TSCA New Chemicals Program: Implementation Update

Public Meeting
December 10, 2019
TSCA New Chemicals Program: Implementation Update

- Updated “Working Approach” for making determinations under Section 5 of TSCA
- Application of “Working Approach”: Case Examples
- Implementation of the TSCA Confidential Business Information (CBI) requirements
- Transparency Initiatives
- Public Feedback
Overview of EPA’s Updated Working Approach to Making Determinations Under Section 5 of TSCA
TSCA New Chemicals Program

• Section 5 of TSCA requires advance notice to EPA from any person intending to manufacture/process either:
  – “New” chemical substances (i.e., not on the TSCA Inventory), or
  – “Significant new uses” of existing chemicals (as defined by EPA via rulemaking)

• EPA must review within 90 days (with possibility for statutory extension and voluntary suspension)

• If the review identifies unreasonable risks, EPA must impose prohibitions or limits on the manufacturing, processing, distribution in commerce or use of the chemical necessary to protect against unreasonable risks
TSCA 5(a)(3) Determinations

• Presents an unreasonable risk of injury to health or the environment

• Available Information is insufficient to allow the Agency to make a reasoned evaluation of the health and environmental effects

• In the absence of sufficient information, may present an unreasonable risk of injury to health or the environment

• Produced in substantial quantities and either enters or may enter the environment in substantial quantities or significant or substantial human exposure to the chemical; or

• Not likely to present an unreasonable risk of injury to health or the environment
2017 Working Approach


December 6, 2017 – Public meeting to discuss and receive additional input
2019 Updated Working Approach

– Additional clarification and detail throughout

– General guiding principles and concepts for making determinations

– Decision-making logic and key questions that EPA must address; and

– Example application of the Working Approach to reach determinations under TSCA section 5(a)(3)
Guiding Principles and Concepts

- Overall Policy
- Risk-Based Approach
- Conditions of Use
- Information Sufficiency
- Unreasonable Risk
- Testing Requirements
- Scientific Standards and Evidence
- Significant New Use Rules
**Guiding Principles and Concepts**

- **Conditions of Use**
  - “Intended”
    - Circumstances as stated in the section 5 submission, including hazard/exposure mitigating practices and controls
  - “Known”
    - Less common for “new” chemicals; circumstances where chemical is already manufactured but is not required to appear on the TSCA Inventory (e.g., under a TSCA section 5(h) exemption)
  - “Reasonably Foreseen”
    - Future circumstances that EPA might expect to occur; fact-specific; based on Agency’s professional judgment, experience and discretion
Guiding Principles and Concepts

Information Sufficiency

– Critical for identifying which among the five available determinations might be appropriate
– “Sufficient” information is not necessarily complete or perfect information
– Analogue data may be sufficient to conduct a reasoned evaluation
Guiding Principles and Concepts

- Significant New Use Rules (SNURs)
  - EPA utilizes SNURs in the TSCA New Chemicals program in three ways:
    - SNURs that follow a TSCA section 5(e) or 5(f) order
    - SNURs that precede a “Not Likely” determination
    - SNURs that follow a “Not Likely” determination
Key Questions:

• What are the intended, known and reasonably foreseeable conditions of use?

• Does EPA have sufficient information to perform a reasoned evaluation? and

• Can EPA address information deficiencies or risk concerns for reasonably foreseeable conditions of use through the issuance of a SNUR?
“Reasonably Foreseen” COUs

• Evidence-based approach supported by professional judgment, experience, and discretion
  – Evidence of a particular use of new chemical outside the U.S.
  – Structural analogues with at least one use in common with an intended condition of use for the new chemical
  – Condition of use in original submission but removed via amendment
**COUs Involving Workers**

- Initial assessment includes consideration of engineering controls described in notice, but not PPE. If risks are preliminarily identified, EPA then considers whether the risks would be mitigated by the use of PPE, considering OSHA’s hierarchy of controls.

- Safety Data Sheet (SDS) reflects Agency analysis of measures necessary to protect workers from hazards identified in EPA’s assessment.

- General expectation of compliance with federal and state laws to protect workers, including OSHA’s worker protection and hazard communication standards.

- With some exceptions, PPE that mitigates risk can lead to a Not Likely determination.
Information Sufficiency

• Sufficient information
  • “presents unreasonable risk”
  • “not likely to present unreasonable risk”
  • Substantial volume/exposure

• Insufficient information
  • “insufficient information”
  • “insufficient information and may present unreasonable risk”
  • Substantial volume/exposure
SNURs

• If reasonably foreseen conditions of use are identified:
  – EPA evaluates whether a SNUR can address any information deficiencies or risk concerns

  – The reasonably foreseen condition(s) of use are identified as “significant new uses”

  – A SNUR ensures that any manufacturing or processing activity for the reasonably foreseen conditions of use would be subject to review by EPA if/before it occurs
Next Steps

• EPA continues to strive for increased transparency with TSCA implementation, including the New Chemicals program

• EPA will release the updated “Working Approach” document by the end of the year
  – Availability to be announced via Federal Register notice, email listserv notification and EPA website

• Provide opportunity for additional public comment
Application of Working Approach: Case Examples
Case Example Overview

- **Step 1. Identification of conditions of use**
  - Intended
  - Known
  - Reasonably foreseen

- **Step 2. Hazard identification/characterization**
  - Human health hazards
  - Environmental hazards

- **Step 3. Risk assessment**

- **Step 4. Risk management, resulting in a determination (regulatory outcome)**

Case examples are based on real cases, but some details have been modified or simplified to protect confidential business information and illustrate key concepts.
Example 1

- Chemical ID: fatty acid polymer
- Intended conditions of use: Import for use as an adhesion-enhancing resin for industrial spray applications to wood products
Example 1

- **Chemical ID**: fatty acid polymer
- **Intended conditions of use**: Import for use as an adhesion-enhancing resin for industrial spray applications to wood products
- **Known conditions of use**: None
  - No previous submissions for the new chemical substance
Example 1

- Chemical ID: fatty acid polymer
- Intended conditions of use: Import for use as an adhesion-enhancing resin for industrial spray applications to wood products
- Known conditions of use: None
- Reasonably foreseen conditions of use: None
  - No patents identified
  - No analogues used for the same use plus another use
  - No amendments to the submission
Example 1

- **Chemical ID:** fatty acid polymer
- **Intended conditions of use:** Import for use as an adhesion-enhancing resin for industrial spray applications to wood products
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:** None
- **Hazard identification:**
  - **Human health hazard:** Low hazard
  - **Environmental hazard:** Low hazard
Example 1

- **Chemical ID:** fatty acid polymer
- **Intended conditions of use:** Import for use as an adhesion-enhancing resin for industrial spray applications to wood products
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:** None
- **Hazard identification:** Low hazard
- **Risk assessment:** Risks were not identified for workers, the general population, consumers, or the environment.
Example 1

- **Chemical ID:** fatty acid polymer
- **Intended conditions of use:** Import for use as an adhesion-enhancing resin for industrial spray applications to wood products
- **Regulatory outcome:** “Not Likely”
  - *The new chemical substance is not likely to present an unreasonable risk.*
  - *Due to low hazard, EPA believes that this chemical substance would be not likely to present an unreasonable risk even if potential exposures were high.*
  - *No SNUR.*
Example 2

- **Chemical ID:** Methylated imidazole
- **Intended conditions of use:** Import for use as a chemical intermediate in the synthesis of a polymer
  - No water releases
  - **PPE described in Safety Data Sheet (SDS)**
    - Impervious gloves
    - Respiratory protection
    - Eye protection
Example 2

– Chemical ID: Methylated imidazole
– Intended conditions of use: Import for use as a chemical intermediate in the synthesis of a polymer
– Known conditions of use: None
  • No previous submissions for the new chemical substance
Example 2

– Chemical ID: Methylated imidazole
– Intended conditions of use: Import for use as a chemical intermediate in the synthesis of a polymer
– Known conditions of use: None
– Reasonably foreseen conditions of use: None
  • No patents identified
  • No analogues used for the same use plus another use
  • No amendments to the submission
Example 2

- **Chemical ID:** Methylated imidazole
- **Intended conditions of use:** Import for use as a chemical intermediate in the synthesis of a polymer
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:** None
- **Hazard identification:**
  - **Human health hazards:** Irritation and corrosion to all tissues, developmental effects, and liver toxicity
  - **Environmental hazard:** Predicted toxicity values indicate high environmental hazard (acute and chronic COC of 115 ppb and 7 ppb, respectively)
Example 2

- **Chemical ID:** Methylated imidazole
- **Intended conditions of use:** Import for use as a chemical intermediate in the synthesis of a polymer
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:** None
- **Hazard identification:**
  - Human health hazards: Irritation and corrosion to all tissues, developmental effects, and liver toxicity
  - Environmental hazard: High hazard

- **Risk assessment:**
  - **Risks to workers:**
    - Developmental and liver toxicity via dermal exposure
    - Irritation and corrosion hazards for dermal and inhalation exposure to workers
    - Exposures can be mitigated with appropriate PPE, consistent with the SDS prepared by the submitter.
  - **Risks to the general population, consumers, or environment were not identified.**
Example 2

- **Chemical ID:** Methylated imidazole
- **Intended conditions of use:** Import for use as a chemical intermediate in the synthesis of a polymer
- **Regulatory outcome:** “Not Likely” followed by SNUR.
  - The new chemical substance is not likely to present an unreasonable risk under the intended conditions of use (which include the PPE described in the SDS), and there were no known or reasonably foreseen conditions of use identified.
  - EPA has followed the determination with a SNUR.
Example 2

- **SNUR to ensure that circumstances which are not reasonably foreseen but may present risk concerns will not occur absent notification to EPA**

<table>
<thead>
<tr>
<th>Significant New Use</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic manufacture</td>
<td>Manufacture was not assessed and could result in greater worker exposures or environmental releases</td>
</tr>
<tr>
<td>Release of a manufacturing, processing, or use stream into waters of the US exceeding a surface water concentration of 7 ppb</td>
<td>Based on high estimated environmental hazard, releases exceeding this level could present an unreasonable risk</td>
</tr>
</tbody>
</table>
Example 3

- **Chemical ID:** Silsesquioxane polymer
- **Intended conditions of use:** Import for use as an additive to asphalt mixtures and asphalt emulsions
  - **PPE described in SDS:**
    - Impervious gloves
Example 3

- **Chemical ID**: Silsesquioxane polymer
- **Intended conditions of use**: Import for use as an additive to asphalt mixtures and asphalt emulsions
- **Known conditions of use**: None
  - No previous submissions
Example 3

- **Chemical ID:** Silsesquioxane polymer
- **Intended conditions of use:** Import for use as an additive to asphalt mixtures and asphalt emulsions
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:** Use as a waterproofing agent for masonry, based on amendments to the PMN
  - The initial PMN described a use as a waterproofing agent for masonry, but due to unreasonable risks to human health identified in EPA’s initial assessment, the PMN was amended to remove this intended use.
  - Therefore, this use is now considered reasonably foreseen.
Example 3

- **Chemical ID:** Silsesquioxane polymer
- **Intended conditions of use:** Import for use as an additive to asphalt mixtures and asphalt emulsions
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:** Use as a waterproofing agent for masonry

- **Hazard identification:**
  - *Human health hazards:* Irritation to skin and eyes, kidney toxicity, and lung effects (waterproofing)
  - *Environmental hazard:* High environmental hazard (acute and chronic COCs of 80 ppb and 8 ppb, respectively)
Example 3

– Chemical ID: Silsesquioxane polymer
– Hazard identification:
  • Human health hazards: Irritation to skin and eyes, kidney toxicity, and lung effects (waterproofing)
  • Environmental hazard: High hazard
– Risk assessment:
  • Risks to workers:
    – Kidney toxicity via dermal exposure
    – Irritation hazards for dermal exposure
    – Exposures can be mitigated with appropriate PPE, consistent with the SDS prepared by the submitter
    – No inhalation exposures to workers under the amended intended conditions of use
  • Risks to the general population, consumers, or environment were not identified.
Example 3

- **Chemical ID:** Silsesquioxane polymer
- **Intended conditions of use:** Import for use as an additive to asphalt mixtures and asphalt emulsions
- **Regulatory outcome:** “Not Likely” preceded by SNUR.
  
  • The new chemical substance is not likely to present an unreasonable risk under the intended conditions of use (which include the PPE described in the SDS).
  
  • **EPA proposed a SNUR to prevent certain conditions of use without notice to EPA, including those which are reasonably foreseen.**
Example 3
– *SNUR to prevent risk from conditions of use which may present an unreasonable risk*

<table>
<thead>
<tr>
<th>Significant New Use</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use other than as an asphalt additive or asphalt emulsion additive</td>
<td>Other conditions of use, including those which are reasonably foreseen, should be reviewed by EPA based on the identified hazards</td>
</tr>
<tr>
<td>Use in a manner that results in inhalation exposure to respirable droplets or particles</td>
<td>Based on the identified hazards, changes to the conditions of use resulting in inhalation of the substance should be reviewed by EPA</td>
</tr>
<tr>
<td>Release of the substance from manufacturing, processing, or use resulting in surface water concentrations that exceed 8 ppb</td>
<td>Based on high estimated environmental hazard, releases exceeding this level could present an unreasonable risk</td>
</tr>
</tbody>
</table>
Example 4

– **Chemical ID:** Phosphorous acid ester

– **Intended conditions of use:** Import as a liquid to be used in rigid and flexible PVC processing as a booster of PVC stabilizers

  • PPE described in SDS:
    – Impervious gloves
    – NIOSH-certified respirator with an APF of 50 (or APF of 1,000 if spray applied)
    – Safety glasses
Example 4

- **Chemical ID:** Phosphorous acid ester
- **Intended conditions of use:** Import as a liquid to be used in rigid and flexible PVC processing as a booster of PVC stabilizers

- **Known conditions of use:** Use as an additive in coating resins
  - *EPA previously received 2 Low Volume Exemptions for this substance (one requires use of a respirator with an APF of at least 1,000 due to spray application)*
Example 4

- **Chemical ID:** Phosphorous acid ester
- **Intended conditions of use:** Import as a liquid to be used in rigid and flexible PVC processing as a booster of PVC stabilizers
- **Known conditions of use:** Use as an additive in coating resins
- **Reasonably foreseen conditions of use:** Multiple uses other than as described in the PMN, including spray application without a respirator with an APF of 1,000
Example 4

- **Chemical ID: Phosphorous acid ester**
- **Reasonably foreseen conditions of use:** Multiple uses other than as described in the PMN, including spray application without a respirator with an APF of 1,000
  - **Patents:**
    - Use as a stabilizer for various polymers
    - Use in hot melt adhesives
    - Use as a liquid antioxidant
    - Use in a method for production of color effects in coatings
    - Use in methods for suppressing isomerization of olefin metathesis products
  - **Information in LVE:** One of the LVEs intended spray application but did not include a respirator with an APF of 1,000.
Example 4

- **Chemical ID:** Phosphorous acid ester
- **Intended conditions of use:** Import as a liquid to be used in rigid and flexible PVC processing as a booster of PVC stabilizers
- **Known conditions of use:** Use as an additive in coating resins
- **Reasonably foreseen conditions of use:** Multiple uses other than as described in the PMN, including spray application without a respirator with an APF of 1,000

- **Hazard identification:**
  - Human health hazards: Irritation, sensitization, and systemic and reproductive effects
  - Environmental hazard: Low
Example 4

- **Chemical ID:** Phosphorous acid ester
- **Intended conditions of use:** Import as a liquid to be used in rigid and flexible PVC processing as a booster of PVC stabilizers
- **Known conditions of use:** Use as an additive in coating resins
- **Reasonably foreseen conditions of use:** Multiple uses other than as described in the PMN, including spray application without a respirator with an APF of 1,000
- **Hazard identification:**
  - **Human health hazards:** Irritation, sensitization, and systemic and reproductive effects
  - **Environmental hazard:** Low hazard
- **Risk assessment:**
  - **Risks to workers:**
    - Systemic and reproductive effects via dermal exposure
    - Irritation and sensitization hazards for dermal and inhalation exposure
    - Exposures can be mitigated with appropriate PPE, consistent with the SDS prepared by the submitter.
  - **Risks to the general population, consumers, or environment were not identified.**
Example 4

- **Chemical ID:** Phosphorous acid ester
- **Intended conditions of use:** Import as a liquid to be used in rigid and flexible PVC processing as a booster of PVC stabilizers
- **Regulatory outcome:** “Not Likely” preceded by SNUR.
  - The new chemical substance is not likely to present an unreasonable risk under the intended conditions of use (which include the PPE described in the SDS).
  - **EPA** proposed a SNUR to prevent certain conditions of use, including those which are reasonably foreseen.
Example 4

- **SNUR to prevent risk from reasonably foreseen conditions of use as well as other circumstances which may present an unreasonable risk**

<table>
<thead>
<tr>
<th>Significant New Use</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use other than for the intended or known conditions of use</td>
<td>Because other uses are reasonably foreseen and have not been assessed, they could present an unreasonable risk to human health and should be reviewed by EPA</td>
</tr>
<tr>
<td>Use of the substance without a respirator with an APF of at least 50, or of at least 1,000 if spray-applied</td>
<td>Because spray use without a respirator with an APF of 1,000 is reasonably foreseen, this term protects against sensitization hazards</td>
</tr>
</tbody>
</table>
Example 5

- **Chemical ID:** Acetyloxy butenenitrile
- **Intended conditions of use:** Manufacture and import for use as a chemical intermediate for a pesticide inert
  - Manufactured, processed, and used in a closed system
  - **PPE described in PMN:**
    - Full body PPE with supplied air
Example 5

- **Chemical ID**: Acetyloxy butenenitrile
- **Intended conditions of use**: Manufacture and import for use as a chemical intermediate for a pesticide inert
- **Known conditions of use**: None
  - No previous submissions
Example 5

- **Chemical ID:** Acetyloxy butenenitrile
- **Intended conditions of use:** Manufacture and import for use as a chemical intermediate for a pesticide inert
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:**
  - *Chemical intermediate in the synthesis of pesticides*
  - *Electrolyte*
    - **Patents:** 47 identified
      - *Chemical intermediate for pesticides, pharmaceuticals*
      - *Use as an electrolyte*
Example 5

- **Chemical ID:** Acetyloxy butenenitrile
- **Intended conditions of use:** Manufacture and import for use as a chemical intermediate for a pesticide inert
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:** Use as a chemical intermediate in the synthesis of pesticides and as an electrolyte
- **Hazard identification:**
  - **Human health hazard:**
    - Acute toxicity based on release of cyanide
    - Neurotoxicity
    - Irritation
    - Developmental toxicity
  - **Environmental hazard:** High environmental hazard (acute and chronic COCs of 150 ppb and 8 ppb, respectively)
Example 5

- **Chemical ID:** Acetyloxy butenenitrile
- **Intended conditions of use:** Manufacture and import for use as a chemical intermediate for a pesticide inert
- **Known conditions of use:** None
- **Reasonably foreseen conditions of use:** Use as a chemical intermediate in the synthesis of pesticides and as an electrolyte
- **Hazard identification:**
  - **Human health hazard:** Acute toxicity based on release of cyanide, neurotoxicity, irritation, and developmental toxicity
  - **Environmental hazard:** High hazard

- **Risk assessment:**
  - **Risks to workers:**
    - Potential for inhalation and dermal exposure, which could result in severe acute effects if appropriate PPE is not used.
  - **Risks to the general population, environment, and consumers** were not identified.
Example 5

– **Chemical ID:** Acetyloxy butenenitrile
– **Intended conditions of use:** Manufacture and import for use as a chemical intermediate for a pesticide inert
– **Regulatory outcome:** “Insufficient Information” and “May Present”
  - **TSCA 5(e) Consent Order** to impose limitations necessary to protect against risk of injury to health and the environment because the consequences of exposure could be so severe (e.g., lethality)
  - **SNUR** requires notice to EPA by any manufacturer or processor who wishes to manufacture or process the chemical in a way other than described in the terms and conditions contained in the Order.
Example 5

- **TSCA 5(e) Consent Order Limitations**
  - The Consent Order requires the company to:
    - Conduct workplace monitoring;
    - Provide full reports of all studies summarized in the REACH Dossier;
    - Provide PPE to prevent dermal and inhalation exposure, including NIOSH-certified respirators with an APF of at least 1,000;
    - Label containers and provide SDSs and training in accordance with the Hazard Communication Program section;
    - Not manufacture, process, or use except in a closed system as described in the PMN;
    - Not use other than as a chemical intermediate;
    - Distribute only to a person who agrees to follow the same restrictions and to not further distribute the substance;
    - No predictable or purposeful release of the substance into the waters of the United States; and
    - Maintain certain records.
Example 5

- **TSCA 5(e) Consent Order Testing Requirements**
  - **Triggered testing:**
    - workplace monitoring for the PMN substance
    - submit an annual report with the results
    - Submission of full reports of all toxicity studies summarized in the REACH Dossier on the substance
  - **Pended testing:** Chronic aquatic toxicity testing would be required to evaluate chronic environmental toxicity if the Order or SNUR were to be modified in a way that would allow for water releases.
Case Example Recap

– **Step 1. Identification of conditions of use**
  - *Intended*
  - *Known*
  - *Reasonably foreseen*

– **Step 2. Hazard identification/characterization**
  - *Human health hazards*
  - *Environmental hazards*

– **Step 3. Risk assessment**

– **Step 4. Risk management, resulting in a determination (regulatory outcome)**

*Using the updated working approach through these steps, EPA reaches a determination for all cases based on the available information.*
TSCA Confidential Business Information (CBI): Implementation Update
Overview

- Background on TSCA CBI
- Common Issues
- TSCA CBI Review Plan Rule
- Impact of the Argus decision
- The Future of TSCA CBI
What is TSCA CBI?

• Confidential Business Information (CBI) under TSCA
  – CBI under TSCA is broadly defined as information, maintained as confidential to the submitter and the submitter has a reasonable basis to conclude that the release of the information is likely to cause substantial harm to the competitive position of the company.
  – Companies generally request CBI protection for confidential information believed to give other companies an advantage in the marketplace, such as details of their manufacturing processes and formulas.
TSCA Requirements for Making CBI Claims

- Certification statement
- Substantiation
- Generic Name
Certification Statement

• Submitter must provide a statement asserting the need for the CBI claim and a certification that the statement of need is true and correct.

• The certification statement has been incorporated into TSCA electronic reporting applications in EPA’s Central Data Exchange (CDX). A submitter making CBI claims in electronic submissions must agree to the statement when making a submission.

• For paper submissions of data not already submitted via CDX, it is up to the submitter to include a signed statement that satisfies the certification statement requirement.
Certification Statement

Recommended Text
I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.
I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that
i. My company has taken reasonable measures to protect the confidentiality of the information;
ii. I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
iii. I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
iv. I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.
Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.
https://www.epa.gov/tsca-cbi/making-cbi-claims-tsca-submissions#certification
Substantiation of CBI Claims

- Any claims of TSCA CBI for information, except for information exempt from substantiation under TSCA § 14(c)(2), must be substantiated at the time the claimed information is submitted to EPA.
Information exempt from substantiation

- TSCA section 14(c)(2) identifies certain information that is generally not subject to substantiation requirements. This information includes:
  - Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
  - Marketing and sales information;
  - Information identifying a supplier or customer;
  - In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
  - Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
  - Specific production or import volumes of the manufacturer or processor; and
  - Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA 5.
Notice of Deficiency

• Between the enactment of the Lautenberg Act in June of 2016, and August 15, 2019, EPA sent Notices of Deficiency to submitters whose submissions were not fully substantiated or where another procedural requirement for making a CBI claim was not followed.

• In July 2019, EPA published a Federal Register notice announcing that EPA would no longer be sending out Notices of Deficiency on submissions which fail to properly substantiate CBI claims.
What is EPA looking for in CBI substantiations?

• A CBI substantiation needs to support two assertions:
  – The information is actually kept confidential.
  – The submitter has a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the company.
What is EPA looking for in CBI substantiations?

• Certain regulatory provisions include specific, required substantiation questions.
• EPA has published substantiation templates to assist with substantiating CBI claims.
• The substantiation questions in the TSCA regulatory provisions and templates help submitters support their CBI claims.
• Submitters may provide to EPA any information (e.g., money spent on R&D, how disclosure would harm competitive advantage) they believe supports the validity of their CBI claims.
Common Issues

• Failure to substantiate all information claimed as confidential

• Claiming certain information as exempt from substantiation that does not fit into one of the categories of information enumerated in section 14

• Over-redaction of health and safety studies
TSCA CBI Review Plan Rule

• TSCA Inventory Active-Inactive Rule
  – EPA promulgated the Active-Inactive rule to obtain the information necessary for EPA to designate as “active” chemical substances that had been manufactured or processed for a nonexempt commercial purpose during the 10-year time period prior the enactment of the TSCA amendments in 2016.

• TSCA CBI Review Plan Rule
  – TSCA section 8(b)(4)(C) requires EPA to promulgate a rule establishing a plan to review all CBI claims to protect the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory that were asserted in retrospective commercial activity notices under the Active-Inactive Rule.
TSCA CBI Review Plan Rule

- The TSCA CBI Review Plan Rule was proposed on April 23, 2019.
- A supplemental notice of proposed rulemaking was published on November 8, 2019, to propose additional substantiation questions relating to reverse engineering.
- The comment period on the supplemental notice closed on December 9, 2019.
- EPA will consider comments received for both the original proposal and supplemental notice of proposed rulemaking and expects to issue the final rule in February 2020.
Impact of the Argus Decision

• *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019)
  
  – On June 24, 2019, the U.S. Supreme Court issued a decision addressing the test for determining whether commercial information qualifies as “confidential” for purposes of Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4).
Impact of the Argus Decision

- The decision *does not* impact substantiation questions or CBI review criteria that incorporate the substantial competitive harm standard.

- Congress amended TSCA section 14 in 2016 to, among other things, specifically require any person asserting a CBI claim under TSCA to include a certified statement that the person has “a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.”

- Because these requirements are included in TSCA section 14, neither the “substantial competitive harm” review criterion nor any related substantiation question for TSCA CBI claims should be removed or modified based on the Court’s decision in *Argus*. 
The Future of TSCA CBI

• EPA is exploring ways to make the procedural and practical aspects relating to TSCA more efficient and less burdensome for both submitters and EPA.

• Options may include:
  – Additional guidance,
  – Enhancements to electronic reporting systems, and/or
  – Promulgating rules relating to the of claiming information as confidential in TSCA submissions
The Future of TSCA CBI

• Provide clarity to submitters on making CBI claims, thereby reducing burden and risk (of inadvertent CBI claim loss) for submitters,

• Streamline and shorten review time for EPA (thereby minimizing backlog and reducing use of TSCA fee funds to administer the CBI review program), and

• Increase the availability and timeliness of non-CBI data to the public.
Update on EPA’s Transparency Efforts in the TSCA New Chemicals Program
Overview

• Transparency milestones since June 22, 2016
• How OPPT makes information publicly available
• Demonstrations
  – Review of New Chemicals site
  – Review of TSCA CBI site
  – Review of TSCA Inventory site
  – Review of ChemView
• Coming Soon
TSCA Transparency Milestones

- Publishing Notices of Receipt
- PMNs & Supporting Doc Availability
- CBI Claims: Review and Publication

Lautenberg Act Signed into Law
- June 2016
  - Posted “Not Likely” determinations: August 2016
  - Launched improved web status table with final determinations: August 2017
  - Improved format and content of monthly new chemical notices: June 2018
  - Published CBI guidance and policy re unique identifier and generic name: June 2018

Published more informative New Chemicals Program Statistics web page: May
- Published TSCA CBI review statistics on epa.gov: July
- Published all new PMNs/MCANS/SNUNs, in ChemView (began in May): July

Begin publishing New Chemical Notices on the web: November
- New Chemicals framework public meeting: December
- Publish list of CBI cases subject to review (quarterly) and updated UID list: December

2016 - 2018

2019
Making Information Publicly Available

- Federal Register
- Public Dockets
- Webpages
- ChemView
New Chemical Information Received

Certain New Chemicals; Receipt and Status Information for July 2019

A Notice by the Environmental Protection Agency on 09/05/2019

New Chemical Information Received

Certain New Chemicals: Receipt and Status Information for July 2019

New Chemical Information Received

Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca
New Chemical Information Received

Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemical-notices-received-epa
New Chemical Information Received

Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)

PMN/SNUN/MCAN/TMEA Submissions Received under TSCA

This page lists submissions received by EPA for pre-manufacture notices (PMNs), Significant New Activity notices (SNAs), High-Volume Commercial Activity Notices (MCANs), and Test-Only Commercial Activity Submissions (TMCAS) pursuant to section 6 of the Toxic Substances Control Act (TSCA) and its implementing regulations at 40 CFR part 721.

EPA provides the following information for the subset of each information that is not subject to confidentiality baseline information (CBI) claim on the notices received by EPA starting with the June 2020 notice:
- the PMN case number assigned for the notice indicates whether the submission is an initial submission or an amendment;
- a notation (s) indicates whether the submission was received by EPA;
- the date the notice was received by EPA;
- the submitting manufacturer (i.e., a domestic producer or importer);
- the potential uses identified by the notice, and;
- the chemical substance identity.

In this table (and [2]) indicates the information is the specific information provided by the submittor, and a (3) indicates this information for the notice is general information because the specific information provided by the submittor was claimed CBI. Submitters submitting new initial submissions will not have a letter following the case number. Submissions for which are not received or pre-manufacture submissions will have a case number followed by the letter "M" (e.g., PM-325-M). The column contains submissions by source as "C" (Chemical), "S" (Test Only), etc. Where that is case, an initial submission is not numbered as section 6.106.1 because earlier notices were inadvertently included in the table. A.

To search for a specific case, enter the case number in the search at the upper right of the table.

Learn more about the types of information received under TSCA section 6:
- TSCA Section 6 Pre-Manufacture Notice (PMN) Submissions Received
- TSCA Section 6 Significant New Activity (SNA) Submissions Received
- TSCA Section 6 High-Volume Commercial Activity (MCAN) Submissions Received
- TSCA Section 6 Test-Only Commercial Activity (TMCAS) Submissions Received

Download the PDF file. The table below lists CBI variables that can contain information from June 2010 through August 2016.

Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tasca/pmnsnunmcantmea-submissions-received
New Chemical Case Tracker

Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca
New Chemical Case Tracker

Active Cases under Review by EPA (PMN/SNUN/MCAN, as of 11/1/2019, 383 cases total)

*To be updated monthly.

To see a list of case numbers in each stage of the review process, click on the number link in the box for that stage. This will open a new tab in your browser window.

Final Status Of Case

Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca
**Final Status Of Case**

**Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)**

**Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) Table**

These tables display the interim status and final determinations for TSCA section 5 PMN and SNUN submissions. The interim status reflects staff-level recommendations made after EPA’s initial risk assessment during the focus meeting. Following the focus meeting, EPA advises the submitter of the case interim status and any risk concerns. EPA often engages in a dialogue with the submitter about the scientific basis for the recommendation. Submitters often choose to provide subsequent information about the chemical substance, offer to conduct testing, or amend their notice to address EPA concerns. As a result of this EPA-submitter dialogue and submitter actions to address identified risks or provide information that leads EPA to revise its initial risk determinations, final risk determinations can differ from the interim recommendations.

Please note: Links to consent orders are generally available within two weeks of the order’s effective date.

- [View the legend of status abbreviations and definitions contained in the table below.](#)
- [View the tables with determinations relating (Download, Exporting toolbar, CSV, PDF).](#)
- [View the tables with exemption decisions for significant new uses, some environmental releases and low human exposure End-use or test marketing (TMDU) exemption applications or modifications under TSCA.](#)

View the chemicals determined not likely to present an unreasonable risk following pre-manufacture notification review.

“Not Likely” Determinations

Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca
## Not Likely” Determinations

### Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)

Chemicals Determined Not Likely to Present an Unreasonable Risk Following Pre-Manufacture Notification Review

This page describes the chemical substances EPA has determined are “not likely to present an unreasonable risk” following review of pre-manufacture notifications under Section 6 of TSCA, as amended by the Frank R. Laubach Chemical Safety for the 21st Century Act, P.L. 114-86.

**Note:** For these chemicals not likely to present an unreasonable risk” means that EPA has determined that the chemical is not likely to present an unreasonable risk of injury to health or the environment, or to the two, based on the data and information currently available.

Certain determinations that a chemical is not likely to present an unreasonable risk are based upon both the agency’s risk assessment for the chemical substance under intended conditions of use described in the PMN and the issuance of a proposed SNUR to address certain reasonably foreseeable uses. Conditions of use that fall under the restrictions of the proposed SNUR are not likely to present unreasonable risks to the environment for the following reasons:

- Conditions of use that are not likely to be commercialized during the period of proposed SNUR and (2) upon finalization of the SNUR; these conditions of use would be prohibited unless and until the EPA makes an affirmative determination that the significant new use is not likely to present an unreasonable risk or takes appropriate action under Sections 5(a) or 5(f). The terms of these proposed SNURs are provided below along with the determination document.

### Table: Case Studies of Section 5 Pre-Manufacture Notices reviewed under TSCA

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Chemical Identity</th>
<th>EPA Determination</th>
<th>Recovery</th>
<th>Review Start Date</th>
<th>Decision Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-19-0122</td>
<td>1,3-Diethyl-2,4,6-Trinitrobenzene, CASRN 1200429-38-9</td>
<td>The chemical substance is not likely to present an unreasonable risk (Sa) (SCE)</td>
<td>A determination of “not likely to present an unreasonable risk” section 6(a)(3)(E) determination.</td>
<td>03/28/2019</td>
<td>03/29/2019</td>
</tr>
<tr>
<td>P-17-0000</td>
<td>1,3-Diethyl-2,4,6-Trinitrobenzene, CASRN 1200429-38-9</td>
<td>The chemical substance is not likely to present an unreasonable risk (Sa) (SCE)</td>
<td>A determination of “not likely to present an unreasonable risk” section 6(a)(3)(E) determination.</td>
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<td>03/28/2019</td>
<td>03/29/2019</td>
</tr>
</tbody>
</table>

TSCA CBI Site: Review Statistics

Source: https://www.epa.gov/tsca-cbi
### TSCA CBI Review Statistics

Since the enactment of the TSCA amendments in June 2016, EPA has established numerous new processes, systems, and procedures to enable submitters to provide the information required when making confidentiality claims and to facilitate EPA’s review, and where applicable, determinations on these claims. The statistics provided below show EPA’s progress toward meeting the requirements of TSCA section 14(d). A “case” is a submission made under a specific section of TSCA and all subsequent submissions and amendments by the same submitter that relate back to the first submission.

#### CBI Review Statistics (cases received between June 22, 2016 and December 2, 2019)

<table>
<thead>
<tr>
<th>Case Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases in which the specific chemical identity is subject to CBI review</td>
<td>2,495</td>
</tr>
<tr>
<td>Cases in which information other than the specific chemical identity is subject to CBI review</td>
<td>2,324</td>
</tr>
<tr>
<td>Cases in which both the specific chemical identity and information other than the specific chemical identity is subject to CBI review</td>
<td>677</td>
</tr>
<tr>
<td>Total cases subject to CBI review</td>
<td>5,496</td>
</tr>
</tbody>
</table>

#### Cases resulting in final CBI determinations

<table>
<thead>
<tr>
<th>Case Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases with all CBI claims subject to review approved</td>
<td>609</td>
</tr>
<tr>
<td>Cases with all CBI claims subject to review, denied</td>
<td>15</td>
</tr>
<tr>
<td>Cases with CBI claims subject to review, approved in part/denied in part</td>
<td>43</td>
</tr>
<tr>
<td>Total cases resulting in final CBI determinations</td>
<td>667</td>
</tr>
</tbody>
</table>

*“Denial - appeal period pending” cases are those for which a CBI determination denying one or more CBI claims in a case has been issued to the submitter of the information, but for which the required 30-day notification period following receipt of the determination under TSCA section 14(g) (2)(B) has not yet passed.

#### Cases reviewed with no final CBI determination necessary

<table>
<thead>
<tr>
<th>Case Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases with all CBI claims screened and found to be exempt from review</td>
<td>1,071</td>
</tr>
<tr>
<td>Cases with all CBI claims withdrawn by submitter</td>
<td>433</td>
</tr>
<tr>
<td>Cases identified for CBI review, for which no determination required (e.g., in some instances, older EPA information systems do not specifically identify which information is claimed as CBI and upon review, it is determined that no claims require review)</td>
<td>1,220</td>
</tr>
<tr>
<td>Total cases reviewed/screened with no final CBI determination necessary</td>
<td>2,724</td>
</tr>
</tbody>
</table>

#### Cases currently undergoing CBI review

<table>
<thead>
<tr>
<th>Case Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases currently undergoing CBI review</td>
<td>2,105</td>
</tr>
</tbody>
</table>

Source: [https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program](https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program)
TSCA Inventory Site: Inventory w/ IUD

Source: https://www.epa.gov/tsca-inventory
TSCA Inventory Site: Inventory w/ IUD
ChemView: UID List

Source: https://chemview.epa.gov/chemview/
ChemView: UID List

Source: https://chemview.epa.gov/chemview/
**ChemView: UID List**

Source: [https://chemview.epa.gov/chemview/](https://chemview.epa.gov/chemview/)
ChemView: New Chemical Notices

Source: https://chemview.epa.gov/chemview/
ChemView: New Chemical Notices

New Chemical Notices

Chemical Name: Copper orthoaminexylin complex, mixed
Chemical Identifier: 14215-52-2
Receipt Date of Notice: June 7, 2013

Notice Number: P-19-0029
Type of Notice: Premanufacture Notice (PMN)
Company Name: AIICH CHEMICALS, INC.
Type of Activity: Domestic Manufacture
Maximum 12-month production volume during the first 3 years(kg/yr): CBI
Type of EPA Review: 90-day

User(s):
- Chemical is used as a component of a hawk cleaning formulation to improve the wettability of the overall cleaning solution on the hawk.

All Versions (including attachments) of this notice from most recent to original:

- Version Received: 06/07/2013 (Download 1201)
- Submission Form
- OIS_SUBMISSION - 06/21/20131865a163_m_CBI_SubmissionFormPMN.docx
- CHEMICAL_STRUCTURE_DIAGRAM - 06/21/2013a1635a20_StructureDiagram_Copper orthaaminexylin complex.docx
- HEALTH_TOXICITY - 06/22/2013a1635a22_PSL 6500 Cautrex Ultra Oral L662 [MID1 45532265]_34.pdf
- HEALTH_TOXICITY - 06/22/2013a1635a22_PSL 6011 Cautrex Ultra eye irritation [MID1 45532265]_34.pdf
- HEALTH_TOXICITY - 06/22/2013a1635a22_PSL 5013 Cautrex Ultra dermal sensitization [MID1 45532265]_33.pdf
- HEALTH_TOXICITY - 06/22/2013a1635a22_PSL 6923 Cautrex Ultra eye irritation [MID1 45532265]_30.pdf
- PMN_PMN_OTHER - 06/22/2013a1635a22_PMN_PMN_OTHER_921552-2.pdf
- PROCESS_DIAGRAM - 06/22/2013a1635a22_ProcessDiagram_PMN_PMN_OTHER_CBI.pdf
- PROCESS_DIAGRAM - 06/22/2013a1635a22_ProcessDiagram_PMN_PMN_OTHER_CBI.pdf

Source: https://chemview.epa.gov/chemview/
ChemView: New Chemical Notices

Source: https://chemview.epa.gov/chemview/
ChemView: PMN Review Determinations

Source: https://chemview.epa.gov/chemview/
ChemView: PMN Review Determinations

Premanufacture Notice Review Determinations

Chemical Name: Benzoic acid, 2,6-dichloro-, sodium salt (1:1)
Chemical Identifier: 10007-94-8
Federal Register Citation: 84 FR 43266 August 20, 2019
Chemical Category: Esters

PMN Determination for: Benzoic acid, 2,6-dichloro-, sodium salt (1:1)
PMN Number: P-17-00571
PMN Determination Date: April 20, 2017

What is the TSCA §5 Determination?
- Insufficient information to permit a reasoned evaluation and the chemical substance may present an unreasonable risk of injury to health or the environment (TSCA § 5(b)(3)(B)(i)(IX))

Is there a TSCA §5 Order related to the chemical substance?
- Yes
  - TSCA § 5 Order

What is the basis for the Order:
- Insufficient information and May Present an Unreasonable Risk: EPA is unable to determine whether the PMN substance will present an unreasonable risk to human health or the environment. Information available to EPA indicates that there is a potential for human or environmental exposure to the PMN substance. Therefore, pursuant to TSCA §5(b)(3)(B)(i)(IX) and 5(b)(1)(A)(i)(IX), EPA has determined that the uncontrolled manufacture, processing, distribution in commerce, use, or disposal of the PMN substance may present an unreasonable risk of injury to human health or the environment and the limitations imposed in the order are necessary to protect against such risk.

Does the chemical have a specific or generic name?
- Benzoic acid, 2,6-dichloro-, sodium salt (1:1) 10007-94-8

Does the substance have a Polymer Exemption flag?
- No

What is the health concern rating associated with the substance?
- A moderate concern for human health hazard

What is the environmental concern rating associated with the substance?
- A low concern for environmental hazard

Source: https://chemview.epa.gov/chemview/
COMING SOON

- 2016 CDR data update

- UID list update - Updated yesterday

- Aggregate CBI review and determination statistics update - Updated yesterday

- CBI determination information table - Provided yesterday