



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

ASSISTANT ADMINISTRATOR
FOR ENFORCEMENT AND
COMPLIANCE ASSURANCE

March 24, 2020

MEMORANDUM

SUBJECT: No Action Assurance Regarding Self-Identification Requirement for Certain
“Manufacturers” Subject to the TSCA Fees Rule

FROM: Susan Parker Bodine *Susan Parker Bodine*

TO: Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention

The U.S. Environmental Protection Agency is providing a no action assurance (No Action Assurance) to certain “manufacturers” subject to the Toxic Substances Control Act (TSCA) Fees Rule with respect to the self-identification requirement associated with EPA-initiated risk evaluations for manufacturers, and subject to certain specified terms and conditions. This No Action Assurance is being issued in response to your request on March 18, 2020. As explained more fully below, this No Action Assurance establishes that the EPA will exercise its enforcement discretion to not pursue enforcement action for violations by certain manufacturers (discussed further below) of the self-identification reporting obligations established in the TSCA Fees Rule and listing notices¹ identifying chemicals and setting deadlines under sections 26 and 6 of the TSCA.

As explained in your request, the TSCA Fees Rule established a structure to collect fees for certain activities to help defray a portion of the costs associated with some TSCA implementation efforts. Among other activities, the rule requires payment of a \$1,350,000 fee in association with EPA-initiated risk evaluations under TSCA section 6.² See 40 C.F.R. § 700.45(c)(2)(ix). Specifically, 40 C.F.R. § 700.45(a)(3) requires payment of a fee from manufacturers of a chemical substance subject to a risk evaluation under section 6(b). Additionally, pursuant to 40 C.F.R. § 700.45(b)(3), the EPA publishes a preliminary list of manufacturers identified through review of certain available data sources. To facilitate the identification of other responsible payers that were not identified on the preliminary list, 40

¹ Specifically, this No Action Assurance addresses provisions of (1) Final Rule on “Fees for the Administration of the Toxic Substances Control Act,” 83 Fed. Reg. 52,694 (Oct. 17, 2018), (2) “High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability,” 84 Fed. Reg. 71,924 (Dec. 30, 2019), (3) “Preliminary Lists Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations Under Section 6 of the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment,” 85 Fed. Reg. 4661 (Jan. 27, 2020), and (4) “Preliminary Lists Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations Under Section 6 of the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment; Extension of Comment Period,” 85 Fed. Reg. 14677 (Mar. 13, 2020).

² The TSCA Fees Rule does not apply to the EPA’s “First 10” chemical risk evaluations, which were identified outside of the prioritization process and initiated prior to the finalization of the fees structure.

C.F.R. § 700.45(b)(5) requires manufacturers to self-identify through submission of a notice to the EPA in the Central Data Exchange (CDX) system. The rule contemplates that the agency would use this information to develop a final list of entities subject to the fee. Per 40 C.F.R. § 700.45(b)(7)-(8), those manufacturers who are identified on the final list are subject to the risk evaluation fee.

Your request explains that TSCA section 3 defines “manufacture” to mean “to import into the customs territory of the United States..., produce, or manufacture.” According to your request, it has long been the agency’s position that “manufacture” under TSCA includes import of a chemical substance within an article, manufacture of a chemical substance as an impurity, and manufacture of a chemical substance as a byproduct. In other TSCA regulatory contexts, the EPA has explicitly exempted those who import chemicals in articles, produce chemicals as byproducts, and import or produce chemicals as impurities from regulatory requirements that otherwise apply to “manufacturers.” However, the final TSCA Fees Rule does not provide any exemptions to specific groups of manufacturers (*e.g.*, importers of chemicals in articles, producers of chemicals as byproducts or impurities, etc.).

Your request highlighted concerns raised by stakeholders since the January 27, 2020 release of the preliminary list of manufacturers regarding the practicalities of self-identifying under the TSCA Fees Rule given its broad definition of “manufacture.” These concerns include: 1) importers of articles containing any one of the twenty listed chemicals could potentially be required to test thousands of imported articles, which would be difficult if not impossible to complete in the time allotted for self-identification under the TSCA Fees Rule, even with the recently announced 60-day extension; 2) manufacturers of chemicals as byproducts or impurities may face similar challenges to pinpointing and tracking when impurities and byproducts are produced, particularly because the “manufacture” of even very small amounts of a high-priority chemical triggers the TSCA Fees Rule requirement to self-identify; and 3) the number of entities potentially subject to the TSCA Fee Rule has far exceeded (by several orders of magnitude) the number contemplated during the rulemaking and the calculation of associated burdens in the supporting economic analysis.

As discussed in your request, the broad scope of the current TSCA Fees Rule unintentionally imposes potentially significant burdens on importers of chemical substances in articles, and manufacturers of byproducts and impurities. Determining whether they may be subject to the TSCA Fee Rule and thus need to self-identify could be difficult or impossible for certain manufacturers across the country. Your request indicates that the inherent uncertainties and difficulties associated with identifying the presence (or not) of one or more of the 20 high-priority chemicals by these stakeholders, especially those that have not previously been subject to a TSCA regulatory requirement, creates a compliance problem and adversely impacts the agency’s implementation of the TSCA Fees Rule. As discussed above, stakeholders in these three categories would be obligated to undertake significant and burdensome efforts, efforts not contemplated when the EPA wrote the rule, to attempt to determine the presence of the listed chemicals in their products and processes.

Additionally, your request indicated the agency’s intention to immediately begin the rulemaking process³ to amend the TSCA Fees Rule and specifically to propose exemptions to the self-identification requirements associated with EPA-initiated risk evaluations for manufacturers that: 1) import the chemical substance in an article; 2) produce the chemical substance as a byproduct; and 3) produce or import the chemical substance as an impurity. For these purposes, the EPA intends to propose these

³ TSCA section 26(b) requires the EPA to consult with parties potentially subject to fees every three year and consider increasing or decreasing the amounts.

exemptions applying the definitions of “article,” “byproduct” and “impurity” in 40 C.F.R. § 720.3. The EPA would propose that such amendments apply both to the 20 EPA-initiated risk evaluations announced on December 30, 2019, and future EPA-initiated risk evaluations.⁴

In light of the extremely unusual circumstances of this situation and the undue hardship imposed on potentially thousands of entities across the country who would unnecessarily be required to collect and report information under the TSCA Fees Rule despite the agency’s plans to revise the rule to remove this requirement for certain entities, the EPA will exercise its enforcement discretion consistent with the planned regulatory change, and as a bridge to the final revised rule. More specifically, the EPA will exercise its enforcement discretion regarding the self-identification requirement for the three categories of manufacturers that the agency plans to propose to exempt from the TSCA Fee Rule. The EPA will exercise its discretion not to pursue enforcement for the following violation:

- Failure to self-identify for TSCA section 6 EPA-initiated risk assessment, as required by the TSCA Fee Rule, on or before May 27, 2020 (see 40 C.F.R. § 700.45(b)(5).)

This exercise of enforcement discretion extends only to certain “manufacturers” subject to the TSCA Fee Rule that:

- import the chemical substance in an “article;”
- produce the chemical substance as a “byproduct;” or
- produce or import the chemical substance as an “impurity.”⁵

I emphasize that this No Action Assurance applies only to the requirement for self-identification by certain “manufacturers.” I also note that nothing in this No Action Assurance affects any other provisions in the TSCA Fees Rule besides the self-identification requirement for EPA-initiated risk assessment.

This exercise of discretion is subject to the following conditions:

- The No Action Assurance is to remain in effect for the above-listed TSCA Fee Rule provision until either (1) 11:59 PM ET, September 30, 2021, or (2) the effective date of a final rule addressing the proposed exemptions to manufacture definition of the TSCA Fees Rule, whichever occurs earlier.
- The EPA reserves the right to revoke or modify this No Action Assurance.

The proposed changes to the TSCA Fees Rule, if finally adopted, would rescind the requirement for these certain manufacturers to self-identify pursuant to the current. Your request explains why this action will not result in any adverse impacts to human health or the environment. The agency’s primary interest in implementing the TSCA Fees Rule is to defray a portion of the EPA’s costs associated with carrying out various statutory provisions of TSCA. Furthermore, this action does not affect any other provision of TSCA or deprive the EPA of information or resources necessary to carry out the purposes of the TSCA Fees Rule. The exclusion of certain activities from fees-related requirements does not prevent the agency from considering those activities as part of the risk evaluation. As such, this

⁴ Note that the TSCA risk evaluation process may take up to 3.5 years to complete, and the EPA does not expect to begin additional EPA-initiated risk evaluations in the timeframe before amendments to the TSCA Fees Rule would be finalized.

⁵ The terms “article,” “byproduct” and “impurity” are defined at 40 C.F.R. § 720.3.

application of enforcement discretion will not jeopardize the agency's efforts to ensure the protection of health and the environment under TSCA.

If you have any further questions regarding this matter, please contact Phil Milton of my staff at (202) 564-5029 or milton.philip@epa.gov.

Attachment

cc: Administrator Andrew R. Wheeler
Matthew Z. Leopold, General Counsel
Rosemarie Kelley, Director, Office of Civil Enforcement
Gregory Sullivan, Office of Civil Enforcement



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SUBJECT: Request for No Action Assurance Regarding Self-Identification Requirements for Certain
“Manufacturers” Subject to the TSCA Fees Rule

FROM: Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention

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TO: Susan Parker Bodine
Assistant Administrator
Office of Enforcement and Compliance Assurance

The purpose of this memorandum is to request that the Office of Enforcement and Compliance Assurance (OECA) exercise its enforcement discretion by issuing a "No Action Assurance" for certain entities that are subject to reporting requirements pursuant to EPA's "Fees for the Administration of the Toxic Substances Control Act" (TSCA Fees Rule) finalized in October 2018.

Consistent with the 2016 amendments to TSCA section 26, the TSCA Fees Rule established a structure to collect fees for certain activities to help defray a portion of the costs associated with some TSCA implementation efforts. Among other activities, the rule requires payment of a \$1,350,000 fee in association with EPA-initiated risk evaluations under TSCA section 6.¹ See 40 CFR 700.45(c)(2)(ix). Specifically, 40 CFR 700.45(a)(3) requires payment of a fee from manufacturers of a chemical substance subject to a risk evaluation under section 6(b). Additionally, pursuant to 40 CFR 700.45(b)(3), EPA publishes a preliminary list of manufacturers identified through review of certain available data sources. To facilitate the identification of other responsible payers that were not identified on the preliminary list, 40 CFR 700.45(b)(5) requires manufacturers to self-identify through submission of a notice to EPA in the Central Data Exchange (CDX) system. The rule contemplates that the Agency would use this information to develop a final list of entities subject to the fee. Per 40 CFR 700.45(b)(7)-(8), those manufacturers who are identified on the final list are subject to the risk evaluation fee. In the absence of a consortium formed to split the cost of the applicable fee, individual fee responsibility is shared amongst identified payers pursuant to a formula and criteria specified at 40 CFR 700.45(f), but is generally divided on a per capita basis with discounts for "small business concerns."

As defined in TSCA section 3, "manufacture" means "to import into the customs territory of the United States..., produce, or manufacture." It has long been the Agency's position that "manufacture" under TSCA includes import of a chemical substance within an article, manufacture of a chemical substance as an impurity, and manufacture of a chemical substance as a byproduct. In other TSCA regulatory

¹ The TSCA Fees Rule does not apply to EPA's "First 10" chemical risk evaluations, which were identified outside of the prioritization process and initiated prior to the finalization of the fees structure.

contexts, EPA has explicitly exempted those who import chemicals in articles, produce chemicals as byproducts, and import or produce chemicals as impurities from regulatory requirements that otherwise apply to “manufacturers.” However, the final TSCA Fees Rule does not provide any exemptions to specific groups of manufacturers (e.g., importers of chemicals in articles, producers of chemicals as byproducts or impurities, etc.). As such, the TSCA Fees Rule requirements apply to all those who manufacture, as broadly defined in TSCA, a chemical substance subject to an EPA-initiated risk evaluation.

EPA did not propose any exemptions from self-identification or fee payment requirements for manufacturers of chemical substances subject to EPA-initiated risk evaluations in the proposed TSCA Fees rule. Although EPA received public comment in favor of adding exemptions, EPA ultimately determined not to include any exemptions in the final rule. In finalizing the rule, the Agency briefly discussed the decision not to include exemptions in both the preamble and response to comments document. EPA noted that the risk evaluation fee was intended to defray the costs of conducting the risk evaluation and that conditions of use – such as import of articles or manufacture of byproducts and impurities - may in fact be evaluated during the course of the risk evaluation. As such, at that time, EPA did not believe it would be appropriate to categorically exempt these categories of manufacturers from fee obligations in the rule and, thus, did not add any exemptions or exclusions from the requirements to self-identify and pay fees. In the ICR supporting the final rule that did not contain any exemptions, EPA estimated that roughly 58 entities would be subject to the self-identification requirements associated with EPA-initiated risk evaluations each year, and an associated burden of less than one hour per year.

On December 30, 2019, EPA finalized high-priority substance designations for 20 chemical substances, marking the beginning of the risk evaluation process, and triggering the first-time requirements under the TSCA Fees Rule for EPA-initiated risk evaluations. On January 27, 2020, EPA released preliminary lists of manufacturers of the 20 chemical substances.

Since that release, certain stakeholders have raised significant concerns about the practicalities of self-identifying under the TSCA Fees Rule given its broad scope. Importers of articles such as manufactured components or finished goods, for example, have acknowledged that there may be barriers to identifying with certainty the chemicals that are present in their imported articles and components. Because import of chemicals in articles has generally been exempted in other regulatory contexts under TSCA (e.g., Chemical Data Reporting rule under section 8, new chemicals program under section 5, import certification under section 13, etc.), many of these companies have not previously been required to know, and would need to undertake significant and expensive product testing efforts to find out, what chemical substances may be present in even very small amounts in the articles they import. As noted above, in the context of other rules, EPA exempted importers of articles from requirements. Imposing reporting requirements on all importers of articles containing any one of the twenty listed chemicals could potentially require the testing of thousands of imported articles and would be difficult if not impossible to complete in the time allotted for self-identification under the TSCA Fees Rule, even with the recently announced 60-day extension.

Additionally, articles importers have noted the compounding challenges of their highly complex and integrated supply chains. Articles containing a high-priority substance may be imported into the United States, exported and re-imported again – perhaps multiple times – and at times by multiple different entities. A single article like an automobile, aircraft or complex manufacturing equipment can have hundreds or thousands of individual components shipped from multiple suppliers across the globe. Importers would be required to collect information from all of these suppliers or test each article to

determine whether or not the import is subject to the TSCA Fees Rule. The nature of this complex supply and manufacturing chain makes both the tracking process and the obligation to self-identify very difficult, if not impossible.

Finally, as noted above, because these companies might not typically report under other TSCA or other environmental regulations, they would also need to register for and become familiar with EPA's reporting system. Clearly, EPA did not contemplate the TSCA Fee Rule imposing this burden on thousands of importers.

Manufacturers of chemicals as byproducts or impurities have raised similar concerns regarding the challenges of knowing whether or not they are subject to the rule. Because impurities and byproducts, by common understanding and as defined in other TSCA regulations, are unintentionally or coincidentally produced, stakeholders have noted similar challenges to pinpointing and tracking when impurities and byproducts are produced, particularly because the "manufacture" of even very small amounts of a high-priority chemical triggers the TSCA Fees Rule requirement to self-identify. Chemical manufacturers, for example, may unintentionally produce impurities of a high-priority substance during the production of another chemical. Because the presence is unintentional, it would require them to test every batch to know with certainty whether or not such substance was present. Likewise, chemical processors - who do not consider themselves "manufacturers" - may coincidentally produce (e.g., "manufacture") small amounts of a chemical as a byproduct of the processing activity. A strict reading of "manufacture" in the TSCA Fee Rule arguably could impose the self-identification and fee requirement on every home and business in the United States that combusts natural gas (e.g., every home with a gas stove or water heater). Again, clearly, that was not EPA's intent when drafting the TSCA Fee Rule.

The inherent uncertainties and difficulties associated with identifying the presence (or not) of one or more of the 20 high-priority chemicals by these stakeholders, especially those that have not previously been subject to a TSCA regulatory requirement, creates a compliance problem and adversely impacts the Agency's implementation of the TSCA Fees Rule. As discussed above, stakeholders in these three categories would be obligated to undertake significant and burdensome efforts, efforts not contemplated when EPA wrote the rule, to attempt to determine the presence of the listed chemicals in their products and processes. Alternatively, they could choose to certify as a "manufacturer" on a precautionary basis and take on the burdens associated with reporting and the responsibility for fee payment - perhaps unnecessarily, if they are not actually a "manufacturer" due to the absence of the listed chemicals in their product or process. As a result, and following the designation of these 20 chemicals for risk evaluation, it became clear that the number of implicated entities has far exceeded the number contemplated during the rulemaking and the calculation of associated burdens in the supporting economic analysis. The decision to provide no exemptions for these entities in the TSCA Fees Rule has resulted in an overly broad universe of entities subject to self-identification requirements for these EPA-initiated risk evaluations. The overly broad scope creates an undue and unavoidable hardship by imposing burdens on potentially thousands of entities across the country who would be required to collect and report information. Moreover, this scope is wholly unnecessary to properly effectuate the ultimate objective of the TSCA Fees Rule - to defray a portion of EPA's TSCA implementation costs - because the Agency will be able to collect the full fee amount regardless of the number of identified fee payers. In short, this information is unnecessary for purposes of the Fees Rule.

For these reasons, OCSPP will announce its intention to immediately begin the rulemaking process² to amend the TSCA Fees Rule and specifically to propose exemptions to the self-identification requirements associated with EPA-initiated risk evaluations for manufacturers that (1) import the chemical substance in an article; (2) produce the chemical substance as a byproduct; and (3) produce or import the chemical substance as an impurity. For these purposes, EPA intends to propose these exemptions applying the definitions of “article,” “byproduct” and “impurity” in 40 CFR 720.3. EPA would propose that such amendments apply both to the 20 EPA-initiated risk evaluations announced on December 30, 2019, and future EPA-initiated risk evaluations³.

OCSPP believes that issuing a No Action Assurance that covers the self-reporting obligation of the same three categories of “manufacturers” of the 20 listed chemical substances in conjunction with OCSPP’s announcement of its intention to propose amendments to the TSCA Fees Rule as outlined above is necessary and appropriate to address the hardships created by the rule as currently promulgated, until such time as the proposed amendments have been finalized. We request that such a No Action Assurance provide enforcement discretion for the above-described manufacturers for the self-identification requirement at 40 CFR 700.45(b)(5) until the effective date of the final rule.

This No Action Assurance would be in the public interest. As noted above, the categories of manufacturers which OCSPP plans to propose to exclude potentially represent hundreds of thousands of entities across the national economy. It would not benefit the general public to insist that these entities expend significant resources to undertake testing or other analysis merely for purposes of complying with the TSCA Fee Rule when the purpose of the rule – to defray a portion of EPA’s costs to conduct the risk evaluation - will be fully satisfied by the manufacturers that remain subject to the TSCA Fee Rule. Moreover, as noted above, it was clearly not the EPA’s intent during the development of the rule that it would have such a broad impact.

In addition, we do not anticipate this action will result in any adverse impacts to human health or the environment. Again, the Agency’s primary interest in implementing the TSCA Fees Rule is to defray a portion of EPA’s costs associated with carrying out various statutory provisions of TSCA. The fee amount for each of the 20 ongoing EPA-initiated risk evaluations is set at \$1,350,000, regardless of the number of manufacturers identified for each chemical. As such, the identification of fewer responsible fee payers as a result of this action is not expected to reduce the amount of money collected by EPA. Furthermore, this action does not affect any other provision of TSCA or deprive EPA of information or resources necessary to carry out the purposes of the TSCA Fees Rule. The exclusion of certain activities from fees-related requirements does not prevent the Agency from considering those activities as part of the risk evaluation. As such, the No Action Assurance would not jeopardize the Agency’s efforts to ensure the protection of health and the environment under TSCA.

Please feel free to contact me for further information, or your staff may contact Mark Hartman at (202) 564-0985. We have worked closely with OECA on determining the extent to which enforcement discretion might appropriately be provided, and their assistance has been extremely helpful. Thank you for your consideration of this request.

² TSCA section 26(b) requires EPA to consult with parties potentially subject to fees every three year and consider increasing or decreasing the amounts.

³ Note that the TSCA risk evaluation process may take up to 3.5 years to complete, and EPA does not expect to begin additional EPA-initiated risk evaluations in the timeframe before amendments to the TSCA Fees Rule would be finalized.

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