E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2024-0029; FRL-11666-01-OCSPP]

Polychlorinated biphenyls (PCBs); TSCA Section 21 Petition for Rulemaking under TSCA Section 6; Reasons for Agency Response; Denial of Requested Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for agency response.

SUMMARY: This action announces the availability of the Environmental Protection Agency (EPA or the Agency) response to a petition received on January 4, 2024, from the Washington State Department of Ecology (the petitioner), asking EPA to initiate rulemaking under the Toxic Substances Control Act (TSCA) to safeguard public health against PCBs in consumer products. EPA shares the petitioner's concerns regarding risks to human health and the environment posed by PCBs, and the Agency continues to work towards better understanding and reducing exposures to PCBs. However, the petitioner failed to point with any specificity to deficiencies in the Agency's 1984 final rule and determination of no unreasonable risk under TSCA. As a result, the petitioner has not provided adequate justification – based on the rulemaking process and record for the 1984 final rule and information provided or otherwise available to the Agency – to support reassessing the limits on allowable inadvertent PCBs in consumer products. Thus, EPA finds that the petition is insufficiently specific, and that the petitioner did not meet their burden under TSCA of establishing that it is necessary to amend the 1984 final rule. These deficiencies, among other findings, are detailed in this notice and serve as the reasons for the Agency's denial of the petition. As necessary and appropriate to supplement ongoing Agency efforts, EPA may consider information gathering activities under TSCA to collect data needed to better understand and characterize exposure and risk associated with inadvertently generated PCBs.

DATES: EPA's response to this petition was signed April 3, 2024.

ADDRESSES: The docket for this petition, identified by docket identification (ID) number

EPA-HQ-OPPT-2024-0029, is available online at *https://www.regulations.gov*. Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. *Does this action apply to me?*

This action is directed to the public in general. This action may, however, be of interest to those persons who manufacture (including import), process, distribute in commerce, use, or dispose of PCBs. Since other entities may also be interested, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. *What is EPA's authority for taking this action?*

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or to issue an order under TSCA sections 4, 5(e), or 5(f). A TSCA section 21 petition must set forth the facts which it is claimed establish that it is necessary to initiate the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the ***Federal Register***. A petitioner may commence a civil action in a U.S. district court seeking to compel initiation of the requested proceeding within 60 days of a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

C. *What criteria apply to a decision on this TSCA section 21 petition?*

1. *Legal standard regarding TSCA section 21 petitions.*

TSCA section 21(b)(1) requires that the petition "set forth the facts which it is claimed establish that it is necessary" to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). Thus, in addition to a petitioner's burden under TSCA section 21 itself, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, EPA has reviewed this TSCA section 21 petition by considering the standards in TSCA section 21 and in the provisions under which actions have been requested.

2. *Legal standard regarding TSCA section 6(e).*

TSCA section 6(e)(1) gives EPA authority to promulgate rules regarding the disposal and marking of PCBs. 15 U.S.C. 2605(e)(1). TSCA section 6(e)(2) and (e)(3) generally prohibit the manufacture, processing, distribution in commerce, and use (other than totally enclosed use) of PCBs. 15 U.S.C. 2605(e)(2) and (e)(3). Under TSCA section 6(e)(2)(B), EPA may by rule authorize the use of PCBs in other than a totally enclosed manner if EPA finds that such use will not present an unreasonable risk of injury to health or the environment. 15 U.S.C. 2605(e)(2)(B). Under TSCA section 6(e)(3)(B), EPA may grant by rule an exemption from the general prohibitions in TSCA section 6(e)(3)(A) on the manufacturing, processing, and distribution in commerce of PCBs if EPA finds that such activities would not result in an unreasonable risk of injury to health or the environment, and good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for PCBs. 15 U.S.C. 2605(e)(3)(B). As provided in TSCA section 6(e)(5), section 6(e) does not limit EPA's authority to take action on PCBs under any other provision of TSCA or any other federal law. 15 U.S.C. 2605(e)(5).

3. *Legal standard regarding TSCA section 26.*

To the extent that EPA makes a decision based on science, TSCA section 26(h) requires EPA, in carrying out TSCA sections 4, 5, and 6, to use "scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science," while also taking into account other considerations,

including the relevance of information and any uncertainties. 15 U.S.C. 2625(h). TSCA section 26(i) requires that decisions under TSCA sections 4, 5, and 6 be "based on the weight of the scientific evidence." 15 U.S.C. 2625(i). TSCA section 26(k) requires that EPA consider information that is reasonably available in carrying out TSCA sections 4, 5, and 6. 15 U.S.C. 2625(k).

II. Summary of the TSCA Section 21 Petition

A. *What action was requested?*

On January 4, 2024, EPA received a TSCA section 21 petition (Ref. 1) from the Washington State Department of Ecology. The petition requests EPA in general to "initiate rulemaking to safeguard public health against polychlorinated biphenyls . . . in consumer products" (Ref. 1, p. 1). More specifically, the petition asks that "EPA commence rulemaking to eliminate the current allowances for PCBs in consumer products" (Ref. 1, p. 1) via five actions: "1. Commence rulemaking to reassess limits on allowable inadvertent PCBs found in consumer products . . . as detailed in the definitions of [']excluded manufacturing process['] and [']recycled PCBs['] found in 40 CFR 761.3. . . . 2. Adopt a new rule that identifies use of pigments containing PCBs as a [']use['] of PCBs. . . . 3. In collaboration with state and tribal governments, establish new, lower limits on allowable inadvertent PCBs in consumer products. . . . 4. In collaboration with state and tribal governments, establish priority consumer products that will be subject to lower allowable limits of inadvertent PCBs at an earlier date. . . . 5. In collaboration with state and tribal governments, reassess limits on all allowable PCBs found in commercial products, as detailed in 40 CFR 761, et seq., and establish a rulemaking schedule for the adoption of revised regulations" (Ref. 1, p. 3).

For the purposes of assessing the petition within the scope of TSCA section 21, EPA is interpreting these requests generally and collectively as requesting the Agency to initiate a proceeding for the amendment of a final rule issued under TSCA section 6(e) in 1984 (Ref. 2) (see Ref. 1, p. 4: "This petition requests EPA to reassess rules adopted June 27, 1984, pursuant to

authority under [TSCA section 6], thereby making it subject to a Section 21 petition."). More specifically, EPA is interpreting this request to amend the definitions of "excluded manufacturing process" and "recycled PCBs" at 40 CFR 761.3, established in the 1984 final rule, to the extent that they refer to and establish limits for "PCBs in products leaving any manufacturing site or imported into the United States" and "PCBs in paper products leaving any manufacturing site processing paper products, or in paper products imported into the United States." EPA is also interpreting this request to amend the exemptions for excluded manufacturing processes and recycled PCBs at 40 CFR 761.1(f)(2) and (3), also established in the 1984 final rule, to the extent that they refer to "[p]ersons who . . . use products containing PCBs generated in excluded manufacturing processes defined in § 761.3" and "[p]ersons who . . . use products containing recycled PCBs defined in § 761.3."

1. *Request for rulemaking associated with limits for inadvertently generated PCBs in "consumer products."*

The petition requests that EPA take three actions related to the authorized limits for inadvertently generated PCBs in consumer products: (1) Commence rulemaking to reassess limits on allowable inadvertent PCBs in consumer products; (2) Collaborate with state and tribal governments to establish new, lower regulatory limits on inadvertent PCBs in consumer products and identify appropriate test methods; and (3) Collaborate with state and tribal governments to phase in lower limits on inadvertently generated PCBs in consumer products, starting with priority consumer products. The requested actions include collaboration with state and local governments, which EPA believes is attendant to the petitioner's general request for rulemaking under TSCA section 6. The Agency's policy on conducting rulemaking encourages appropriate and meaningful consultation with external stakeholders, including state, tribal and local officials. As the petitioner is seeking to amend an existing rule under TSCA section 6, this ***Federal Register*** document addresses this request.

2. *Request for rulemaking associated with "use of pigments containing PCBs."*

The petition requests that EPA adopt a new rule that identifies the use of pigments containing inadvertent PCBs to be a "use" of PCBs, subject to the applicable limitations under 40 CFR 761.20(a). EPA interprets this request as the petitioner seeking to amend an existing rule under TSCA section 6; this ***Federal Register*** document addresses this request.

3. *Request for rulemaking associated with "all allowable PCBs found in commercial products."*

The petition requests that EPA collaborate with state and tribal governments to reassess limits on allowable non-inadvertent PCBs in commercial products. The requested action includes collaboration with state and local governments, which EPA believes is attendant to the petitioner's general request for rulemaking under TSCA section 6. The Agency's policy on conducting rulemaking encourages appropriate and meaningful consultation with external stakeholders, including state, tribal and local officials. As the petitioner is seeking to amend an existing rule under TSCA section 6, this ***Federal Register*** document addresses this request.

B. *What support did the petitioner offer?*

To support the requests for rulemaking under TSCA section 6(e), the petitioner provided a discussion of legislative and regulatory authorities related to PCBs and inadvertently generated PCBs (Ref. 1, pp. 5-6), as well as information on the historical manufacture and uses of PCBs (Ref. 1, pp. 7-8), impacts of PCBs on human health and the environment, including sensitive species (Ref. 1, pp. 8-11), the presence of and potential for exposure to inadvertently generated PCBs in consumer products (Ref. 1, pp. 11-14), and the availability of safer alternatives to paints and inks that contain inadvertently generated PCBs (Ref. 1, pp. 14-15). The petitioner also provided a bibliography of references cited (Ref. 1, pp. 16-20). The Agency appreciates the information provided in the petition and finds it generally consistent with decades of peer-reviewed and published data on PCBs.

III. Disposition of TSCA Section 21 Petition

A. *What is EPA's response?*

EPA shares the petitioner's concerns regarding risks to human health and the environment posed by PCBs, including information related to indigenous populations in Washington State and to sensitive species like orcas and seals, and the Agency continues to work towards better understanding and reducing exposures to PCBs. However, as described in Unit III.B.1., the petitioner failed to point with any specificity to deficiencies in the Agency's promulgation of the 1984 final rule and determination of no unreasonable risk under TSCA section 6(e). As a result, the petitioner has not provided adequate justification – based on the rulemaking process and record for the 1984 final rule, as well as information provided or otherwise available to the Agency – for reassessing the limits on allowable inadvertent PCBs in consumer products. Thus, EPA finds that the petition is insufficiently specific and that the petitioner did not meet their burden under TSCA section 21(b)(1) of establishing that it is necessary to amend the 1984 final rule under TSCA section 6(e). Therefore, after careful consideration, EPA has denied this TSCA section 21 petition. As necessary and appropriate to supplement ongoing Agency efforts (see Unit III.B.1.e.), EPA may consider information gathering activities under TSCA (e.g., TSCA sections 4 or 8) to collect data needed to better understand and characterize exposure and risk associated with inadvertently generated PCBs.

A copy of the Agency's response, which consists of the letter to the petitioner and this document, is posted on the EPA TSCA petition website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#PCBs*. The response, the petition (Ref. 1), and other information is available in the docket for this TSCA section 21 petition (see **ADDRESSES**).

B. *What was EPA's reason for this response?*

TSCA section 21 provides for the submission of a petition seeking the initiation of a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 6. The petition must set forth the facts which it is claimed establish that it is necessary to initiate the action requested. 15 U.S.C. 2620(b)(1). EPA considered whether the petition established that it is

necessary to amend the 1984 TSCA section 6(e) final rule establishing definitions of "excluded manufacturing process" and "recycled PCBs" at 40 CFR 761.3 and exemptions for excluded manufacturing processes and recycled PCBs at 40 CFR 761.1(f)(2) and (3). For EPA to be able to conclude within the statutorily-mandated 90 days of receiving the petition that the initiation of a proceeding for the amendment of the 1984 final rule is necessary, the petition needs to be sufficiently clear and robust.

EPA evaluated the information presented in the petition and considered that information in the context of the applicable authorities and requirements of TSCA sections 6, 21, and 26. Notwithstanding that the burden is on the petitioner to set forth the facts which it is claimed establish that it is necessary for EPA to initiate the action requested, EPA nonetheless also considered relevant information that was reasonably available to the Agency during the 90-day petition review period. As detailed further in Units III.B.1., 2., and 3., EPA finds that the petition is insufficiently specific and that the petitioner did not meet their burden under TSCA section 21(b)(1) of establishing that it is necessary to amend the 1984 final rule under TSCA section 6(e). These deficiencies, among other findings, are detailed in this notice.

1. *Necessity of rulemaking associated with limits for inadvertently generated PCBs in consumer products.*

The "primary issue" (Ref. 1, p. 4) raised by the petitioner is the "Recommendation of the Parties for a Final EPA Rule on Inadvertent Generation of PCBs" (hereinafter "consensus proposal"), which formed part of the framework for the finding of no unreasonable risk in the 1983 proposed rule "Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations; Proposed Rule" (Ref. 3), and 1984 final rule, "Toxic Substances Control Act; Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Exclusions, Exemptions, and Use Authorizations" (Ref. 2), and led to the establishment of the definitions for "excluded manufacturing process" and "recycled PCBs" (see 40 CFR 761.3). The former definition contains the allowance related to inadvertently generated

PCBs in consumer products in general: "The concentration of inadvertently generated PCBs in products leaving any manufacturing site or imported into the United States must have an annual average of less than 25 [parts per million (ppm)], with a 50 ppm maximum" (see 40 CFR 761.3). The latter definition contains a similar allowance for PCBs that appear in the processing of paper products from PCB-contaminated raw materials: "The concentration of PCBs in paper products leaving any manufacturing site processing paper products, or in paper products imported into the United States, must have an annual average of less than 25 ppm with a 50 ppm maximum" (see 40 CFR 761.3). The petitioner states "[t]here is no indication in the 1984 rulemaking notice that the limits proposed [in the consensus proposal] and adopted by EPA are based on any specific scientific study or reasoning." (Ref. 1, p. 4). The Agency disagrees with this characterization.

a. *1983 proposed rule for inadvertently generated PCBs.*

In the 1983 proposed rule (Ref. 3), EPA described the litigation and related processes that led to the submission of the consensus proposal to the Agency, as well as the receipt of comments and information related to inadvertently generated PCBs and recycled PCBs. The Agency also described how it determined that it was appropriate to use, in part, the consensus proposal as a framework for rulemaking, based on "data analyses EPA had completed when it received the consensus proposal" (Ref. 3). EPA also described modifications that EPA intended to make to the underlying framework linked to the consensus proposal, including consideration of recycled PCBs and lower concentration limits for certain products with a greater potential for exposure, as well as the rejection of provisions that could result in high level releases of PCBs in air, water, or products that could cause injury to health or the environment (Ref. 3).

The Agency then summarized several approaches it considered and rejected in its effort to "provide regulatory relief from the prohibitions of section 6(e) for PCBs at very low levels that do not present unreasonable [risks] to public health," including the exemption process of TSCA section 6(e)(3)(B) and developing regulatory limits on concentration levels for each chemical process in which inadvertently generated PCBs are generated (Ref. 3). EPA also

considered the use of "generic exposure assessments" that could be used to estimate "risks of cancer and reproductive/developmental health" and, ultimately "in developing generic exclusions, if warranted, based on a determination that particular classes of processes generating PCBs at low levels would not present unreasonable risks" (Ref. 3). The generic risk assessments were then focused on a group of 70 chemical processes determined to have a high potential for PCB generation, which the Agency narrowed from an initial list of approximately 200 chemical processes with a potential for generating PCBs (Ref. 3). EPA then acknowledged that "[t]he generic exposure assessment approach is less resource-intensive than the chemical-specific approach; however, it is protective of human health and the environment" (Ref. 3). In addition, EPA explained "[t]he regulatory strategy initially pursued by EPA, based on generic exclusions, is more detailed and specific than the consensus approach which sets a simple regulatory limit. EPA has adopted the generic exclusion approach in developing this rulemaking; however, EPA's approach supports the regulatory framework submitted . . . in the consensus proposal" and "in using the consensus proposal to develop this proposed rule, EPA has also used the Closed and Controlled Waste Manufacturing Processes Rule as a framework. Furthermore, the PCB analytical chemistry methodology developed to determine PCB concentration under that rule serves this proposed rule" (Ref. 3).

The Agency then declared "EPA has considered the consensus proposal in terms of the required findings of sections 6(a) and 6(e) of TSCA and has decided to adopt an unreasonable risk test to support this proposed rule. By adopting this approach, EPA believes . . . that the Agency is consistent with congressional intent and is reasonably regulating inadvertently generated and recycled PCBs" (Ref. 3). The Agency then arrived at its determination of no unreasonable risk (including the listing of applicable risk and hazard assessments and a regulatory impact analysis) by stating "[a]fter the Closed and Controlled Waste Manufacturing Processes rule was published, EPA completed quantitative risk assessments for PCBs. Based on the risk assessment for carcinogenicity as well as information on reproductive/developmental

effects, environmental effects, and costs, EPA has determined that the manufacture, processing, distribution in commerce, and use of PCBs below the limits proposed in the consensus proposal would not present an unreasonable risk of injury to human health or the environment" (Ref. 3). EPA then concluded "[b]ased on the risk assessments conducted by EPA and the consensus proposal, the Agency is proposing to exclude from the prohibitions of section 6(e) of TSCA those activities (including manufacture, processing, distribution in commerce, and use) that meet" a list of criteria (Ref. 3) that would become the requirements listed in the definition of "excluded manufacturing process" at 40 CFR 761.3, including the current concentration limits for inadvertently generated PCBs in products. EPA also evaluated the risk of exposure to recycled PCBs and concluded that "these risks are substantially similar to those risks for the inadvertently generated PCBs" and therefore proposed to establish the same concentration limits for recycled PCBs in products (Ref. 3).

b. *1984 final rule for inadvertently generated PCBs.*

In the 1984 final rule (Ref. 2), the Agency largely repeated the discussion of its process to reach the no unreasonable risk determination presented in the 1983 proposed rule, but also provided a summary of the general comments submitted. The comments discussed mentioned recommendations to modify the proposed rule and supporting documents, including requested edits to the nomenclature for specific consumer products (i.e., "detergent bars" and "plastic building materials"), uncertainty among commenters about which Aroclor products were to be included under the definition of "recycled PCBs," the limit of quantification for Aroclor PCBs in water, and the designation of certain chemical processes as having a high potential to inadvertently generate PCBs (Ref. 2). The Agency also stated that the "majority of the comments received in this rulemaking generally agreed with the exclusions proposed" (Ref. 2). Absent from this summary were comments that questioned or otherwise challenged key aspects of the process the Agency used, including the framework involving the consensus proposal, to reach the no unreasonable risk determination (Ref. 2).

c. *2010 advance notice of proposed rulemaking*

In 2010, EPA issued an advance notice of proposed rulemaking (ANPRM) for the use and distribution in commerce of certain classes of PCBs and PCB items, as well as other PCB regulations (Ref, 4). Among the items in the ANPRM's request for public comment was reassessment of definitions of "excluded manufacturing process" and "recycled PCBs" (Ref. 4). EPA stated the "objective of this ANPRM is to announce the Agency's intent to reassess the current use authorizations for certain PCB uses to determine whether they may now pose an unreasonable risk to human health and the environment. This reassessment will be based in part upon information and experience acquired in dealing with PCBs over the past 3 decades" (Ref. 4). Related to the definitions of "excluded manufacturing process" and "recycled PCBs," as well as other topics related to inadvertently generated PCBs, EPA received an array of comments available in the docket at *https://www.regulations.gov/docket/EPA-HQ-OPPT-2009-0757*. Commenters seeking to lower or eliminate allowances for excluded manufacturing processes mentioned concerns related to PCBs in dyes, pigments, and inks in imported products; elimination of all federal exclusions or exceptions for inadvertently generated PCBs; the status of monochloro-biphenyls and dichloro-biphenyls from total PCB regulation due to lower potential for bioaccumulation and human health toxicity; and lowering the allowable concentration of PCBs in dyes, inks and pigments using a phased approach and in concert with federal and state actions involved in developing water quality criteria and implementation. Commenters seeking to maintain the allowances for excluded manufacturing processes offered that establishing a 1 ppm threshold would eliminate three important pigment groups from commerce and affect color printing, paint, and plastics due to the absence of technology to eliminate PCBs in all organic pigments to a level below 1 ppm; and raised concerns that U.S. pigment and product manufacturers could be at additional competitive disadvantage versus pigment and product importers. After reviewing comments received, the Agency took no actions related to the definitions of "excluded manufacturing process" and "recycled PCBs," which remain as defined

in the 1984 final rule (Ref. 2).

d. *Petition's lack of specificity in citing flaws in EPA's 1984 determination of no unreasonable risk.*

As described in Unit III.B.1.a. and b., the Agency articulated in both the 1983 proposed rule and 1984 final rule how and why it used, in part, the consensus proposal as part of the rule framework, as well as its additional processes to gather information and perform scientific and regulatory analyses to support its no unreasonable risk determination for excluded manufacturing processes and recycled PCBs. As part of the discussion, EPA described its own assessment of the consensus proposal, as well as the statements of the organizations that negotiated and presented it. Through the course of the rulemaking, the Agency solicited, received, and responded to public comment on various aspects and processes set forth in the proposed and final rules, as well as supporting documents. In addition, the 2010 ANPRM provided opportunity for public comment on the definitions of "excluded manufacturing process" and "recycled PCBs" (Ref. 4).

Thus, while the petitioners assert that the 1984 final rule does not indicate that the "limits proposed [in the consensus proposal] and adopted by EPA are based on any specific scientific study or reasoning" (Ref. 1, p. 4), the rulemaking record shows that EPA applied a pragmatic, transparent, and appropriate scientific approach to reach its no unreasonable risk determination. As described in Unit III.B.1.a., the 1983 proposed rule (Ref. 3) describes in detail the Agency's scientific risk assessments; and copies of these documents are included in the docket for this notice (see EPA-HQ-OPPT-2024-0029). The petitioner did not provide details about how the Agency failed to meet its burden when it promulgated the 1984 final rule. In fact, the 1984 final rule states how the Agency carefully considered each of the factors for determining unreasonable risk and concluded that the exclusions for inadvertently generated PCBs and recycled PCBs are "based on a finding that such PCBs present no unreasonable risk of injury to human health and the environment" (Ref. 2).

Furthermore, the 1984 final rule requires that manufacturers or importers of products

containing inadvertently generated PCBs must notify EPA within 90 days if those products contain greater than 2 ppm PCB concentration in any resolvable gas chromatographic peak (see 40 CFR 761.185). Since 1994, EPA has received about 80 notices from 28 companies, and the frequency of such notifications has been decreasing; EPA has not received any new notice in several years. The infrequency of notification indicates that there may be little ongoing manufacture or import of products containing inadvertently generated PCBs at concentrations greater than 2 ppm PCBs. Similarly, after issuing the 2010 ANPRM and receiving comments on the definitions of "excluded manufacturing process" and "recycled PCBs," the Agency did not find a compelling rationale to take immediate action to reassess the no unreasonable risk determination. Therefore, based on the robust rulemaking record for the 1984 rule, and limited information indicating that EPA's unreasonable risk determination supporting the rule was flawed or is now outdated, the Agency has decided not to reassess the limits for inadvertently generated PCBs or recycled PCBs at this time. Nonetheless, EPA recognizes the concerns related to human health and the environment posed by PCBs in general and is working towards better understanding those concerns, as described in Unit III.B.1.e.

e. *Information provided and substantial ongoing and expected Agency actions.*

As previously mentioned, the Agency appreciates the information provided in the petition and finds it generally consistent with decades of peer-reviewed and published data on PCBs. In a discussion of EPA actions, activities, and regulations (Ref. 1, pp. 3-4), the petitioner focuses on the legislative, regulatory, and adjudicative milestones spanning the enactment of TSCA to the 1984 final rule. The petitioner also summarizes comprehensive information developed by EPA, other government authorities, and scientific researchers, which contribute to the collective scientific knowledge about the characteristics, sources, exposure pathways, and environmental and human health effects of PCBs. In addition, EPA is mindful of the information submitted regarding the impacts of PCBs among sensitive wildlife and human populations in Washington, including local indigenous populations whose diet typically consists of greater amounts of fish

than other communities. EPA also notes the petitioner's acknowledgment that among the 209 identified PCB congeners, which have "different physical properties, toxicity, and environmental fates, [. . .] there are characteristics that are applicable to all PCBs [and the] petition is based on these common characteristics" (Ref. 1, pp. 5-6). Finally, EPA finds that the product category for which the petitioner provides the bulk of the information for inadvertently generated PCBs is paints and printing inks, as well as other components of those products (e.g., pigments and dyes).

Throughout the implementation of TSCA section 6(e), the Agency has generated and collected a large amount of information related to PCBs. In addition, the widespread presence of PCBs in the environment is reflected by the manner in which EPA programs study, regulate, and enforce the PCB program under TSCA and other authorities across multiple offices within the Agency. The Agency's Integrated Risk Information System (IRIS) established in 1994 a non-cancer reference dose for oral exposure (RfD) for the PCB mixture Aroclor 1254 of 20 ng PCB/kg body weight per day and an RfD for Aroclor 1016 of 70 ng PCB/kg body weight per day. A 1996 weight-of-evidence characterization classified PCBs as a probable human carcinogen, and IRIS currently provides cancer dose oral slope factors of 2 per mg PCB/kg body weight per day (high risk and persistence, upper bound), 0.4 per mg PCB/kg body weight per day (low risk and persistence), and 0.07 per mg PCB/kg body weight per day (lowest risk and persistence). Additionally, the IRIS program is currently in the process of updating its non-cancer assessment of PCB mixtures available at *https://iris.epa.gov/ChemicalLanding/&substance_nmbr=294*.

While EPA has substantial information on PCBs in general, inadvertently generated PCBs remain an area of interest for the Agency. EPA is currently studying and anticipates continuing to study the complex issues involved in the generation, release, exposure, hazards, and risks to human health and the environment associated with inadvertently generated PCBs. For example, EPA has a workgroup on inadvertently generated PCBs, with members from the Office of Land and Emergency Management (OLEM), the Office of Research and Development

(ORD), and EPA Regions, that has been conducting and assessing water samples from watersheds in EPA Region 10 and other watersheds in the United States.

Before proposing more stringent regulations on the inadvertent generation of PCBs in consumer products, EPA would seek to further understand the complexities and contributions of individual PCB congeners associated with inadvertently generated PCBs that may be present in U.S. waters. At present, there are not sufficient data to assess such PCB congeners. However, in a step toward addressing this deficiency, in 2014, the Agency requested toxicity testing for PCB-11, a PCB congener often associated with inadvertent PCB generation, through the National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences (NIESH). As of November 2021, NTP had completed several steps for evaluating toxicity in liver cells: (1) Evaluated and compared activation of three different receptors in rat and human hepatocytes; (2) Performed hepatocyte clearance on rat and human hepatocytes; and (3) Estimated rat and human equivalent exposures at the point of departure.

In 2016 (Ref. 5) and again in 2022 (Ref. 6), the Agency's Office of Water promulgated science-based federal human health criteria for PCBs and other pollutants in Washington surface waters pursuant to the Clean Water Act. The implementation of those criteria is ongoing.

EPA's Office of Chemical Safety and Pollution Prevention operates the Pollution Prevention (P2) program, which supports the development and implementation of P2 solutions through grant programs, technical assistance, and by connecting researchers, industry experts, and others to develop innovative solutions to environmental challenges. In October 2019, the Washington State Department of Ecology used EPA P2 grant funds to host a workshop (see *https://www.epa.gov/sites/default/files/2021-04/documents/p2-pcb-factsheet-508.pdf* and *https://srrttf.org/?page_id=10745*) on inadvertently generated PCBs in partnership with EPA Region 10, the Spokane River Regional Toxics Task Force (SRRTTF), the Color Pigments Manufacturers Association, Northwest Green Chemistry, the Bullitt Foundation, and industry representatives to discuss opportunities to reduce inadvertently generated PCBs in inks and

pigments and the downstream products and processes using those inks and pigments. The workshop helped establish lines of communication between chemical manufacturers, product manufacturers, purchasers, and end-of-life managers with the intention of formulating actionable steps to stimulate innovation and create markets for safer products. Since the October 2019 workshop, participants have continued to participate on working groups facilitated by Northwest Green Chemistry.

In EPA Region 10, the regional PCB and P2 programs have collaborated to address inadvertently generated PCBs. The programs have worked together to evaluate potential options for reducing inadvertently generated PCBs in products and to support state environmental agencies, ORD, and industry experts in developing upstream P2 approaches to reduce the release of inadvertently generated PCBs into the environment. In addition, the EPA regional PCB and P2 programs and inadvertently generated PCBs workgroup collaborated with the EPA Small Business Innovation Research Grant program, which provides research and development funding to small businesses to support commercialization of innovative technologies that help support EPA's mission of protecting human health and the environment, to solicit proposals in 2020 for innovative coloration technologies that do not result in the generation of inadvertently generated PCBs. Collaboration led to furthering research of innovative technologies that seek to develop PCB-free pigments (Refs. 7 and 8).

ORD, with support from the EPA PCB and P2 programs, is conducting testing to determine the range of concentrations of inadvertently generated PCBs within consumer products, with a special emphasis on children's products. Since 2017, ORD has led cross-Agency efforts to conduct consumer product testing for inadvertently generated PCBs. In 2022, EPA staff from across the Agency published findings related to concentrations, fate and transport, and a preliminary exposure assessment associated with inadvertently generated PCBs in consumer products (Ref. 9). In that publication, the authors stated "[w]hether the solution lies in preferred purchasing programs, green chemistry, effluent controls, regulatory changes, or elsewhere,

understanding the fate, transport, and exposure pathways is a critical step in designing the ultimate solution" and "[t]his research will be foundational for additional future research to better understand the concentrations, fate, and transport of [inadvertently generated PCBs] in yellow pigmented consumer products and their cumulative risk assessment" (Ref. 9). The authors also mentioned "data generated from this study will be valuable to contextualize the toxicity data for PCB-11 generated by the NTP, once it is released" (Ref. 9). As summarized above, the NTP toxicity testing for PCB-11 remains ongoing.

Thus, after assessing information provided by the petitioner, as well as information otherwise available, the Agency cannot conclude that it currently has information necessary to reassess the limits on allowable inadvertent PCBs in consumer products. For example, EPA is interested in new information pertaining to the toxicity of PCB-11 (including data on how PCB-11 bioaccumulates in fish), how PCBs in products leach to water, and efforts to reduce uncertainties in the data associated with testing inadvertently generated PCBs in consumer products.

TSCA section 21 requires a petitioner to set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under TSCA section 6. As described in Unit III.B.1., the petitioner failed to point with any specificity to deficiencies in the Agency's promulgation of the 1984 final rule and determination of no unreasonable risk under TSCA section 6(e). In addition, while EPA acknowledges that pigments and dyes are the most reported product category per reporting and recordkeeping requirements for manufacturers, importers, processors, distributors, and users of inadvertently generated PCBs (see 40 CFR 761.1(f)), the petitioner's focus on paints, printing inks, pigments, and dyes and omit other categories of reported consumer products. This renders the petitioner's request applicable to all consumer products to be overly broad. As a result, the petitioner has not provided adequate justification – based on the rulemaking process and record for the 1984 final rule, as well as information provided or otherwise available to the Agency – for reassessing the limits on allowable

inadvertent PCBs in consumer products. Nonetheless, as necessary and appropriate to supplement the ongoing efforts previously listed (including the new information EPA cited to be of interest), the Agency may consider information gathering activities under TSCA (e.g., TSCA sections 4 or 8) to collect data needed to better understand and characterize exposure and risk associated with inadvertently generated PCBs.

2. *Necessity of rulemaking for "use of pigments containing PCBs."*

The petitioner requests that EPA "adopt a regulation that identifies the use of pigments containing inadvertent PCBs to be a [']use['] of PCBs, subject to the applicable limitations under 40 CFR 761.20(a) . . . [or] identify use of pigments containing inadvertent PCBs is a [']use['] of PCBs when an alternate process is available and does not create inadvertent PCBs" (Ref. 1, p. 2). The petitioner advocates that "non-essential uses of PCBs be eliminated" and "scientific evidence demonstrates that PCBs in pigments result in both human exposures and environmental contamination" (Ref. 1, p. 2). The petitioner provides several studies that attribute human exposure and environmental releases of PCBs to inadvertently generated PCBs linked to pigments, paints, inks, and dyes, and – more specifically – PCB-11 (Ref. 1, pp. 11-13). The petitioner also provides information on the availability of "low-PCB or PCB-free" paints and printed material products, as well as organizations that have implemented purchasing policies to prohibit certain products based on PCB concentration levels (Ref. 1, pp. 14-15). As such, the petitioner argues "there is insufficient justification to allow continued use of processes that knowingly create PCBs in paints, inks, and pigments" (Ref. 1, p. 15).

Although the petitioner generally requests that EPA adopt a new rule identifying the use of pigments containing inadvertently generated PCBs to be a use of PCBs, the existing regulations at 40 CFR 761.1(f)(2) and (3), established in the 1984 final rule, already identify the use of products containing PCBs generated in excluded manufacturing processes and the use of products containing recycled PCBs as uses of PCBs exempt from the general use prohibition in 40 CFR part 761, subpart B. Moreover, 40 CFR 761.20(a)(2) provides that a use authorization is

not required to use PCBs resulting from an excluded manufacturing process or recycled PCBs, provided that all applicable conditions of 40 CFR 761.1(f) are met. Therefore, as stated in Unit II.A.2., EPA is interpreting this request as one seeking to amend the exemptions at 40 CFR 761.1(f)(2) and (3) to the extent they exempt the use of pigments containing inadvertently generated PCBs from the general prohibition against the use of PCBs.

As stated in Unit III.B.1.e., the Agency is aware of and intends to continue to gather and assess information related to the generation, release, exposure, hazards, and risks to human health and the environment associated with inadvertently generated PCBs. The 2022 study conducted by EPA staff acknowledged PCB-11, as well as other congeners found in pigments and consumer products such as PCB-5, PCB-8, PCB-12, PCB-13, PCB-15, PCB-28, PCB-35, PCB-36, PCB-40, PCB-52, PCB-56, PCB-77, PCB-206, PCB-207, PCB-208, and PCB-209 (Ref. 9). That study was designed to "to collect data to quantify the transport of [inadvertently generated PCBs] from consumer products to the environment" and generated the "first data on migration pathways of [inadvertently generated PCBs] from consumer products into the environment and potential routes of human exposure." Those efforts also included: "(1) Identification of [inadvertently generated PCBs] from 39 consumer products purchased on the current retail market; (2) Selection of PCB-11 as the major [congener] to be studied for fate and transport and exposure assessment; (3) Measurement of PCB-11 emissions from consumer products; (4) Investigation of PCB-11 migration from the source to settled dust; and (5) Preliminary assessment of potential exposure to PCB-11" (Ref. 9). The study found that "generated data enhances our ability to predict [inadvertently generated PCB] exposure" and could "assist the regional efforts of the SRRTTF and state and local partners who are trying to find upstream solutions to [inadvertently generated PCB] contamination" (Ref. 9). Finally, as mentioned in Unit III.B.1.e., the study generally concluded that more information was required to better understand and characterize the concentrations, fate, transport, exposure, hazard, and risk associated with inadvertently generated PCBs in pigmented consumer products.

Similarly, after assessing information provided by the petitioner, as well as information otherwise available and in light of ongoing and expected Agency actions, EPA cannot conclude that it currently has information necessary to reassess the exemptions for the use of pigments containing inadvertently generated PCBs.

3. *Necessity of rulemaking for "all allowable PCBs found in commercial products."*

The petitioner requests that EPA "reassess limits on any PCBs currently allowed in all commercial products, including instances where EPA has determined the PCBs are [']totally enclosed['] or result from an ['']excluded manufacturing process['] (Ref. 1, p. 2). The petitioner also asks that EPA set a "rulemaking schedule for the adoption of revised regulations" (Ref. 1, p. 2). Thereafter, there is no discussion or data offered by the petitioner on such products or occurrences of PCBs beyond the enumerated requests.

As stated in Unit III.B.1.e., the Agency is aware of and intends to continue to gather and assess information related to the generation, release, exposure, hazards, and risks to human health and the environment associated with inadvertently generated PCBs. However, aside from overall discussion of PCBs in general, the petitioner does not provide a clear argument or data to support this request. Thus, after assessing information provided by the petitioner, as well as information otherwise available and in light of ongoing and expected Agency actions, EPA cannot conclude that it currently has information necessary to reassess the limits on any PCBs currently allowed in all commercial products.

C. *What were EPA's conclusions?*

TSCA section 21 requires a petitioner to set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under TSCA section 6. In general, the petitioner failed to point with any specificity to deficiencies in the Agency's promulgation of the 1984 final rule and determination of no unreasonable risk under TSCA section 6(e). Furthermore, the petitioner did not provide sufficiently complete scientific information (including hazard and exposure information indicating unreasonable risk) with regard to

inadvertently generated PCBs to enable the Agency to make a determination that its approach in the 1984 rule was in error or ripe for revision. As a result, the petitioner is not able to provide adequate justification – based on the rulemaking process and record for the 1984 final rule, as well as information provided to or otherwise available to the Agency – for reassessing the limits on allowable inadvertent PCBs in consumer products. Similarly, after assessing information provided by the petitioner, as well as information otherwise available and in light of ongoing and anticipated Agency efforts, EPA cannot conclude that it currently has information necessary to reassess the exemptions for the use of pigments containing inadvertently generated PCBs or the limits on any PCBs currently allowed in all commercial products. Thus, EPA finds that the petition is insufficiently specific and that the petitioner did not meet their burden under TSCA section 21(b)(1) of establishing that it is necessary to amend the 1984 final rule under TSCA section 6(e). Accordingly, EPA denied the request to initiate a proceeding for the amendment of a rule under TSCA section 6(e).

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. State of Washington Department of Ecology. 2024. Petition under TSCA Section 21 – Polychlorinated Biphenyls. January 4, 2024.

2. EPA. Toxic Substances Control Act; Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Exclusions, Exemptions, and Use Authorizations; Final Rule. *Federal Register*. 49 FR 28172, July 10, 1984 (TSH-FRL-2587-1).

3. EPA. Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations; Proposed Rule. *Federal Register*. 48 FR 55076, December 8, 1983 (TSH-FRL-2456-6).

4. EPA. Polychlorinated Biphenyls (PCBs); Reassessment of Use Authorizations; Advance Notice of Proposed Rulemaking (ANPRM). *Federal Register*. 75 FR 17645, April 7, 2010 (FRL-8811-7).

5. EPA. Revision of Certain Federal Water Quality Criteria Applicable to Washington; Final Rule. *Federal Register*. 81 FR. 85417, November 28, 2016 (FRL-9955-40-OW).

6. EPA. Restoring Protective Human Health Criteria in Washington; Final Rule. *Federal Register*. 87 FR 69183, November 18, 2022 (FRL-7253.1-02-OW).

7. Cypris Materials, Inc. Easy to Apply, Tunable Structural Color: Color Without Pigments, Dyes, Metals, or PCBs. (May 31, 2022). Available at *https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract_id/11249*.

8. Kebotix, Inc. Machine-Learning-Assisted Development of Alternatives to Diarylide Pigments. (May 31, 2022). Available at *https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract_id/11246/report/F*.

9. Xiaoyu Liu, Michelle R. Mullin, Peter Egeghy, Katherine A. Woodward, Kathleen C. Compton, Brian Nickel, Marcus Aguilar, and Edgar Folk IV. Inadvertently Generated PCBs in Consumer Products: Concentrations, Fate and Transport, and Preliminary Exposure Assessment. Environ. Sci. Technol. 2022, 56, 17, 12228-12236. (August 9, 2022). Available at *https://doi.org/10.1021/acs.est.2c02517*.

Authority: 15 U.S.C. 2601 *et seq*.

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