Strengthening Inadvertent PCB Regulation through Citizen Petition under Section 21 of the Toxic Substances Control Act

Prepared for the Spokane River Regional Toxics Task Force by AKWA-DC LLC

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Roadmap: Strengthening iPCB Regulation through TSCA Section 21 Petition

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- Introduction

Polychlorinated biphenyls (PCBs) are man-made chemicals made up of carbon, hydrogen, and chlorine atoms. PCBs were broadly manufactured for a variety of industrial or commercial applications during much of the 20th century. In 1979, as information came to light regarding their toxicity to humans and the environment, PCBs were banned under authorities contained in the Toxic Substances Control Act of 1976 (TSCA; P.L. 94-469), landmark environmental legislation that established a comprehensive national policy for regulating and managing risks from chemicals. Section 6(e) of TSCA prescribed specific regulations for PCBs, including a complete ban on the manufacturing, processing, distribution in commerce, and use of PCBs, effective one year after enactment. PCBs produced in a “totally enclosed manner” – preventing significant exposure to humans or the environment – continued to be permitted.\(^1\)

Section 6(e)(B) of TSCA allowed the EPA Administrator to authorize the manufacture, processing, distribution in commerce or use (or any combination of those activities) of any PCB in an unenclosed manner if the Administrator determined that this did not present “an unreasonable risk of injury to health or the environment.” In 1984, acting under the authority in Section 6(e)(B) of TSCA, the EPA promulgated rules allowing some inadvertent generation of PCBs to occur in excluded manufacturing processes. Inadvertently-generated PCBs (iPCBs) are permitted at defined concentrations, under certain conditions, and with requirements to report to EPA and maintain specific records.\(^2\)

Despite growing challenges for communities working to address and manage PCB pollution, including ongoing inputs of iPCBs, EPA’s iPCB regulations have not received a second look since they were first established in 1984. When the 1984 Final Rule amending the 1982 Closed and Controlled Waste Manufacturing Processes Rule was finalized, EPA noted in the Federal Register:

> *EPA emphasizes that while today’s rule sets certain limits on inadvertently generated and recycled PCBs released to air, water, products, and waste in certain processes, the Agency is not implying that these release limits represent an absolutely safe level. Rather, the Agency has decided that the risks associated with allowing the levels of PCBs in this regulation are not unreasonable. This means that EPA has set these levels based on a balancing of the costs associated with setting even lower limits (or removing PCBs entirely from the products in question) with the attendant*

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\(^2\) Polychlorinated biphenyls: Inadvertent PCBs. Environmental Protection Agency: https://www.epa.gov/pbcs/inadvertent-pcb
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reduction in risk that would result from stricter regulation. EPA has concluded that stricter regulation would result in great expense for a small increment in risk reduction.9

EPA arrived at the iPCB rulemaking thanks in part to comments from the chemical industry arguing that “some of their manufacturing processes inadvertently generate PCBs that present virtually no health or environmental risk because of limited PCB exposure potential.” (Emphasis added). Industry representatives further stated that “processes generating PCBs as byproducts are designed and operated so that no releases of PCBs occur or that the PCBs formed in the processes are disposed of in accordance with the PCB disposal regulations at 40 CFR 761.60.” The final rule developed by EPA was ultimately based on a consensus proposal regarding iPCB regulation developed jointly by the Environmental Defense Fund, Natural Resources Defense Council, and the Chemical Manufacturers Association.

Forty years later, we now know that statements from industry regarding iPCB’s “limited” exposure potential are untrue. While additional studies are needed, a growing body of research and environmental data shows that iPCBs are widespread in the environment and have high exposure potential for humans and aquatic organisms.4,5,6,7

Nowhere is this more apparent than in the Spokane River, where efforts to bring down PCB levels in the waterway have stalled as local stakeholders reach the maximum extent of what can be achieved with available treatment technologies targeting legacy PCBs and Aroclor mixtures.8

Until the amount of iPCBs entering commerce and, subsequently, the environment is reduced or eliminated, Spokane River stakeholders will likely may be unable to comply with new Water Quality Standards that limit total PCB concentrations to 7 parts per quadrillion (ppq).

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1 Toxic Substances Control Act; Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Exclusions, Exemptions, and Use Authorizations, 49 Fed. Reg. 28172 (July 10, 1984)


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- Section 21 Petitions

The Section 21 Petition Process

Section 21 of TSCA states that any person may petition the EPA Administrator to initiate a rulemaking to issue, amend, or repeal a regulation under TSCA Sections 4, 6, and 8, which cover chemical testing, regulation, and data reporting, or to issue an order under TSCA section 4, 5(e), or 5(f). To be successful, a Section 21 petition must “set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule” under TSCA. In evaluating a Section 21 petition, the EPA Administrator must consider whether the petition does in fact set forth the facts that are claimed to establish the necessity for the action requested. EPA has 90 days after a petition is submitted to either grant or deny it. If granting the petition, EPA must “promptly commence an appropriate proceeding” consistent with the approved petition. If denying the petition, EPA must publish the reasons for denial in the Federal Register.

If a petition is denied, the petitioners may commence a civil action in district court to compel the Administrator to initiate a rulemaking as requested in the petition. The petitioner must do so within 60 days of the petition’s denial, or, if the Administrator neither grants nor denies the petition, within 60 days after the expiration of the 90 period that began when the petition was submitted. Petitioners who pursue civil action to compel EPA to act shall be given an opportunity to have their petition considered in a de novo proceeding, meaning the court will review the petition with “fresh eyes” and without consideration of EPA’s prior denial of the petition.

Third parties can bring a civil action after a petition filed by other groups or individuals has been denied, but the third party filing the action would have to demonstrate that it has standing to do so (i.e. that the agency had caused the plaintiff injury and the plaintiff was within the “zone of interest” that the agency’s action was supposed to protect). A civil action on a petition denial brought by a third party could result in challenges to the plaintiff’s standing and tie up the action in litigation. Additionally, if the third party’s concerns don’t precisely align with the relief sought by the petition, it is possible that the Court would direct the plaintiff to develop and file its own Section 21 petition. In general, the process for bringing a civil action after a petition denial is made easier when the plaintiff is also the original petitioner.

EPA sets a high bar for granting relief under Section 21 of TSCA, as demonstrated by the number of petition denials over the past 15 years. Of 31 Section 21 petitions filed since 2007 that are available on EPA’s website, 24 were denied; 1 was granted; and 6 were granted partially, granted after initial denial, or granted under authorities other than TSCA Sec. 21.9

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9 Assessing and Managing Chemicals Under TSCA: Section 21. Environmental Protection Agency:
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petitions were denied on procedural grounds because they did not seek appropriate relief that EPA was authorized to provide under TSCA (ex: Chemical Mixtures in Cosmetics, Cigarettes). Others seeking regulation of certain chemicals did not “provide sufficient facts establishing that it is necessary for the Agency to issue a rule under TSCA Section 6(a).”

Requirements for a Successful Petition

In 1984, EPA published guidance for citizens or organizations considering filing a Section 21 petition.10 This document still provides a helpful overview of the petition process and what petitioners should consider as they develop their request and justifications for agency action. We recommend the Task Force review this document to understand the specific components of a petition and consider suggestions from EPA for a successful petition.

In brief, a successful petition must include:

1. Information about the petitioner
2. Description of the relief requested
3. Description of the problem
   a. Toxicity: The nature and severity of harm to humans or the environment from the chemicals of concern;
   b. Exposure: The actual or potential release of the chemical to the environment or its actual / potential contact with humans (exposure);
   c. Risk: The extent of harm the chemicals of concern present or may present; and
   d. Risk reduction: Possible methods to reduce risk and information on the costs, efficacy, and impact of such methods.

In light of the specific requirements that petitioners must satisfy to set forth the facts that iPCBs present an unreasonable risk to human health and the environment, the conflict between TSCA’s iPCB allowance and the strict PCB water quality standards implemented under the Clean Water Act is not sufficient justification, on its own, to grant a Section 21 petition to close the iPCB allowance. The Task Force, should it decide to petition EPA to close the iPCB allowance, will need to provide information documenting the “nature and severity of harm to humans or the environment” from iPCBs, data on exposure describing the “actual or potential release” of iPCBs

10 Guidance for Petitioning the Environmental Protection Agency Under Section 21 of the Toxic Substances Control Act, 50 Fed. Reg. 46825 (November 1, 1985)
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to the environment or their “actual or potential contact with humans,” and information regarding “the extent of harm the chemicals of concern present or may present.”

Overall, the collection of information provided by the Task Force in a potential Section 21 petition would need to be sufficient to demonstrate that iPCBs present an unreasonable risk, consistent with Section 6 of TSCA governing regulatory controls on chemicals. The agency’s guidance document for prospective petitioners notes that because rulemaking will require “defensible assessments of risk” based on toxicity and exposure, petitioners should either submit sufficient data for EPA to conduct its own risk assessment or develop and submit a risk assessment as part of their petition.

The Task Force would also need to provide information on risk reduction, including what mechanisms or methods it is proposing to reduce risk (in this case, closing the existing regulatory allowance for iPCBs), and what those actions would likely cost for small businesses, regulated entities, and the broader economy. While the Task Force likely does not have all of the information described here, especially regarding the economic impact of closing the iPCB allowance, EPA notes in its guidance document that petitioners should submit “any data that might facilitate this analysis” around the potential social and economics costs of the requested action to reduce risk from iPCBs.

Importantly, in our final discussion with EPA staff, they made it clear that the determination of risk made by EPA for PCBs under the Clean Water Act was a separate process without bearing on EPA’s implementation of TSCA. In other words, just because EPA has determined that PCBs – including iPCBs – in surface waters at certain levels pose a risk to human health, this does not mean that a finding of “unreasonable risk” automatically exists for iPCBs under TSCA. The risk assessment processes under these two statutes are effectively separate, and EPA will have to make a separate finding of unreasonable risk for iPCBs under TSCA for a Section 21 petition to be successful.

Other Considerations for Petitioners

Pre-Consultation with EPA

For individuals or organizations planning to submit a Section 21 petition to EPA, the agency offers and recommends a pre-consultation process to allow both agency staff and petitioners to undertake preparations that will make the petition evaluation process fruitful. Pre-consultation may include discussions with agency staff that offer alternative routes or requests for action to address the petitioner’s concern.

11 50 FR 46825
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If a petition is denied by the Administrator, this does not necessarily mean that EPA will not take action on a particular chemical of concern. In the past, EPA has taken action to regulate chemicals through other mechanisms after denying a Section 21 seeking such regulations. (Ex: Lead Dust Hazard Standard and Definition of Lead-based Paint - APA Sec. 552(e), Formaldehyde in Pressed Wood Products - ANPRM). While the requirements for a successful Section 21 petition are highly specific and set a high bar for petitioners seeking a specific form of regulatory relief, EPA may have flexibility to undertake a rulemaking or other action if it agrees with the premise of a Section 21 petition but cannot grant that petition under the requirements of Section 21. As a result, there may be value in submitting a Section 21 petition on iPCBs, even if it is likely that the petition will be denied under the requirements of Section 21.

Administrative Procedure Act (APA) Challenges

An APA challenge may be brought when a party believes that a federal agency has exceeded its statutory authority or otherwise abused its discretion in the course of a specific agency action. APA claims are brought in federal district court through the filing of a civil claim. The statute of limitations on an APA claim is, generally speaking, six years—meaning that any claim must be filed within six years of the agency action being challenged. There is a certain amount of leeway as to what point an action is deemed “final”—meaning that there should not be any concern whether a TSCA iPCB challenge is timely.

When filing an APA claim, a plaintiff may request injunctive relief on the agency action in question, including a preliminary injunction that bars the enforcement of a contended rule. Discretion whether to grant such an injunction rests in the court.

There are four main types of APA claim:

1) that the agency failed to abide by notice and comment procedures during a rulemaking;
2) that an agency action was arbitrary and capricious;
3) that an agency action is not in accordance with federal law; or
4) that an agency has caused unreasonable delay during decisionmaking.

An APA lawsuit concerning the conflict between TSCA regulations and the CWA would be type 2) or, more likely, 3)—that is to say, this lawsuit would either allege that the regulatory iPCB allowance is arbitrary and capricious in its disregard of the CWA PCB limit, or that it violates federal law because of its conflict with the CWA.

“Arbitrary and Capricious” Challenges

A reviewing court will determine that an agency action is arbitrary and capricious when a plaintiff can demonstrate that “the agency has relied on factors which Congress has not intended
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it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” Motor Vehicle Manufacturers Association v. State Farm Auto Mutual Insurance Co., 463 U.S. 29, 43 (1983). This standard is extremely narrow, and discretion is given to the agency—meaning that the court may only question the reasonableness of the agency’s decisionmaking rather than the resulting action, and that the agency is generally considered to be the best authority in its decisionmaking.

Despite these strict standards, an APA challenge on the iPCB allowance would not necessarily fail. The language cited above could apply to the TSCA iPCB - CWA PCB disparity with a strong enough foundation in the scientific evidence and the administrative record.

“Not in Accordance with the Law” Challenges

A reviewing court will determine that an agency action is not in accordance with the law when it either exceeds an agency’s statutorily-granted authority or violates another federal statute. An APA challenge brought under this provision would be complicated given that both the CWA and the TSCA standards are being promulgated by the agency under its statutorily-granted authority. A plaintiff would have to demonstrate that the iPCB standard clearly violates the EPA’s authority granted by TSCA or that, in setting the iPCB standard at its current level, the EPA has violated the plain text of the CWA.

An APA challenge on the iPCB allowance could include both “arbitrary and capricious” and “not in accordance with the law” arguments, though it would be more likely to succeed on “arbitrary and capricious” grounds.

Further Considerations in an APA Challenge:

- **Is There Unreviewable Agency Discretion?**
  As outlined above, courts tend to give agencies a great deal of discretion when reviewing an action under the APA. The burden of proof is on the plaintiff to show that an agency’s action was arbitrary and capricious. In addition, certain statutes grant agencies unlimited discretion over specific matters—however, since TSCA does not explicitly grant the agency unlimited discretion over setting the iPCB allowance, the plaintiff will simply need to demonstrate that the agency acted unreasonably.

- **Is Judicial Review Precluded?**
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Before filing a challenge under the APA, a plaintiff must ensure that judicial review is not statutorily precluded under the specific governing law. Judicial review is not precluded for TSCA.

- **Were All Administrative Remedies Exhausted?**
  A plaintiff may not file an APA challenge of an agency action until that plaintiff has exhausted the potential administrative remedies for such an action. In the case of the iPCB allowance, this would likely mean that an APA challenge could only proceed after a denied Section 21 petition.

- **Is the Agency Action Final?**
  This ties into the question of exhaustion (see above)—essentially, no challenge may be filed until the agency has issued a final decision. A plaintiff could file an APA challenge either after a denied Section 21 petition or after a final rulemaking on the iPCB allowance, as both of these would consist of a final agency action.

- **How Friendly is the Circuit?**
  Though the legal standards are the same for APA challenges across circuits, trends in decisionmaking can mean that certain circuits tend to be more or less generous towards agencies generally, or towards specific agencies. The Ninth Circuit has stated that deference is given to the EPA in interpreting its own regulations so long as that interpretation is not unreasonable. Generally, the EPA tends to prevail in this circuit. See *Western States Petroleum Ass’n v. EPA*, 87 F.3d 280, 283 (9th Cir. 1996); *Ober v. Whitman*, 243 F.3d 1190, 1193 (9th Cir. 2001); *Pronsolino v. Nastri*, 291 F.3d 1123, 1131-32 (9th Cir. 2002).

**Summary: APA Challenges**

In short, there is a path forward to bring an APA challenge against the EPA for the disconnect between the TSCA iPCB limit and the CWA PCB limit. A plaintiff would have to demonstrate that the EPA’s disregard for this disconnect during the rulemaking process was arbitrary and capricious or violated the CWA, and the court would give the EPA a fair amount of discretion in its review, meaning that there would be a fairly high burden of proof for the plaintiff to meet. It is also worth noting that federal cases tend to be multi-year and quite expensive, whereas a Section 21 petition must be resolved within 90 days.

An APA challenge could (and arguably, should) also follow an unsuccessful Section 21 petition, so this option would not be erased through the petition process. In fact, a petition could easily form much of the argument in a subsequent lawsuit. Furthermore, agency record of decisionmaking will be helpful to inform a potential APA challenge. EPA will have to clearly
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explain why they’ve denied the Section 21 petition through notice published in the Federal Register.

Recommended Roadmap for Section 21 Petition

1. Determine what type of relief is being sought
   a. Close iPCB Allowance altogether?
   b. Lower permissible iPCB concentrations under allowance?

2. Begin gathering available information on toxicity; exposure
   a. The Task Force must gather information sufficient to challenge EPA’s 1984 determination that inadvertently generated non-Aroclor PCBs in certain processes present no unreasonable risk of injury to human health and the environment.
   b. iPCB toxicity and exposure are current topics of interest for EPA and other agencies, like the National Institutes of Health (NIH). NIH is currently studying toxicity of a predominant iPCB congener, PCB 11. EPA has completed studies on iPCBs in consumer products,12 and is currently working to understand exposure pathways for iPCBs.
   c. Some PCB 11 toxicity data is available for other species,13,14 but these studies may not be relevant for EPA’s evaluation of iPCB toxicity – EPA will be looking for toxicity information that is specific to humans and covers additional iPCB congeners.

3. Develop other relevant information to support Petition
   a. This information should include steps that have already been taken, or are already being taken, at the state and local level to address iPCBs. Additional information regarding the economic burden created by iPCB inputs to the Spokane River watershed may be valuable – the Task Force can describe the significant financial resources that dischargers, including the City of Spokane, have invested to bring down levels of both legacy PCBs and iPCBs. It is important for EPA to understand that the iPCB allowance is imposing an economic burden on communities.

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b. The Task Force should also include information on available alternatives to iPCBs, or information on how excluded manufacturing processes could pivot to mitigate or eliminate production of iPCBs. If the Task Force can demonstrate a willingness from industry to consider adjusting their processes to phase out iPCBs, that may add weight to a petition to close the iPCB allowance or incentivize EPA to consider alternative pathways such as a separate rulemaking that will allow industry and affected stakeholders to cooperatively develop a solution.

4. Pre-Consultation Meetings with the Agency
   a. As it develops the petition and assembles supporting information, the Task Force should consider requesting pre-consultation meetings with agency staff, both as a means to provide advance notification of the intent to petition and to help develop the strongest potential basis to justify action closing the iPCB allowance. The Task Force can likely do so by sending a request letter to Michal Freedhoff, Assistant Administrator for Office of Chemical Safety and Pollution Prevention (OCSPP), and/or to Region 10 Administrator Casey Sixkiller.
   b. The Task Force should be aware that EPA staff will likely discourage plans to submit a Section 21 petition to close the iPCB allowance. Agency staff have reiterated the agency’s position that iPCBs do not pose any documented risk to exposed populations or the environment, and that closing the iPCB allowance would present a massive and costly undertaking for the agency and the complying industries. (We suggest reviewing notes from the April 26, 2017 Task Force meeting with EPA officials. EPA’s reasoning has not changed since this 2017 meeting.) The Task Force should expect pushback from the agency in the pre-consultation process, but this does not necessarily mean that a Section 21 petition on iPCBs can’t move the needle on this issue and exert pressure on EPA to find a workable solution for Spokane River stakeholders.

5. Develop and Submit Section 21 Petition
   a. The Task Force should engage with technical scientific experts and legal analysts with expertise in chemical regulation to develop a Section 21 petition that meets the requirements of TSCA. AKWA-DC is best suited to provide support on a political and legislative advocacy strategy to help shepherd a petition through the process and ensure that EPA is receiving clear support from Congress and other stakeholders for the petition’s goal.

6. EPA Acts on Petition within 90 Days
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a. If a petition is granted, EPA must promptly commence a proceeding to provide the relief sought by the petition.
b. If the petition is denied, the Task Force must decide if it wants to bring a civil action to District Court with 60 days of petition denial. The EPA Administrator’s reasoning for the denial will be published in the Federal Register, and may inform future efforts to address the iPCB allowance in the event that the Task Force (or one or more of its members) does not pursue a civil action.

7. Possible Next Steps After Petition Decision
   a. If the petition is granted, the Task Force should work with the agency as it proceeds to a rulemaking to address the iPCB allowance. The Task Force may wish to develop a coalition to support EPA’s rulemaking, and to counter likely pushback from affected industry members who currently generate iPCBs through excluded manufacturing processes.
   b. If the petition is denied, the Task Force may want to consider additional efforts to address the iPCB allowance, including:
      i. Working with the Washington Congressional Delegation to identify and develop a legislative proposal that can provide either temporary or permanent relief.
      ii. Preparing and filing a challenge under the Administrative Procedure Act for arbitrary and capricious decisionmaking by EPA in promulgating Spokane River Water Quality Standards without addressing iPCBs.

● Conclusion

The Spokane River watershed faces a significant challenge in regulating inputs of inadvertent PCBs due to a key conflict between the Toxic Substances Control Act and the Clean Water Act. Unfortunately, EPA currently cannot offer any recommended solutions to stakeholders hoping to resolve this conflict, and discussions with agency staff indicate that EPA remains opposed to closing the existing allowance for inadvertently-generated PCBs. The Spokane Regional Toxics Task Force can develop and submit a petition under Section 21 of TSCA to close the iPCB allowance, but for such a petition to succeed, the Task Force will have to make a strong case for unreasonable risk presented by iPCBs using data regarding both toxicity and exposure of iPCB congeners. While the likelihood of a Section 21 petition succeeding is low due to the high bar EPA sets for granting such petitions, an unsuccessful petition combined with an aggressive advocacy strategy may bring pressure to bear on EPA to develop workable solutions for Spokane River stakeholders. In summary, a Section 21 petition to close the iPCB allowance is unlikely to succeed but may still hold value as a policy exercise to draw greater attention to the existing and currently unresolvable conflict between TSCA and CWA.
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- **Resources**


Guidance for Petitioning the Environmental Protection Agency Under Section 21 of the Toxic Substances Control Act, 50 Fed. Reg. 46825 (November 1, 1985)


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*Polychlorinated biphenyls: Inadvertent PCBs.* Environmental Protection Agency
https://www.epa.gov/pcbs/inadvertent-pcb


Toxic Substances Control Act (P.L. 94-469)

Toxic Substances Control Act; Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Exclusions, Exemptions, and Use Authorizations, 49 Fed. Reg. 28172 (July 10, 1984)