



December 17, 2021

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

Re: Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting ((Docket ID No. EPA-HQ-TRI-2017-0434)

Dear Administrator Regan:

On October 18, 2021, the Environmental Protection Agency (EPA) published a notice of proposed rulemaking titled “Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting.”¹ In this proposed rule, EPA is proposing to add twelve chemicals, including 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB), to be reported in its Toxic Release Inventory (TRI) publicly available database. Advocacy is concerned that the impact of this rule may be underestimated. The Office of Advocacy’s (Advocacy) recommends the agency to use the most recently available public information and to engage in targeted small business outreach to inform its analysis for this rulemaking.

I. Background

A. The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),² as

¹ 86 Fed. Reg. 57614 (October 18, 2021).

² 5 U.S.C. §601 et seq.

amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),³ gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.⁴ The agency must include, in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.⁵

B. The Proposed Rule

In response to a petition filed under the Emergency Planning and Community Right-to-Know Act (EPCRA),⁶ EPA has proposed to add HHCB, along with 11 other chemicals, to the list of toxic chemicals subject to the reporting requirements under EPCRA and the Pollution Prevention Act (PPA).⁷ HHCB is primarily used as a fragrance additive in a number of consumer products including perfumes, cosmetics, shampoos, lotions, detergents, fabric softeners, and household cleaners. Prior to its incorporation into a final product, HHCB is processed with various other chemicals. As a result, it is used throughout the supply chain, various layers removed from the manufacturer or importer.

Under these reporting requirements, owners or operators of certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above the reporting threshold levels must annually report their facilities' environmental releases and other waste management information on such chemicals.⁸ They are also required to report pollution prevention and recycling data for such chemicals.⁹ This information is submitted on a form and is included in a publicly available database, TRI.¹⁰ EPA is authorized to amend its list of toxic chemicals by adding chemicals¹¹ if one of the three criteria is satisfied.¹²

³ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

⁴ Small Business Jobs Act of 2010 (PL. 111-240) §1601.

⁵ *Id.*

⁶ 42 U.S.C. § 11023.

⁷ 42 U.S.C. § 13101 et seq.

⁸ 42 U.S.C. § 11023.

⁹ 42 U.S.C. § 13106.

¹⁰ 42 U.S.C. § 11023(a).

¹¹ *Id.* at 11023(d).

¹² "(A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases. (B) The chemical is known to cause or can reasonably be anticipated to cause in humans—(i) cancer or teratogenic effects, or (ii) serious or irreversible—(I) reproductive dysfunctions, (II)

Moreover, EPA is proposing to add HHCB to the list of chemicals of special concern as a persistent, bioaccumulative, and toxic (PBT) chemical¹³ with the lower reporting threshold of 100 pounds.¹⁴ The regular threshold for reporting is 25,000 pounds for manufacturing and processing and 10,000 pounds for a chemical “otherwise used.”¹⁵ EPA reports that its PBT classification is based on information demonstrating that HHCB bioaccumulates in aquatic species and is persistent in soil and sediment.¹⁶

EPA is also currently evaluating HHCB under the Toxic Substance Control Act (TSCA) as a high priority chemical; however, the risk evaluation required by TSCA has not been completed.¹⁷

II. Advocacy’s Small Business Concerns

Advocacy is concerned about the impact of this rule, given the extremely low threshold for reporting and the multiple downstream users of HHCB who would be subject to the rule’s requirements. Advocacy recommends the agency assess the number of small entities that could be subject to the proposed requirements using the most recently available information. The agency should also engage in targeted outreach to address any gaps in its analysis and to offer compliance assistance to the potentially regulated small entities. These improvements will allow the agency to promulgate a rule that takes those impacts into account, achieves its statutory goals, and ensures compliance with its rule.

neurological disorders, (III) heritable genetic mutations, or (IV) other chronic health effects. (C) The chemical is known to cause or can reasonably be anticipated to cause, because of—(i) its toxicity, (ii) its toxicity and persistence in the environment, or (iii) its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section. The number of chemicals included on the list described in subsection (c) on the basis of the preceding sentence may constitute in the aggregate no more than 25 percent of the total number of chemicals on the list.

A determination under this paragraph shall be based on generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to the Administrator.” 42 U.S.C. § 11023(d)(2).

¹³ See 40 C.F.R. § 372.28(a)(2). “...EPA established the PBT classification criteria for chemicals on the EPCRA section 313 chemical list. For purposes of EPCRA section 313 reporting, EPA established persistence half-life criteria for PBT chemicals of 2 months in water, sediment and soil and 2 days in air, and established bioaccumulation criteria for PBT chemicals as a bioconcentration factor (BCF) or bioaccumulation factor (BAF) of 1,000 or higher.” 86 Fed. Reg. at 57616.

¹⁴ See, *Persistent Bioaccumulative Toxic (PBT) Chemicals; Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Community Right-to-Know Toxic Chemical Reporting*, 64 Fed. Reg. 58666 (October 29, 1999).

¹⁵ *Id.* at 372.25(a)-(b).

¹⁶ See 86 Fed. Reg. at 57618.

¹⁷ See, *Assessing and Managing Chemicals under TSCA, Risk Evaluation for 1,3,4,6,7,8-Hexahydro-4,6,6,7,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)*, U.S. Environmental Protection Agency, *available at* <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-134678-hexahydro-466788>.

A. EPA Must Use the Most Recently Available Data and Engage in Small Entity Outreach to Inform its Analysis

1. EPA should update its economic impact analysis with the most recently available information in the final rule

EPA's economic analysis is dated "November 7, 2018"¹⁸ and relies on the 2016 Chemical Data Reporting (CDR)¹⁹ information reported for HHCB, which accounts for 2015 activities.²⁰ EPA partly relied on the knowledge of the importers subject to CDR to estimate the number of downstream users of HHCB. Therefore, Advocacy recommends EPA incorporate the 2020 CDR data, if available, into the final rule to determine whether additional entities could be impacted by this proposed rule. In addition, Advocacy urges the agency to use the most recent U.S. Census data available to determine the number of affected small entities when writing the final rule.

EPA partly relied on the user knowledge of the importers reporting under CDR to estimate the number of downstream users. According to small business representatives, this is not sufficient and will not account for all users of HHCB that would be subject to the reporting requirement. In estimating the number of potentially impacted entities, EPA acknowledges that "[d]ue to the lack of information on downstream users..., estimates of total HHCB industrial users and processors may be underestimated."²¹ For example, small business representatives pointed out that while importers can identify users they sell to directly, they may not be able to identify downstream users when their direct customers are distributors. Further, the chemical can be sold to a reseller or a custom manufacturer who then sells it to another user. These downstream users may not be included in EPA's impact analysis assessing the number of entities that will be subject to the reporting requirement. In addition, if the costs to these downstream users, such as chemical identification, differ from the costs to the importer's immediate customers, then EPA may have omitted important impacts of the rule. Advocacy urges EPA to engage in outreach with small businesses to address any gaps in its analysis given the shortcomings of CDR as well as the multiple layers within the supply chain of this chemical's use. Furthermore, through its engagement with stakeholders, EPA should ensure that the estimated burden reflects whether these users are already familiar with the TRI, especially for small businesses that may need to establish a reporting framework.

2. EPA should use the most recent information available to inform analysis for its PBT classification of HHCB in the final rule

Small business representatives have expressed concerns that EPA does not use the most recently available and relevant studies in support of its classification of HHCB as a PBT chemical of

¹⁸ Economic Analysis of the Proposed Rule to Add Twelve Chemicals Identified in a Petition from the Toxics Use Reduction Institute to the EPCRA Section 313 List of Toxic Chemicals, [Economic Analysis] (November 7, 2018).

¹⁹ The Chemical Data Reporting rule requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce. See, 40 C.F.R. § 711.1.

²⁰ Economic Analysis at pg. 2-4.

²¹ *Id.* at pg. 2-27.

concern. In addition, they have also expressed concerns about EPA's work on the HHCB risk evaluation under TSCA. Advocacy urges the agency to ensure that it is using the most recently available and relevant information to inform its determination of HHCB as a PBT chemical of concern. Advocacy also suggests the agency provide the public with as much transparency as permissible regarding any overlap with its ongoing risk evaluation for HHCB under TSCA with its PBT analysis under EPCRA.

B. EPA Should Offer Targeted Compliance Assistance for First-Time Reporters

Advocacy is concerned about the large number of entities that will likely be subject to this rulemaking given the 100-pound reporting threshold. Many of these entities will likely be first-time reporters under TRI. To assist with compliance, Advocacy urges EPA to develop targeted resources such as a HHCB-specific guidance for small entities or update its existing guidance for PBT chemicals to address any reasonably foreseeable issues with this chemical. Advocacy also urges the agency to engage in additional outreach with small entities to offer compliance assistance by providing training webinars targeted towards first-time reporters for HHCB.

III. Conclusion

Advocacy is concerned that the impact of this rule may be underestimated. Therefore, Advocacy has provided recommendations for the agency to use the most recently available public information and to engage in targeted small business outreach to inform its analysis for this rulemaking. Advocacy urges EPA to give full consideration to the above issues and recommendations. We look forward to working with you to reduce the regulatory burden on small businesses.

If you have any questions or require additional information please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 798-7405 or by email at tayyaba.zeb@sba.gov.

Sincerely,

/s/

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Deputy Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

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Copy to: Sharon Block, Associate Administrator
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