

Strengthening iPCB Regulation through TSCA Section 21

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Inadvertent PCBs (iPCBs)

- + Allowance at 40 CFR 761.3 permits “some inadvertent generation of PCBs to occur in excluded manufacturing processes” under TSCA
- + iPCB congener (PCB 11) now detected in air, water nationwide
- + SRRTTF has raised profile of iPCBs through –
 - + Advocacy
 - + Conference presentations
 - + Articulating policy dilemma between TSCA and Clean Water Act
- + “EPA, through the Office of Research and Development, has been working to better understand the concentrations of iPCBs in products, potential emission and migration of iPCBs out of products, and potential exposure pathways to users or other potentially exposed populations.”

TSCA Section 21

- + Under Section 21 of TSCA, any person may petition the EPA Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under:
 - + Section 4 – rules or orders requiring chemical testing;
 - + **Section 6 – rules imposing regulatory controls on chemicals;**
 - + Section 8 – rules requiring information; or
 - + Section 5(e) or (f) – orders affecting new chemical substances.
- + Petition must “set forth the facts that are claimed to establish the necessity for the action requested.”

Section 21 Petitions (2007 – present)

Date	Substance	Outcome
11/14/2022	Polyvinyl Alcohol	Denied
6/16/2022	Greenhouse Gas Emissions	Denied
8/16/2021	Chemical Mixtures in Cosmetics	Denied
8/2/2021	Chemical Mixtures in Cigarettes	Denied
2/8/2021	Phosphogypsum and Process Wastewater	Denied
10/14/2020	54 Per- and Polyfluoroalkyl substances (PFAS)	Initially denied; Granted after re-review
8/7/2019	Prohibiting the Use of Hydrofluoric Acid at Oil Refineries	Denied
1/31/2019	Asbestos Reporting Rule Under TSCA Section 8(a)	Denied
9/27/2018	Asbestos Information Collection for the CDR Rule	Denied
1/6/2017	Chlorinated Phosphate Ester Cluster	Denied
12/13/2016	Tetrabromobisphenol A	Denied
11/23/2016	Fluoride Chemicals in Drinking Water	Denied
10/7/2015	Nomenclature System for Natural Sources of Oil and Fat	Denied
6/30/2015	Anthropogenic Emissions of Carbon Dioxide	Denied
6/24/2015	Mercury/Recordkeeping and Reporting	Denied
10/21/2014	Biodiesel Partial Exemption from CDR Reporting	Denied / Granted under other authority
7/29/2014	Polyvinyl Chloride (PVC)	Denied
10/31/2013	Lead in Paint - Public and Commercial Buildings	Denied
5/9/2013	Hydrofluorosilicic acid (HFSA) as a Water Fluoridation Agent	Denied
4/11/2012	PCBs - Navy SINKEX	Denied
3/13/2012	Lead in Shot and Bullets	Denied
11/17/2011	Lead in Fishing Tackle	Denied
8/4/2011	Oil and Gas Exploration and Production Chemicals and Mixtures	Partially granted
8/3/2010	Lead for Shot, Bullets, and Fishing Sinkers	Denied
5/28/2010	Cadmium in Consumer Products, Especially Toy Metal Jewelry	Granted; rule withdrawn
11/19/2009	Natural Rubber in Tires	Denied
8/10/2009	Lead Dust Hazard Standard and Definition of Lead-based Paint	Granted but not under Sec. 21
5/29/2009	Lead Wheel Weights	Granted
3/24/2008	Formaldehyde	Granted in part; denied in part
3/6/2008	Natural Rubber Latex Adhesives	Denied
9/20/2007	Air Fresheners	Denied

Petition Process

- + Pre-consultation opportunity with EPA – recommended for petitioners
 - + Opportunity to ask questions, share information
 - + Goal is to produce stronger petition and facilitate smoother process for agency
- + **Petition filed** – clock starts for EPA
 - + Administrator has 90 days to grant or deny
 - + Administrator may hold public hearings to inform petition decision
 - + Petition denied? Administrator must publish reasons in Fed Register
 - + Denial provides petitioner with opportunity to bring civil action in District Court to compel EPA Administrator to act
 - + Civil Action must be filed within 60 days of petition denial
 - + *De novo* proceeding: review will examine, and can expand upon, administrative record

Petition Process (cont.)

- + Denial of petition doesn't mean EPA won't act!
- + EPA has taken action to regulate chemicals through other mechanisms after denying Section 21 petition:
 - + Lead Dust Hazard Standard and Definition of Lead-based Paint
(Administrative Procedure Act Section 553(e))
 - + Formaldehyde in Pressed Wood Products
(Advance Notice of Proposed Rulemaking)
- + EPA may have flexibility to undertake rulemaking independently if it agrees with the premise of a petition

Establishing “Unreasonable Risk”

- + The existence of a conflict between TSCA and implementation of the Clean Water Act is not sufficient justification to grant a petition under Sec. 21.
 - + This conflict could be sufficient basis for a petition through a different pathway, like the Administrative Procedure Act.
- + Section 21 petition to address iPCB allowance must provide enough information for EPA Administrator to determine that iPCBs present an **unreasonable risk** consistent with TSCA Section 6 and should be regulated more strictly.
- + Petitioner must “set forth the facts that are claimed to establish the necessity for the action requested” = provide data and information

Petition Components

- + Information about petitioner(s)
- + Description of relief requested
- + Description of problem
 - + Nature & severity of harm to humans and environment from chemicals of concern
 - + Exposure
 - + Extent of harm chemicals present / may present
- + Steps being taken at State & local level
- + Why Federal controls would be more effective

Is there a case to be made for iPCBs?

- + 1984 Rulemaking establishing iPCB allowance included conclusions about exposure that we know are not true today.
- + EPA did not determine that iPCB concentrations allowed under 40 CFR 761.3 "represent an absolutely safe level."
- + Agency took a balancing approach: determined that likely costs of stricter iPCB regulation outweighed any additional risk reduction.
- + Recent data demonstrates ubiquity of PCB-11 in environment.
- + **Time for EPA to take a second look?**

described in greater detail in the remainder of this Unit of the preamble.

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 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.

Key Pieces Needed for a Section 21 Petition

+ Toxicity Data

- + Some studies available regarding toxicity of PCB 11 to mice, zebrafish
- + NIH currently examining toxicity of PCB 11

+ Exposure Data

- + EPA conducting studies on exposure, concentration of PCB 11 in consumer products

+ **Questions for SRRTTF:**

- + What other information is available?
- + Can we make a compelling case for unreasonable risk based on available toxicity and exposure information?

Other Considerations...

- + What specific relief should the petition seek?
 - + Close iPCB allowance altogether?
 - + Lower permissible iPCB concentrations under allowance?
- + How should a Sec. 21 petition sync up with SB 5369?
 - + If Sec. 21 iPCB petition is denied, EPA's reasoning could inform State's petition under another authority such as the APA
 - + What is State's timeline for submitting their own petition?

Recommended Steps for SRRTTF

- + Identify groups willing to co-author and submit petition
- + Request and initiate pre-consultation with EPA
- + Develop and publish RFPs for:
 - + Technical expert(s) to develop scientific information
 - + Attorney(s) to support petition development / legal basis
- + Coordinate with State of WA on SB 5369 implementation
- + Determine next steps if Sec. 21 petition is denied
- + Political advocacy to increase pressure on EPA, attention to iPCB issue

Our Remaining Work

- + Meeting with EPA Office of Water
 - + Sara Hisel-McCoy, Director of Office of Standards and Health Protection Division
- + Finalizing deliverable documents for SRRTTF Review
 - + Section 21 Petition Roadmap (described here)
 - + Broader iPCB Engagement Strategy
- + Presenting to full SRRTTF Meeting - May 24
- + SRRTTF review period for deliverable documents

Questions?

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