA Section 6

EPA estimated its total annual costs for prioritization at approximately $8.8 million with approximately $6 million of this required to cover 35.9 FTEs.[40] No substantive information is in the record justifying these numbers. EPA already has a list of prioritized existing chemical substances from its *TSCA Work Plan for Chemical Assessments: 2014 Update*.[41] TSCA Section 6(b)(2)(B) requires that "at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments."[42] EPA published a document in June 2021 titled *A Proof-of-Concept Study Integrating Publicly Available Information to Screen Candidates for Chemical Prioritization under TSCA*[43] in which EPA concluded that it was capable of discriminating

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39 87 Fed. Reg. at 68654.

40 *Id.*

41 EPA, *TSCA Work Plan for Chemical Assessments: 2014 Update* (Oct. 2014), available at https://www.epa.gov/sites/default/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

42 15 U.S.C. § 2605(b)(2)(B).

43 EPA, A Proof-of-Concept Case Study Integrating Publicly Available Information to Screen Candidates for Chemical Prioritization under TSCA, EPA Document # EPA/600/R-21-106

"between high- and low priority candidate chemical substances and identified potential information gaps."[44] Together, these tools should make EPA's selection of substances for prioritization relatively low effort. Though the Coalition acknowledges that staff time is required to prepare prioritization documentation, manage the notice-and-comment process, and publish the prioritization in final, it is not clear how EPA determined a cost estimate of approximately $6 million for TSCA Section 6 prioritization.

EPA's stated need for 35.9 FTEs for prioritization appears to justify a level of support required to complete prioritization at an accelerated pace, which is inconsistent with the requirements under TSCA. For example, TSCA Section 6(b)(2)(C) states:[45]

> The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with this subsection at a pace consistent with the ability of the Administrator to complete risk evaluations …

In the next three years, EPA will likely need to issue prioritizations for 20 substances, or about seven per year. Even at three FTEs per prioritization, that only accounts for 21 FTEs for prioritization. We acknowledge that these FTEs will be spread across disciplines and will include scientists, risk assessors, and risk managers. Based on this information alone, it is difficult to understand why EPA needs 35.9 FTEs to work on prioritization. The Coalition presumes based on EPA's non-payroll cost estimate that EPA plans to rely upon contractors to prepare initial documents to support prioritization activities. EPA's estimate of $2,566,900 corresponds to $128,354 per prioritization, which, at $200/hour, is 642 hours of contract support per prioritization. Absent additional supporting facts from EPA that are not in the record, the Coalition's estimate is that EPA needs $3.66 million for payroll expenses and $1.5 million for non-payroll expenses (using EPA's ratio of 2.44 for payroll-to-non-payroll expenses) for prioritization.

B. EPA Does Not Provide Sufficient Support for Its Annual Cost Estimates and Projected Increases for Completing TSCA Section 6 EPA-initiated Risk Evaluations

EPA does not provide sufficient support for the estimates costs to conduct an EPA-initiated risk evaluation under TSCA Section 6. Section 6 evaluations are more complex than Section 5 notice reviews, EPA's estimate that 161.4 FTEs are required to perform 20 risk

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(June 2021), available at https://cfpub.epa.gov/si/si_public_pra_view.cfm?dirEntryID=349776&Lab=CCTE.

44 *Id*. at 8.

45 15 U.S.C. § 2605(b)(2)(C).

evaluations at 840 hours/year per FTE[46] equates to 135,576 hours per year for all 20 risk evaluations combined, or 6,779 hours per year for each risk evaluation. In multiplying the 6,779 hours per year estimate per risk evaluation by 3.5 years (the length of the risk evaluation specified in the statute), it would require 23,726 total hours to complete one risk evaluation. This means that EPA expects each risk evaluation to occupy fully eight FTEs (6,779 hours per year divided by 840 hours/FTE per year) for the entirety of the 3.5 years review period (or 32 employees each working one quarter time on each of four risk evaluations). This effort *excludes* the substantial contract support that EPA uses to generate its risk evaluations. This estimation appears high as it is difficult to understand how a risk evaluation would require this level of effort -- the equivalent of eight FTEs reviewing contractor reports full time for 3.5 years.

A more reasonable estimate is that each risk evaluation requires the equivalent of two FTEs, rather than eight FTEs, for the entire duration of the risk evaluation (as stated above, these FTEs are likely an aggregate of contributions from several individuals working part time on each risk evaluation that averages to two people working full time on a single risk evaluation). If each FTE only works on an assessment 50 percent of their time, two FTEs produce 1,680 hours per year. Over 3.5 years, this corresponds to 5,880 hours to complete a risk evaluation; the Coalition can round this estimate to 6,000 hours per risk evaluation over 3.5 years. Using the same payroll average cited above of $174,748, the Coalition can calculate a cost of $1.22 million ($174,748×2 FTEs×3.5 years). This corresponds to $7 million per year for payroll costs for 40 FTEs to perform risk evaluations on 20 substances, which is significantly lower than EPA's estimate of approximately $28 million in payroll costs per year. If the Coalition again assumes its estimate is low by a factor of two, the total FTEs would be 80 and the total payroll costs would be $14,000,000.

It is much more difficult to estimate the required level of extramural support necessary to complete a risk evaluation. EPA's estimate of $26,585,900 per year corresponds to $1.33 million per year per risk evaluation.[47] At $200/hour (fully loaded contract rate), this would correspond to about 6,650 hours per risk evaluation per year or 23,275 hours over 3.5 years. These estimates appear to be quite high. Based on EPA's ratio of $1.2 of payroll costs per $1 of non-payroll costs and the Coalition's estimate of 80 FTEs to support risk evaluations, the Coalition estimates $14 million in payroll costs (80 × $174,748) and $11.6 million in non-payroll costs for a total of $25,600,000. The Coalition expects that the effort to complete an MRRE is identical to the effort to complete an EPA-initiated risk evaluation. EPA's estimate of two MRREs is ten percent of the estimate of 20 risk evaluations.

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46 As described in the Section 5 analysis above, one FTE generates 1,680 hour per year. Accounting for support FTEs that do not participate on the assessment and accounting for work (such as training, staff meetings, and job functions other than working on the risk assessment), we estimate that each FTE (on average) only works on an assessment 50 percent of the time, or 840 hours per year.

47 87 Fed. Reg. at 68654.

As with the Coalition's estimates for new chemicals, the Coalition is seeking additional transparency and explanation from EPA regarding its proposed cost estimates and how these justify EPA's proposed fee increases and would welcome additional clarity from EPA on its estimates. At present, EPA's estimates are not sufficiently supported by the facts or record to justify a fee increase, and do not justify an increase of the magnitude proposed. Based on the Coalition's estimates, EPA should need 40 FTEs to perform 20 risk evaluations. The Existing Chemicals Risk Assessment Division (ECRAD) has, to the best of the Coalition's knowledge, 79 FTEs (close to the Coalition's number if its estimate of two FTE/risk evaluation is low by a factor of two). At 50 percent time per FTE, this corresponds to 40 FTEs split over 20 risk evaluations, or approximately two FTEs per risk evaluation. In the Coalition's view, this level of staffing is sufficient, especially now that EPA has completed the "first 10" risk evaluations, reducing the number under review from 30 to 20. While ECRAD's current staffing appears to be sufficient to support risk evaluation activities, ECRAD will need additional resources to support prioritization and test order activities.

Regarding the basis for EPA's cost estimates, though EPA states that its estimates "have been informed" by EPA's experience with the "first 10" risk evaluations, the level of effort required to develop a risk evaluation process on the fly, as EPA was required to do during its evaluations of the "first 10," is not representative of the level of effort required for future risk evaluations. EPA provides no additional detail on this assessment and is unclear if EPA has accounted for additional efficiency from the experience that EPA has gained as part of its "first 10" risk evaluations in estimated costs over FYs 2023 through 2025. EPA should further clarify whether it accounted for the institutional knowledge EPA acquired in completing the "first 10" and increased efficiencies to its processes going forward.

C. EPA Does Not Provide Sufficient Information to Assess Its Proposed Estimates of the Costs to Conduct Risk Management under TSCA Section 6 to Support Its Proposed Cost and Fee Increases

EPA will likely be completing nine of the risk management rules for the "first 10" over the next few years and will be initiating risk management rules on the "next 20" and MRREs as EPA completes each. EPA estimates that it needs 77.3 FTEs for risk management. For the sake of argument, we will assume that EPA will be issuing 25 total risk management rules during the three years covered by this fee rule, or 8.3 rules per year. At the same 50 percent overhead rate for FTEs, this corresponds to 4.7 FTEs per rule per year ((77.3 FTE ÷ 8.3 rules per year) × 50 percent FTE capacity). EPA does not provide in the record a basis for its estimate of 77.3 FTEs, so the Coalition cannot evaluate EPA's basis for the need for 4.7 FTEs to address each risk management rule. EPA also estimates $11 million in non-payroll costs. The Coalition's estimate is that a risk management rule should not require more than two FTEs per year (or four FTEs with overhead), or 33.2 FTEs (8.3 rules/year × 4 FTEs). Existing Chemicals Risk Management Division (ECRMD) currently has 56 FTEs, a number that should be sufficient for EPA to issue risk management rules timely. Absent significant additional information and visibility into EPA's estimates, EPA does not need additional resources to propose and promulgate risk management rules.

IV. GENERAL COMMENTS

A. The Coalition Suggests That EPA Ensure Its Proposed Fee Allocation Methodology for Manufacturers of Chemicals Subject to EPA-initiated Risk Evaluations Is Equitable by Considering a Tonnage Band Approach That Is More Proportionate to Companies' Respective Volumes

The proposed volume-based fee allocation methodology for manufacturers of chemicals subject to EPA-initiated risk evaluations allocates 80 percent of the cost (after small businesses discounts applied) to the top 20th percentile of companies that are manufacturers (*i.e.*, based on their respective volumetric ordinal ranks). This can result in gross inequalities when companies' resulting fee responsibility is viewed as a fee per pound manufactured. For example, in a group of seven companies, the top two would be responsible to pay 80 percent of the fee and the remaining five would split the last 20 percent. As a result, companies #6 and #5 may pay vastly different amounts per pound and absolute amounts of the fee even if they produce similar quantities. In some circumstances, small businesses may even end up paying more than large businesses.

If EPA will use a volumetric approach, it must use a different technique that is more proportionate to companies' respective volumes. Once the fee band has been calculated, a small business's individual fee would then reflect 20 percent of what it would have paid if it was a larger business.

1. Tonnage Band Approach to Allocating Risk Evaluation Fees

The Coalition supports EPA's suggested primary alternative approach to rank fee payers based on the reporting of production volume ranges instead of production volume averages to alleviate potential CBI concerns and simplify reporting and the fee calculation. The Coalition agrees with using narrower fee ranges to increase the equitable distribution of fees based on production volume and refers EPA to the alternative methodologies for calculating fees outlined by the American Chemistry Council (ACC) in its March 26, 2021, comments in response to EPA's January 11, 2021, proposed rule revising the fees rule under TSCA.[48] A variation on the ACC tonnage banding approach for calculating fees is provided below for EPA's consideration.

2. Proposed Calculation Methodology (Based on Derivative of ACC Alternative 2)

- Step 1 -- Count the total number of small and large business fee payers for a substance;

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48 "Comment submitted by American Chemistry Council," EPA-HQ-OPPT-2020-0493-0066 (Mar. 26, 2021), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0066.

- Step 2 -- Divide the fee by the total number of fee payers (small and large);
- Step 3 -- Calculate the base small business fee by dividing the fee by the total number of fee payers and multiplying by 20 percent;
- Step 4 -- Multiply the base small business fee by the number of small business payers;
- Step 5 -- Subtract the amount from Step 4 from the total fee and divide the result by the total of large business fee payers to calculate the large business base fee;
- Step 6 -- Split small and large business fee payers into each tonnage band (1-10, 10-100, 100-1000, >1000);
- Step 7 -- Multiply the number of small business fee payers in each band by the tonnage band multiplier for each band;
- Step 8 -- Sum the products of total payer×band multiplier from Step 7 to calculate the total of small business fee shares;
- Step 9 -- Repeat Step 7 for large businesses;
- Step 10 -- Repeat Step 8 for large businesses to calculate the total large business fee share;
- Step 11 -- For each tonnage band, multiply the small business fee share by the tonnage band multiplier to calculate the small business invoice amount for payers in that band;
- Step 12 -- For each tonnage band, multiply the large business fee share by the tonnage band multiplier to calculate the large business invoice amount for payers in that band;
- Step 13 -- Invoice small fee payers based on the result of Step 11; and
- Step 14 -- Invoice large fee payers based on the result of Step 12.

Under this suggested methodology, any business under one metric ton would be exempt from fees. It is unlikely that, in the next three years, EPA will perform risk evaluations for substances for which all or the majority of manufacturers and importers produce under one ton. Tonnage shall be calculated by determining the tonnage in metric tons (1,000 kg) using the actual production (or import) quantity in kilograms or the quantity in pounds multiplied by 2.2, rounded to two significant figures. This method discloses minimal production volume information, similar to what is disclosed under the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, and provides balance between the size of the business and the size of the market.

B. The Coalition Supports EPA's Proposed Exemptions to Risk Evaluation Fees

The Coalition supports EPA's proposed exemptions to the risk evaluation fees:

- Importers of articles containing chemical substances;
- Manufacturers of a substance as a byproduct not later used for or distributed for commercial uses;

- Manufacturers and importers of substances present as an impurity;
- Manufacturers of substances as non-isolated intermediates;
- Manufactures of substances solely for research and development (R&D); and
- Manufacturers of substances with an annual production volume of less than 2,500 pounds unless all manufacturers are under that threshold (1,100 pounds for test rules).

For the years covered by this fee rule, EPA is unlikely to be evaluating substances for which article importers are the primary source of the substance in the United States. EPA will be able to identify manufacturers, importers, and processors for purposes of collecting the risk evaluation fee. If, in the future, EPA seeks to prioritize a substance that does not have any manufacturers or importers other than those that would be otherwise exempt, EPA can, in a future fee rule, develop criteria under which EPA can document its need to collect fees from entities that would otherwise be exempt from such fees.

Similarly, the Coalition supports EPA exempting manufacturers of a substance as a byproduct that is not later used or distributed for a commercial purpose. This exempts from risk evaluation fees entities that create and dispose of the substance as a waste. That is not to say that there are no risks from waste, rather that the risk evaluation fees should be borne by entities intentionally manufacturing or importing the substance. We also support exempting manufacturers and importers of a substance when present as an impurity. As with the byproduct exemption, there is no implication that there is no risk from the substance being present as an impurity, only that the fee should not be paid by such manufacturers -- it should be paid by those intentionally manufacturing or importing the substance.

Manufacturers of non-isolated intermediates already engage in strenuous effort to control releases and exposures and should not be forced to bear the cost of risk evaluation fees. Manufacturers of small quantities are likely minor contributors to the overall production volume, and the effort to force such entities to pay fees will be disproportionate to the contribution to the market and to the economic activity conducted by those small producers.

Manufacturers of substances for R&D only are generally operating at very small volumes and are unlikely to be able to bear the cost of a risk evaluation. Charging fees to those that manufacture or import for R&D could starve laboratories from needed reference material if R&D houses refuse to carry substances out of fear of being charged fees. EPA is unlikely to be selecting for prioritization substances produced exclusively at such low volumes.

The Coalition cautions EPA about the possibility of double collection of fees. As EPA is aware, some manufacturers produce a substance, some of which is exported and then re-imported. As it stands, for example, during Chemical Data Reporting (CDR), quantities that are re-imported are reported as imports. It is not fair to charge fees to re-importers or to double-count quantities re-imported in production volume totals for purposes of establishing fee payment levels.

If a recipient of a test order can document that EPA inappropriately issued such an order, the recipient will not be subject to the fee. While the Coalition agrees that effort is required

by EPA to develop test orders and identify order recipients, a company should not be penalized for EPA issuing such an order to an inappropriate recipient (*e.g.*, a company that does not manufacture, import, or process the subject substance and does not intend to in the future).

When identifying potential fee payers, reporting to the Toxics Release Inventory (TRI) is not sufficient evidence that an entity should be subject to a fee. There are many reasons that a facility might report to TRI and yet should not be assumed to be manufacturing or processing for a commercial purpose.

For example, hazardous waste incinerators operate to manage hazardous substances generated by others. If such incinerators become the target of risk evaluation fees, they may cease to offer to manage high-priority substances for fear of having to pay fees. This could leave those with wastes that contain a high-priority substance without a reasonable or appropriate disposal method that minimizes risk to health and the environment. Even if all manufacturers and importers exit the market for a high-priority substance, leaving no fee payers, the incinerators will still be needed to manage any waste identified (*e.g.*, during a site clean-up). As EPA is aware, TSCA fees are a disincentive, and EPA should exercise care not to disincentivize the business of managing hazardous waste. TRI may be appropriate as an initial screen, but EPA should follow that screen with additional analyses, such as reporting to other data systems, researching the function of the facility, and other research before identifying TRI reporters as fee payers.

C. The Coalition Supports EPA's Proposals to Facilitate the Payment of Fees, Including Lengthening the Time before a Fee Is Due to Allow Time for the Formation of Consortia and the Payment of Fees in Installments; the Coalition Further Suggests That EPA Provide Invoice or Wire Options for Fees That Exceed Credit Card Limitations

The Coalition supports EPA's proposal to lengthen the time before a fee is due. Establishing a consortium to address the risk evaluation process can easily take several months. EPA's initial deadline for the fee payment made it very difficult for some groups to form and fund the consortium so that the consortium could pay the fee timely.

The Coalition also supports EPA allowing fee payers to pay in installments. This makes it easier for fee payers to budget the substantial expense and aligns with EPA's level of effort on the risk evaluation -- as EPA is aware, only a portion of its activity on a risk evaluation occurs in the year immediately following the commencement of a risk evaluation. Given the extended timeline for EPA's review, it is appropriate and fair for fee payers to only pay a portion of the fee in the first year.

Next, the Coalition suggests that EPA provide an invoice or wire option for PMN submissions, which must be paid through the Central Data Exchange (CDX), as the new fee proposed exceeds the limit (*i.e.*, $24,999.99) for immediate payment via credit card. The Coalition recommends that EPA implement a payment process like the one used for payment of the risk assessment fees for high-priority substances.

D. The Coalition Suggests That EPA Consider Providing a Mechanism in the Proposed Rule That Accounts for Post-fee Market Reentry and New Market Entry

The Coalition supports the comments from B&C® Consortia Management, L.L.C. (BCCM) submitted to EPA on the January 11, 2021, proposed updates and adjustments to the 2018 TSCA fees rule relating to post-fee market reentry and new market entry.[49] A company that certifies cessation of manufacturing or import, and thus is not subject to payment of the EPA-initiated risk evaluation fee under the current fees rule, is prohibited from reentering the market for five years. Recognizing that this may impose additional transaction costs on EPA, EPA should provide a mechanism that enables a company that has certified cessation to reenter the market sooner if it reimburses the entities that have already paid the EPA-initiated risk evaluation fees. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), for example, follow-on pesticide registrants are required to pay data compensation to data owners if their entry into the market occurs at any time the data remain compensable. Similarly, registrants are responsible to pay a share of data production costs required under FIFRA Data Call-Ins (DCI) regardless of when they enter the market, and are often assessed by consortia a "late fee" to help compensate consortia for the up-front costs of timely addressing the DCI.

A company may similarly wish to enter the market for the first time after the initial and/or final fees are paid. EPA should provide a mechanism for a company that enters the market within some period, *e.g.,* five years of the final fee payment for a risk evaluation, to provide fair reimbursement to the entities that have paid EPA-initiated risk evaluation fees. Failure to impose a fee on these persons is not equitable to those that are subject to fees. There is precedent for such an approach under TSCA for data reimbursement for testing conducted pursuant to Section 4 test rules. Generally, under the TSCA Section 4 testing reimbursement procedures at 40 C.F.R. Part 791, persons subject to test rules that, for example, begin manufacture of a chemical substance subsequent to the initiation of testing by another manufacturer during the testing reimbursement period may be required to provide fair amounts of reimbursement to the manufacturer conducting the testing. FIFRA operates similarly. In a manufacture volume-based system for allocating fee shares, fair fee amounts for market entrants and reentrants could be based on the average volume of manufacture intended over a set period, such as the subsequent three years or five years.

Fee reimbursements may be much simpler when there is (or was) a consortium that paid the fee on behalf of a group of fee payers, especially if the consortium represents all or most of the fee payers. When this is the case, the consortium can manage the receipt of the payment from the new entrant (or reentrant) and reimburse members according to the bylaws of the consortium. EPA may decide to permit market entry during the five-year prohibitory period, but only if the new entrant joins the consortium that paid the fee. This provides an incentive to maximize consortium participation and minimize EPA's role in managing fee reimbursement.

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[49] 86 Fed. Reg. at 1890; "Comment submitted by B&C® Consortia Management, L.L.C. (BCCM)," EPA-HQ-OPPT-2020-0493-0054 (Mar. 26, 2021), available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0493-0054.

E. EPA Must Reevaluate, in Consideration of the Fiscal Year 2023 Omnibus Appropriations Bill, Its Budget for Reasonable Baseline Costs to Administer TSCA

EPA must ensure its proposed fee increases are based on an appropriate budget baseline. On December 29, 2022, the Fiscal Year 2023 Omnibus Appropriations Bill was signed into law, increasing OPPT's operating budget by 20 percent. EPA must address the impacts of EPA's FY 2023 appropriation, budget increase, and any subsequent impacts on EPA's proposed fees.

TSCA Section 26(b)(3)(C) states: "Fees authorized under this section shall be collected and available for obligation *only to the extent and in the amount provided in advance in appropriations Acts*, and shall be available without fiscal year limitation for use in defraying the costs of the activities described in paragraph (1)."[50] As EPA is not allowed to spend more than Congress authorizes for a given FY, EPA's baseline costs must be set no higher than those authorized by Congress for Sections 4, 5, 6, and 14. Yet, EPA's estimated annual costs exceed its FY 2023 appropriation.

EPA's enacted FY 2023 budget for "Toxics Risk Review & Prevention" -- a category that the Coalition interprets to encompass all of the Office of Pollution Prevention and Toxics (OPPT) budget -- is $117,782,000. In the proposed rule, EPA estimates that the annual costs to EPA for FYs 2023 through 2025 in administering TSCA Sections 4, 5, 6, and 14, including Agency indirect costs, is $181,897,400.[51] In short, EPA cannot increase its fees to substantially more than 25 percent of its appropriation: EPA's fees must be reasonable to meet current and projected costs of administering TSCA, which must be in accordance with EPA's budget based on EPA's resource requirements. If the entire OPPT budget were to be used to implement Sections 4, 5, 6, and 14, 25 percent of that amount is about $29 million. This view is supported by the fact that EPA must adjust fees under TSCA Section 26(b)(4)(F) to account for inflation and to ensure that funds are sufficient to defray not more than 25 percent of the cost to administer the key sections of TSCA.

EPA's proposed cost estimates are considered based on numerous, complex factors, including estimated activity levels, projected FTEs needed to support an activity under TSCA, and other costs, with consideration of EPA's past TSCA work experience as a basis for EPA's anticipated implementation efforts and required resources. The Coalition acknowledges that increased resources may be necessary to increasing the transparency, efficiency, and quality of EPA's administration of TSCA, but that furthermore, the process of estimating EPA's Agency costs for activities under TSCA Sections 4, 5, and 6 itself requires the availability of additional information and clarity from EPA.

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50 15 U.S.C. § 2625(b)(3)(C) (emphasis added).

51 87 Fed. Reg. at 68651.

Many essential changes that may help achieve these necessary improvements to EPA's administration of TSCA, such as increasing collaboration with stakeholders before issuing TSCA Section 4 test orders and communication with submitters during TSCA Section 5 reviews, will reduce costs to EPA and to stakeholders independent of the provision of additional resources. In ensuring accountability, EPA's appropriation serves as one of the only measures against which to evaluate EPA's estimated costs and to ensure that EPA's subsequent fees are reasonable and based on the efficient use of EPA resources. As such, it is critical that EPA address the impacts of the FY 2023 budget on EPA's proposed rulemaking.

Conclusion

EPA's justification for significant fee increases is, for the most part, not supported by sufficiently detailed analysis or facts. Rather, EPA simply asserts a level of FTEs and a level of extramural funding it assumes it needs, without providing support for these assertions for stakeholders' review. As discussed above, albeit concerns regarding EPA's estimates of the number of activities per year, the Coalition largely agrees with EPA's estimate of its needs for Section 4, but strongly disagrees with EPA's estimates of its needs for Sections 5 and 6, even with generous assumptions on its part. Absent the provision of significant additional details for EPA, the Coalition must strenuously object to EPA raising the Section 5 and Section 6 fees as proposed. EPA simply has not provided a sufficient factual foundation to justify the stated increases.

Furthermore, the Coalition's view is that EPA cannot defray costs above 25 percent of its appropriation. If EPA were not limited by its appropriation, EPA could simply estimate an extraordinarily high level of activity, for example, under Section 6, and charge fees to defray 25 percent of those costs, regardless of whether the estimated costs or level of activity were reasonable, reflected an accurate or efficient allocation of resources, or accounted for EPA's ability to perform the estimated number of evaluations.

Last, EPA must ensure transparency and demonstrate improved performance in the implementation of TSCA in congruence with any proposed fee increases. The Coalition supports EPA's objective to improve on the timeliness and quality of EPA's implementation of TSCA and the need for adequate resources to support these activities but emphasizes the criticality of ensuring that proposed fee increases result in measurable improvements.