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)

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

From 50 FR 46825 - Guidance for Petitioning the Environmental Protection Agency under Sec. 21 of TSCA
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?**
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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