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

November 6, 2017 – EPA released the "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA" for public comment

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 foreseen conditions of use?

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

- Can EPA address information deficiencies or risk concerns for reasonably foreseen 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: <u>Import</u> 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***

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

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***

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

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***

Significant New Use	Rationale
Use other than for the intended or known conditions of use	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
Use of the substance without a respirator with an APF of at least 50, or of at least 1,000 if spray-applied	Because spray use without a respirator with an APF of 1,000 is reasonably foreseen, this term protects against sensitization hazards

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

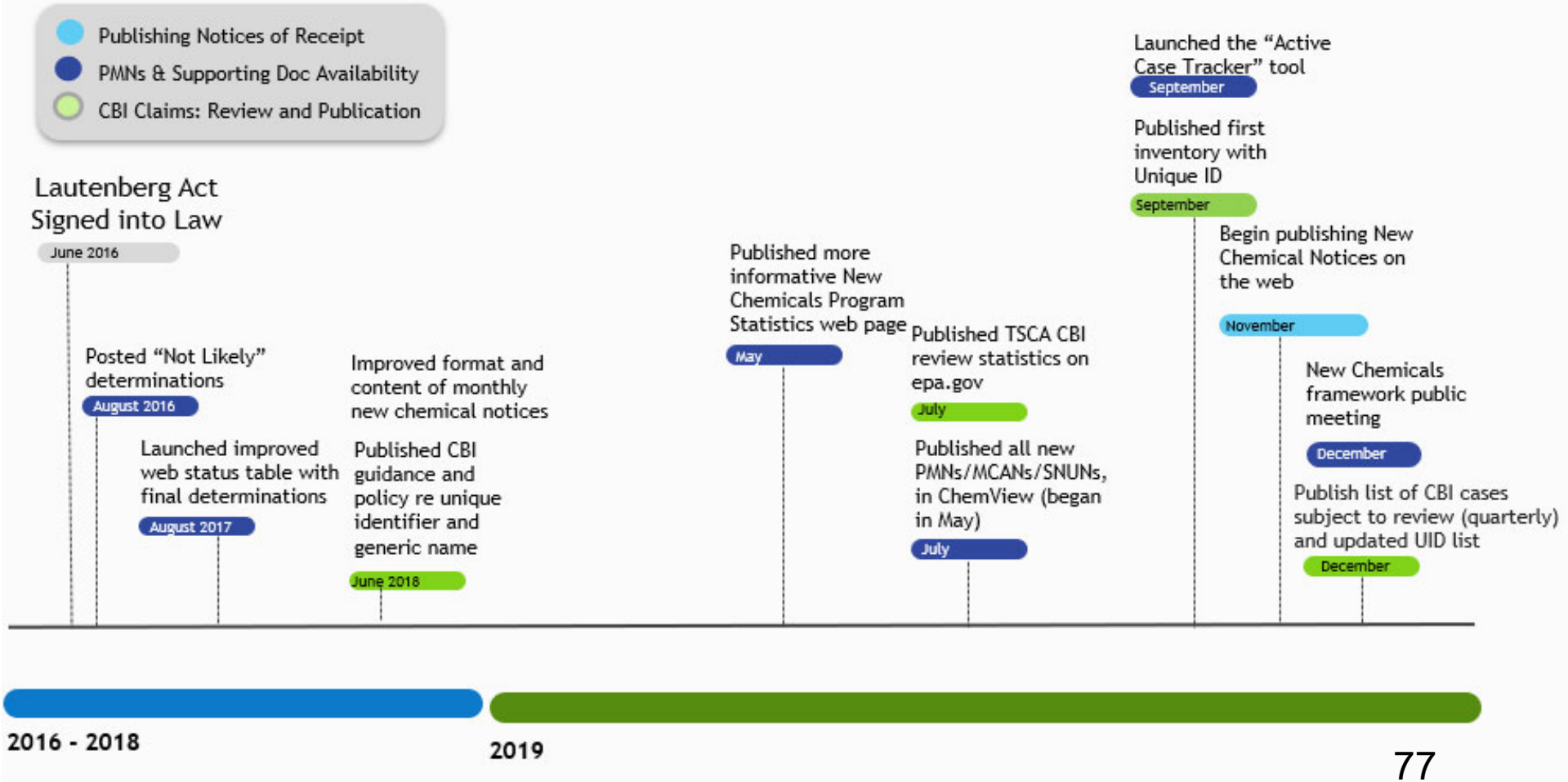
- Increase the availability and timeliness of non-CBI data to the public.

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

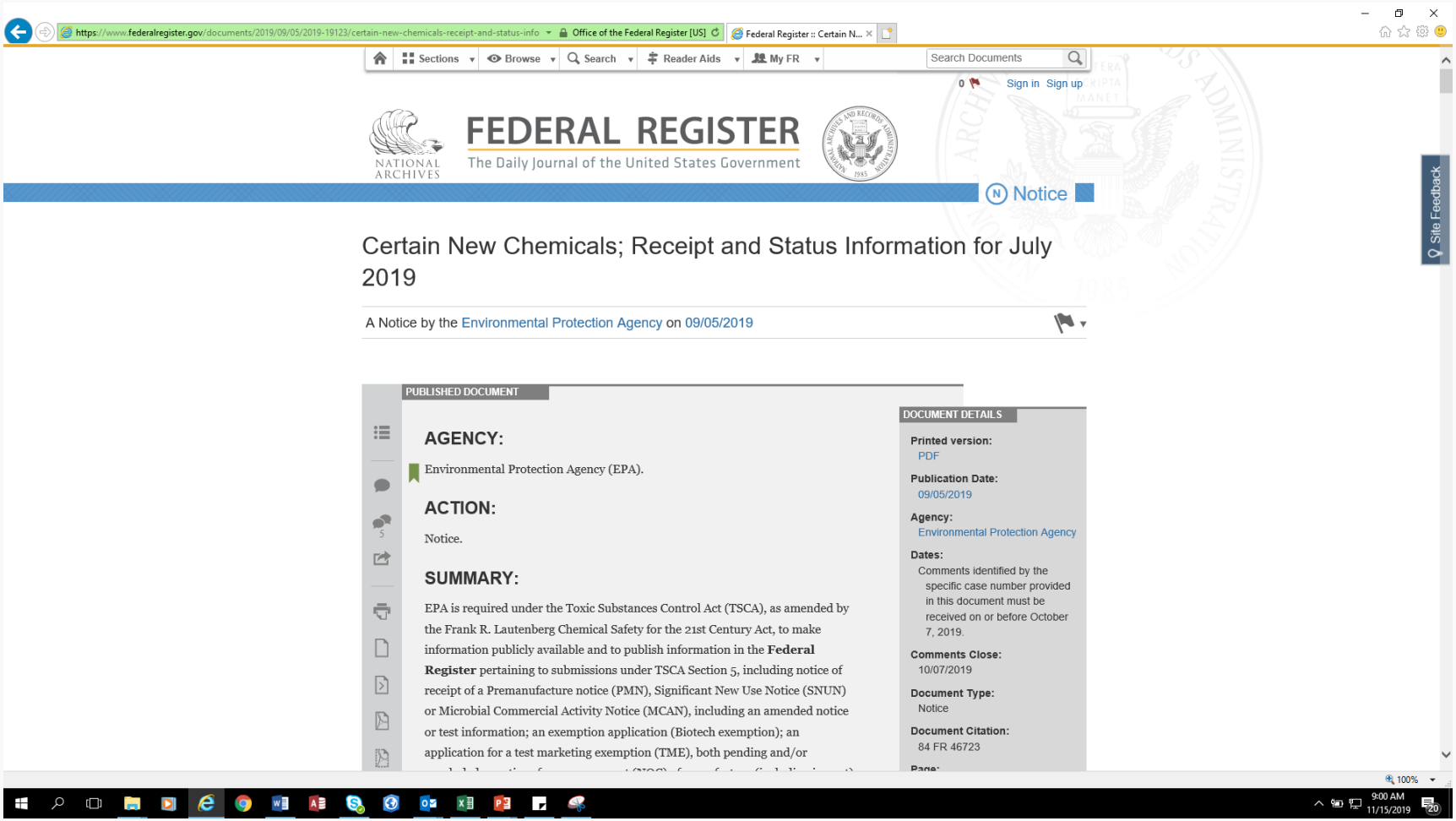
TSCA Transparency Milestones



Making Information Publicly Available

- Federal Register
- Public Dockets
- Webpages
- ChemView

New Chemical Information Received



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The Daily Journal of the United States Government

Notice

Certain New Chemicals; Receipt and Status Information for July 2019

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

PUBLISHED DOCUMENT

AGENCY:

Environmental Protection Agency (EPA).

ACTION:

Notice.

SUMMARY:

EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the **Federal Register** pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or

DOCUMENT DETAILS

Printed version: PDF

Publication Date: 09/05/2019

Agency: Environmental Protection Agency

Dates: Comments identified by the specific case number provided in this document must be received on or before October 7, 2019.

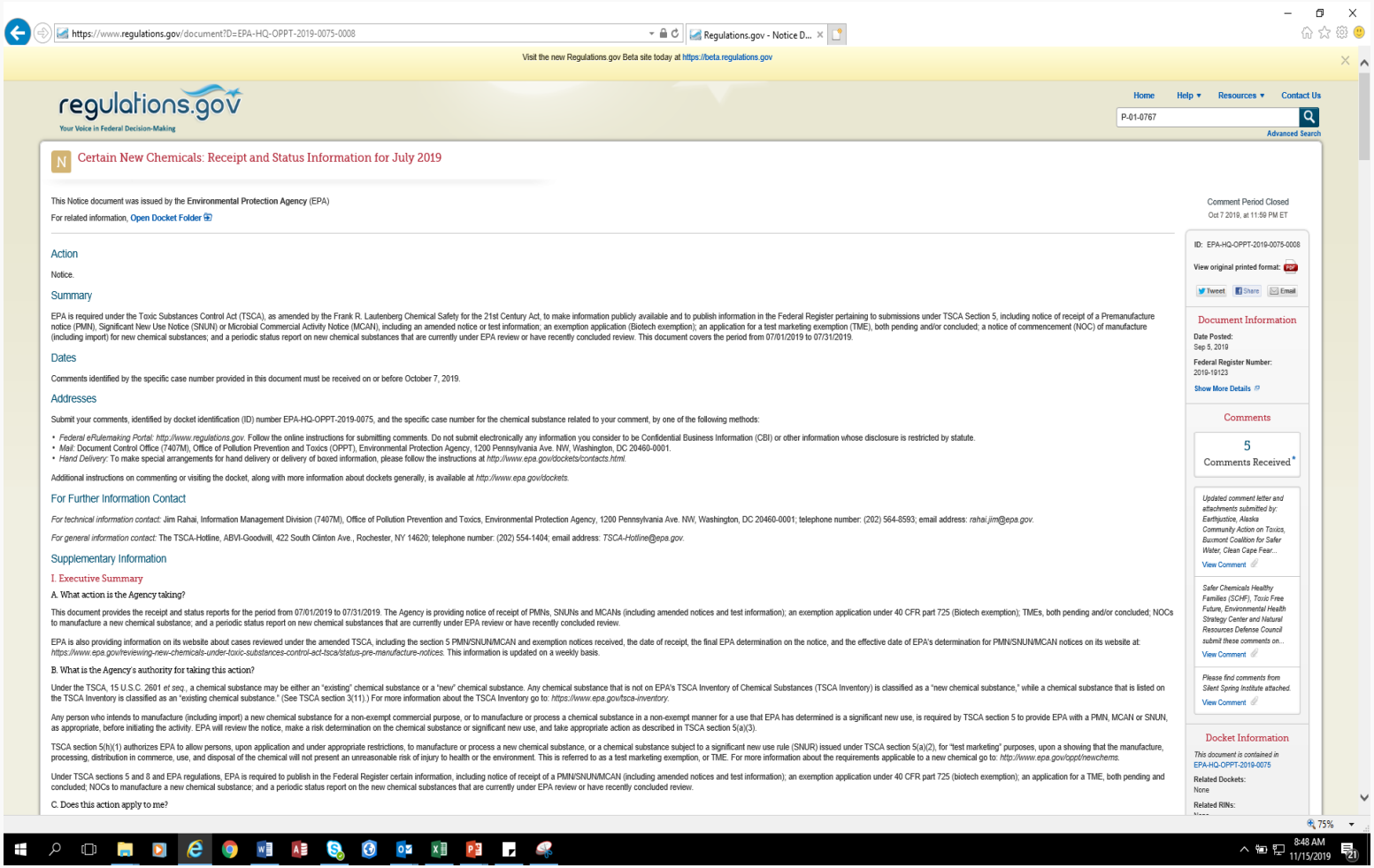
Comments Close: 10/07/2019

Document Type: Notice

Document Citation: 84 FR 46723

Source: https://www.federalregister.gov/documents/2019/09/05/2019-19123/certain-new-chemicals-receipt-and-status-information-for-july-2019

New Chemical Information Received



https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0075-0008

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P-01-0767

Advanced Search

Certain New Chemicals: Receipt and Status Information for July 2019

This Notice document was issued by the **Environmental Protection Agency** (EPA)

For related information, Open Docket Folder

Comment Period Closed
Oct 7 2019, at 11:59 PM ET

ID: EPA-HQ-OPPT-2019-0075-0008

View original printed format:

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Action

Notice.

Summary

EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the Federal Register pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information, an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 07/01/2019 to 07/31/2019.

Dates

Comments identified by the specific case number provided in this document must be received on or before October 7, 2019.

Addresses

Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0075, and the specific case number for the chemical substance related to your comment, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

For Further Information Contact

For technical information contact: Jim Rahai, Information Management Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: *rahai.jim@epa.gov.*

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

Supplementary Information

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 07/01/2019 to 07/31/2019. The Agency is providing notice of receipt of PMNs, SNUNs and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the TSCA, 15 U.S.C. 2601 *et seq.*, a chemical substance may be either an "existing" chemical substance or a "new" chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a "new chemical substance," while a chemical substance that is listed on the TSCA Inventory is classified as an "existing chemical substance." (See TSCA section 3(11).) For more information about the TSCA Inventory go to: *https://www.epa.gov/tsca-inventory.*

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for "test marketing" purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *http://www.epa.gov/oppt/newchems.*

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the Federal Register certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

Document Information

Date Posted:
Sep 5, 2019

Federal Register Number:
2019-19123

Show More Details

Comments

5
Comments Received*

Updated comment letter and attachments submitted by: Earthjustice, Alaska Community Action on Toxics, Buxmont Coalition for Safer Water, Clean Cape Fear...
View Comment

Safer Chemicals Healthy Families (SCHF), Toxic Free Future, Environmental Health Strategy Center and Natural Resources Defense Council submit these comments on...
View Comment

Please find comments from Silent Spring Institute attached.
View Comment

Docket Information

This document is contained in EPA-HQ-OPPT-2019-0075

Related Dockets:
None

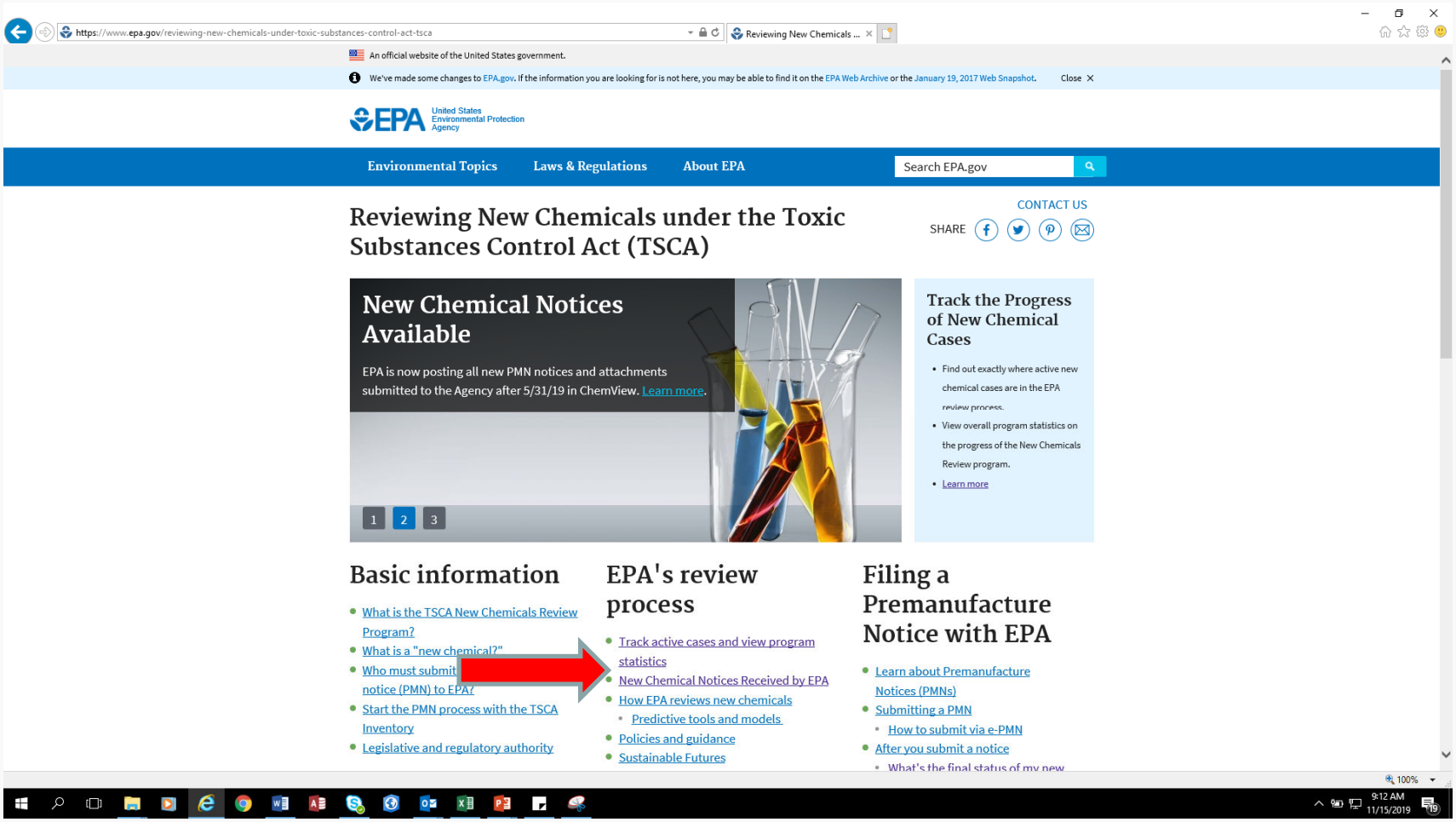
Related RINs:

75%

8:48 AM
11/15/2019

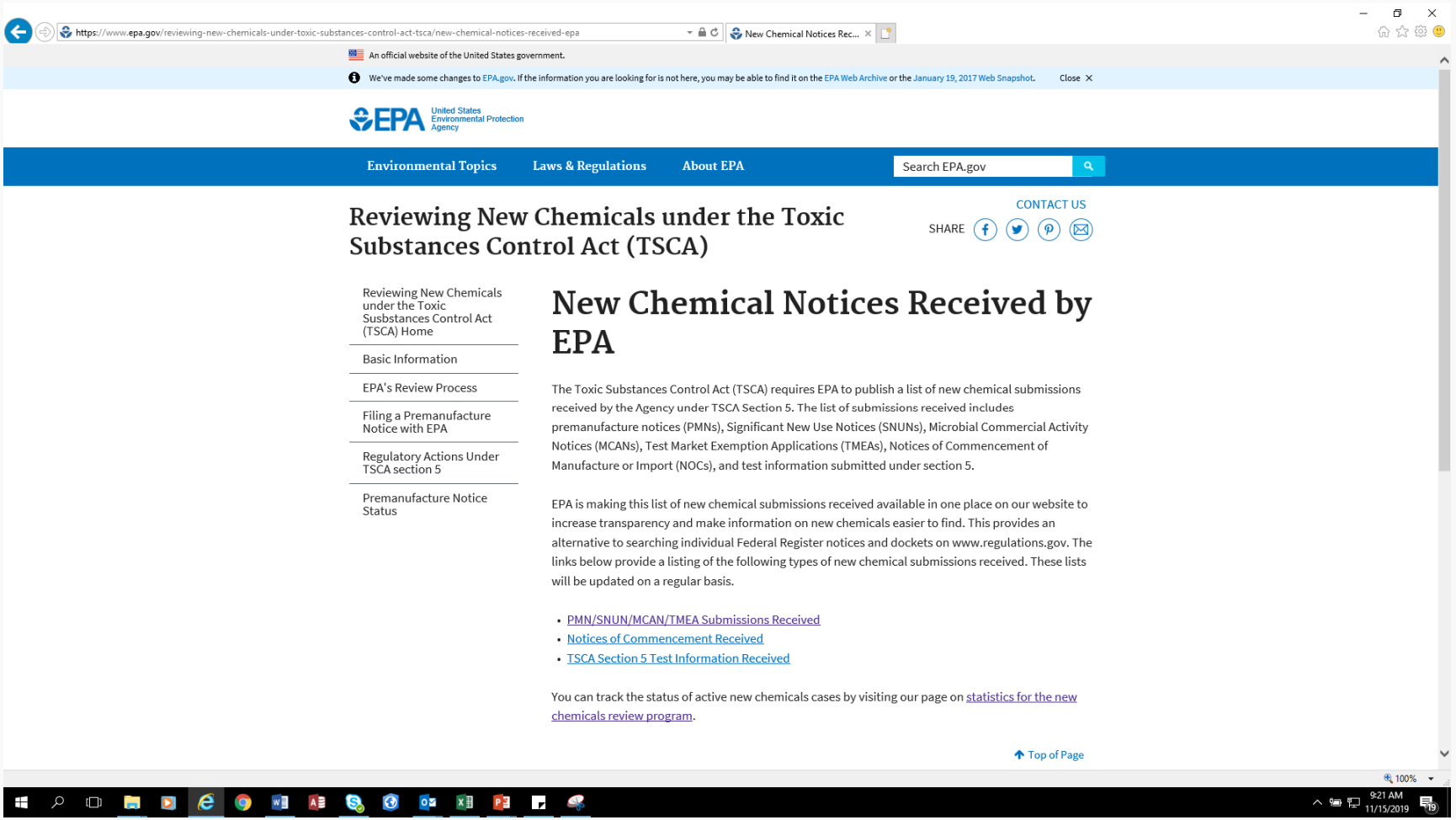
Source: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0075-0008

New Chemical Information Received



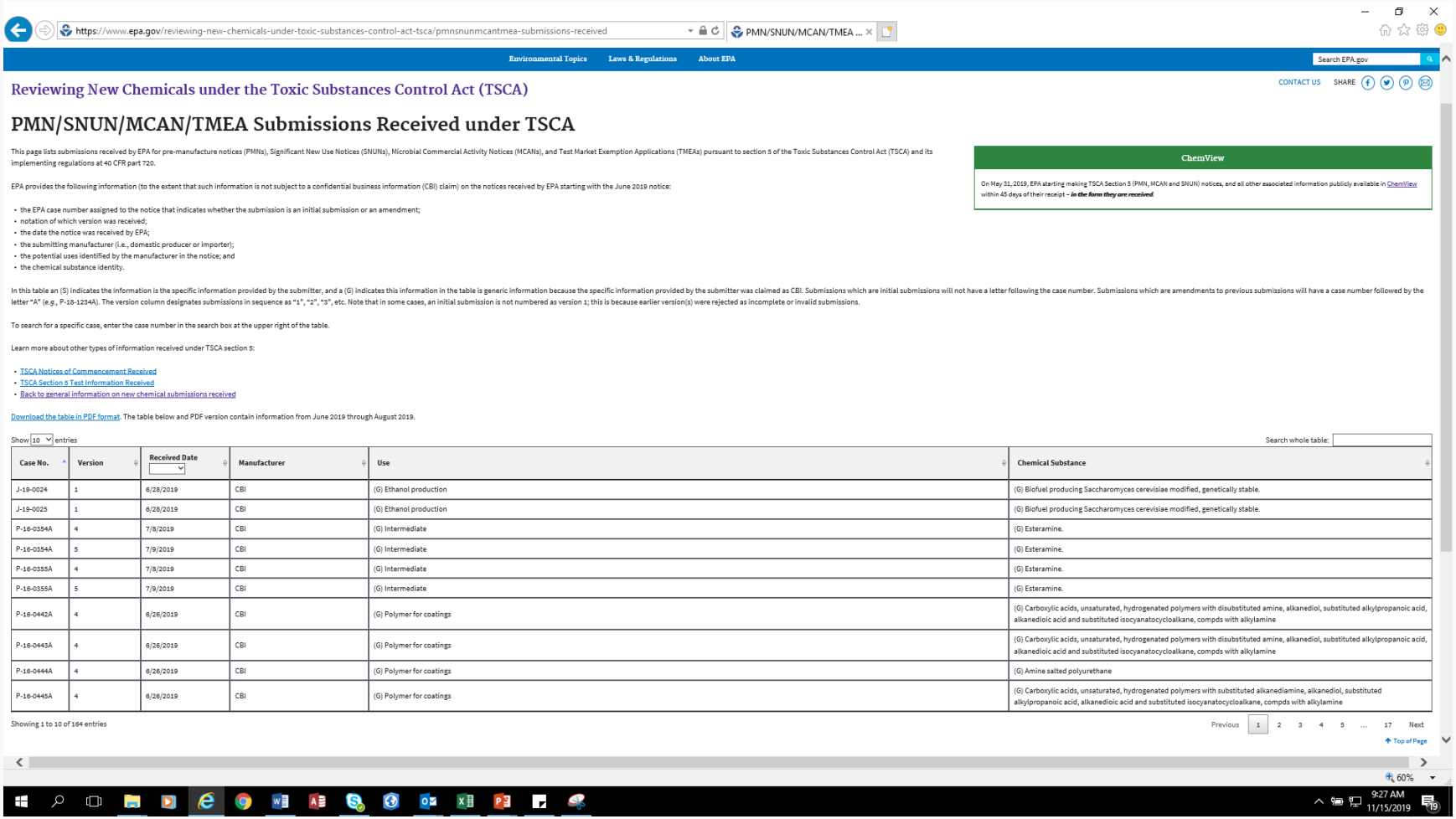
Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca

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



https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pmnsnunmcantmea-submissions-received

PMN/SNUN/MCAN/TMEA ...

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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 Use Notices (SNUNs), Microbial Commercial Activity Notices (MCANs), and Test Market Exemption Applications (TMEAs) pursuant to section 5 of the Toxic Substances Control Act (TSCA) and its implementing regulations at 40 CFR part 720.

ChemView

On May 31, 2019, EPA starting making TSCA Section 5 (PMN, MCAN and SNUN) notices, and all other associated information publicly available in ChemView within 45 days of their receipt – ***in the form they are received***.

EPA provides the following information (to the extent that such information is not subject to a confidential business information (CBI) claim) on the notices received by EPA starting with the June 2019 notice:

- the EPA case number assigned to the notice that indicates whether the submission is an initial submission or an amendment;
- notation of which version was received;
- the date the notice was received by EPA;
- the submitting manufacturer (i.e., domestic producer or importer);
- the potential uses identified by the manufacturer in the notice; and
- the chemical substance identity.

In this table an (S) indicates the information is the specific information provided by the submitter, and a (G) indicates this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter "A" (e.g., P-18-1234A). The version column designates submissions in sequence as "1", "2", "3", etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions.

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

Learn more about other types of information received under TSCA section 5:

- TSCA Notices of Commencement Received
- TSCA Section 5 Test Information Received
- Back to general information on new chemical submissions received

Download the table in PDF format. The table below and PDF version contain information from June 2019 through August 2019.

Show 10 entries — Search whole table:

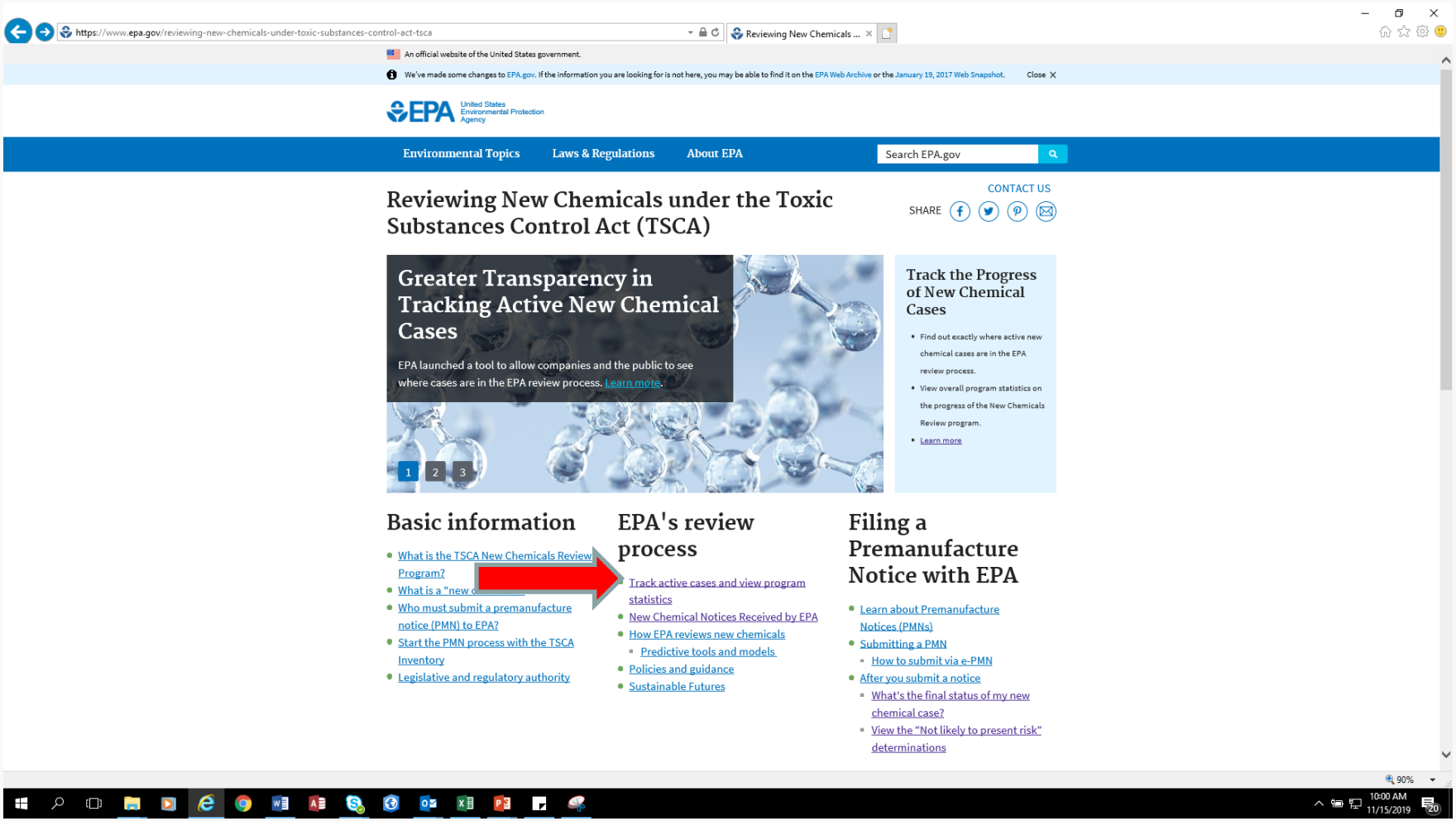
Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-19-0024	1	6/28/2019	CBI	(G) Ethanol production	(G) Biofuel producing Saccharomyces cerevisiae modified, genetically stable.
J-19-0025	1	6/28/2019	CBI	(G) Ethanol production	(G) Biofuel producing Saccharomyces cerevisiae modified, genetically stable.
P-16-0354A	4	7/8/2019	CBI	(G) Intermediate	(G) Esteramine.
P-16-0354A	5	7/9/2019	CBI	(G) Intermediate	(G) Esteramine.
P-16-0355A	4	7/8/2019	CBI	(G) Intermediate	(G) Esteramine.
P-16-0355A	5	7/9/2019	CBI	(G) Intermediate	(G) Esteramine.
P-16-0442A	4	6/26/2019	CBI	(G) Polymer for coatings	(G) Carboxylic acids, unsaturated, hydrogenated polymers with disubstituted amine, alkanediol, substituted alkylpropanoic acid, alkanedioic acid and substituted isocyanatocycloalkane, compds with alkylamine
P-16-0443A	4	6/26/2019	CBI	(G) Polymer for coatings	(G) Carboxylic acids, unsaturated, hydrogenated polymers with disubstituted amine, alkanediol, substituted alkylpropanoic acid, alkanedioic acid and substituted isocyanatocycloalkane, compds with alkylamine
P-16-0444A	4	6/26/2019	CBI	(G) Polymer for coatings	(G) Amine salted polyurethane
P-16-0445A	4	6/26/2019	CBI	(G) Polymer for coatings	(G) Carboxylic acids, unsaturated, hydrogenated polymers with substituted alkanediamine, alkanediol, substituted alkylpropanoic acid, alkanedioic acid and substituted isocyanatocycloalkane, compds with alkylamine

Showing 1 to 10 of 184 entries — Previous 1 2 3 4 5 … 17 Next — Top of Page

60% 9:27 AM 11/15/2019

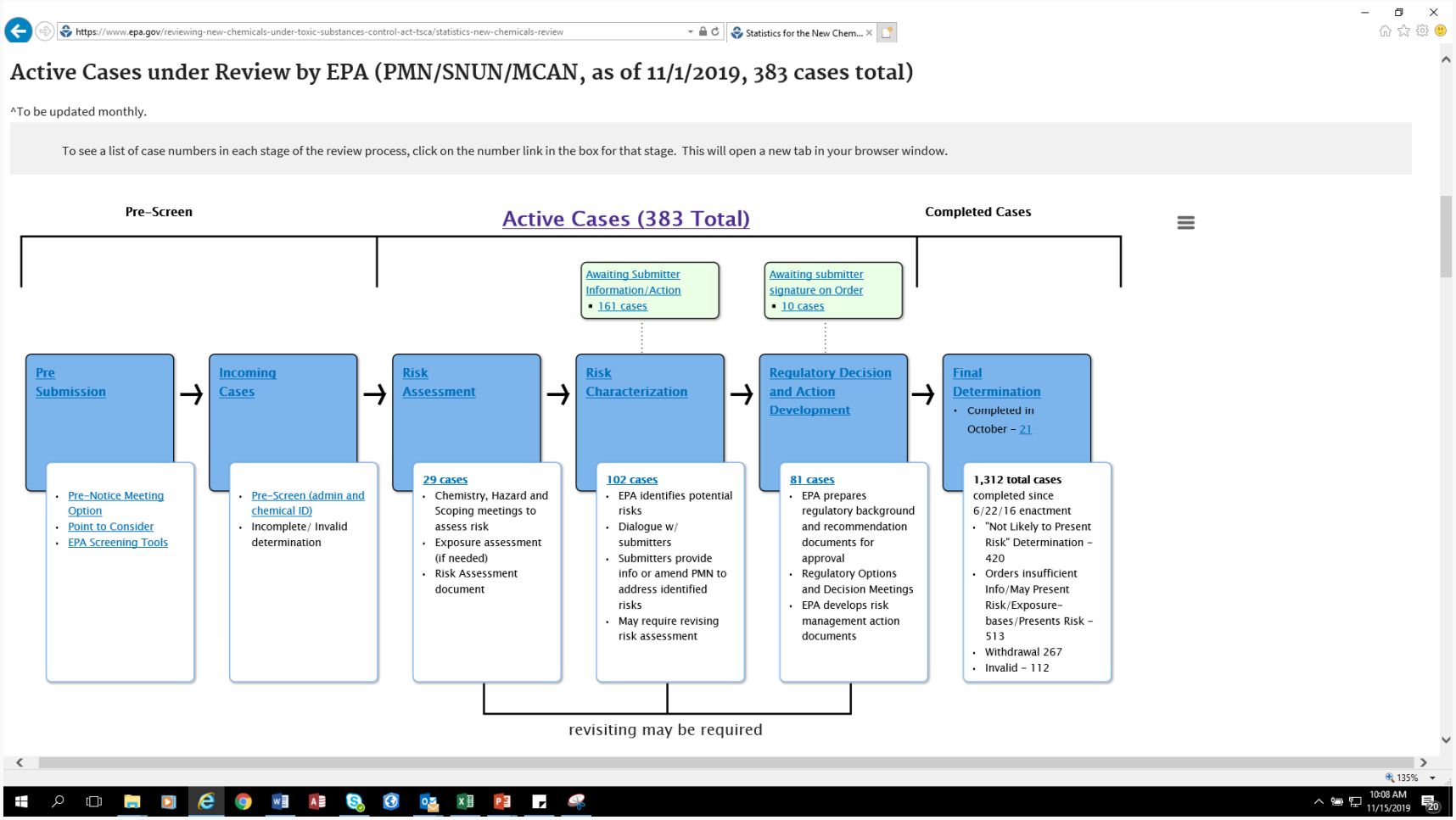
Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pmnsnunmcantmea-submissions-received

New Chemical Case Tracker



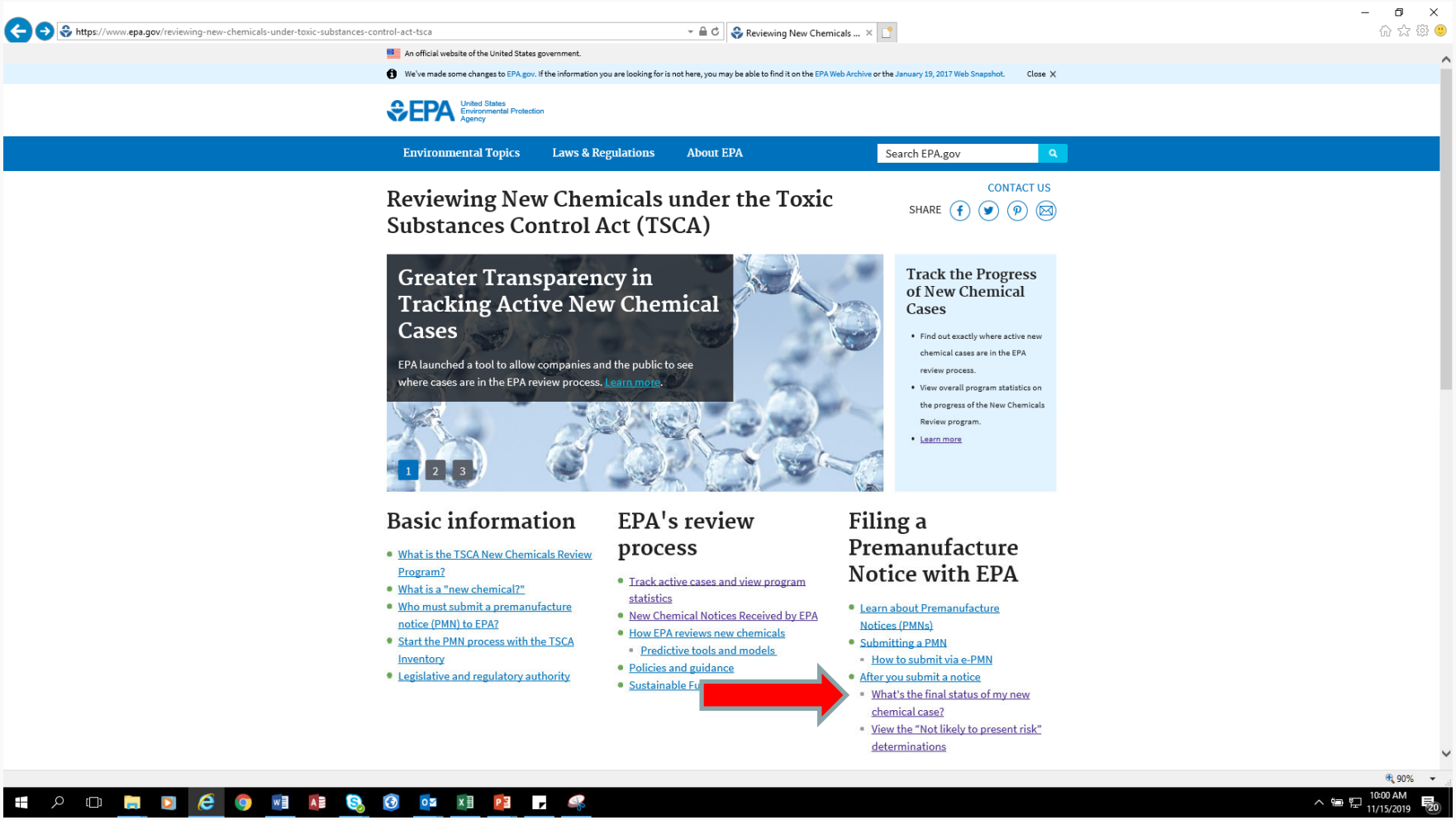
Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca

New Chemical Case Tracker



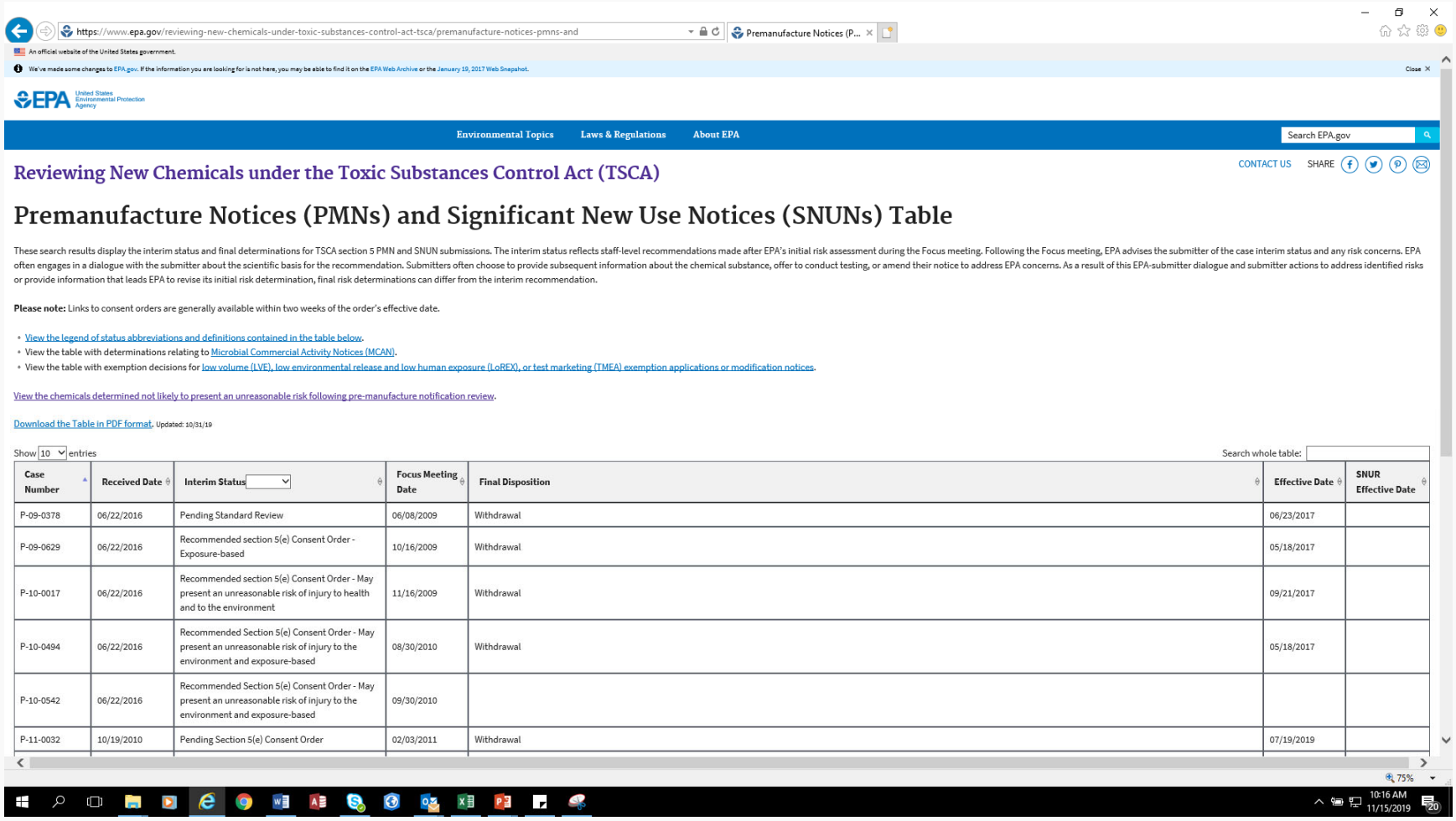
Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review

Final Status Of Case



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

Final Status Of Case



https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and

Premanufacture Notices (P...

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We've made some changes to EPA.gov. If the information you are looking for is not here, you may be able to find it on the EPA Web Archive or the January 19, 2017 Web Snapshot.

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

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

These search results 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 determination, final risk determinations can differ from the interim recommendation.

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 table with determinations relating to Microbial Commercial Activity Notices (MCAN).
- View the table with exemption decisions for low volume (LVE), low environmental release and low human exposure (LoREX), or test marketing (TMEA) exemption applications or modification notices.

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

Download the Table in PDF format. Updated: 10/31/19

Show 10 entries | Search whole table:

Case Number	Received Date	Interim Status	Focus Meeting Date	Final Disposition	Effective Date	SNUR Effective Date
P-09-0378	06/22/2016	Pending Standard Review	06/08/2009	Withdrawal	06/23/2017	
P-09-0629	06/22/2016	Recommended section 5(e) Consent Order - Exposure-based	10/16/2009	Withdrawal	05/18/2017	
P-10-0017	06/22/2016	Recommended section 5(e) Consent Order - May present an unreasonable risk of injury to health and to the environment	11/16/2009	Withdrawal	09/21/2017	
P-10-0494	06/22/2016	Recommended Section 5(e) Consent Order - May present an unreasonable risk of injury to the environment and exposure-based	08/30/2010	Withdrawal	05/18/2017	
P-10-0542	06/22/2016	Recommended Section 5(e) Consent Order - May present an unreasonable risk of injury to the environment and exposure-based	09/30/2010			
P-11-0032	10/19/2010	Pending Section 5(e) Consent Order	02/03/2011	Withdrawal	07/19/2019	

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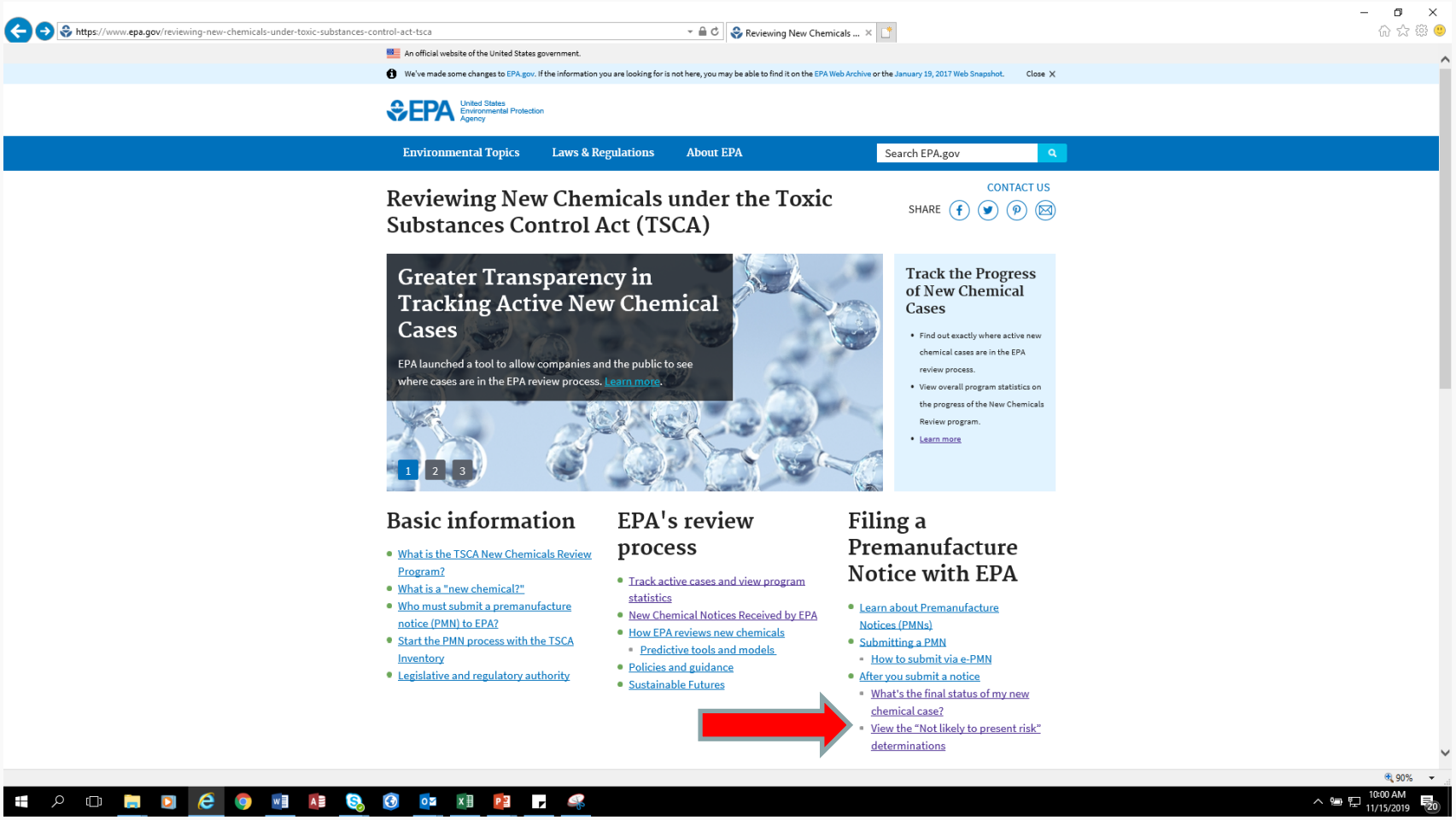
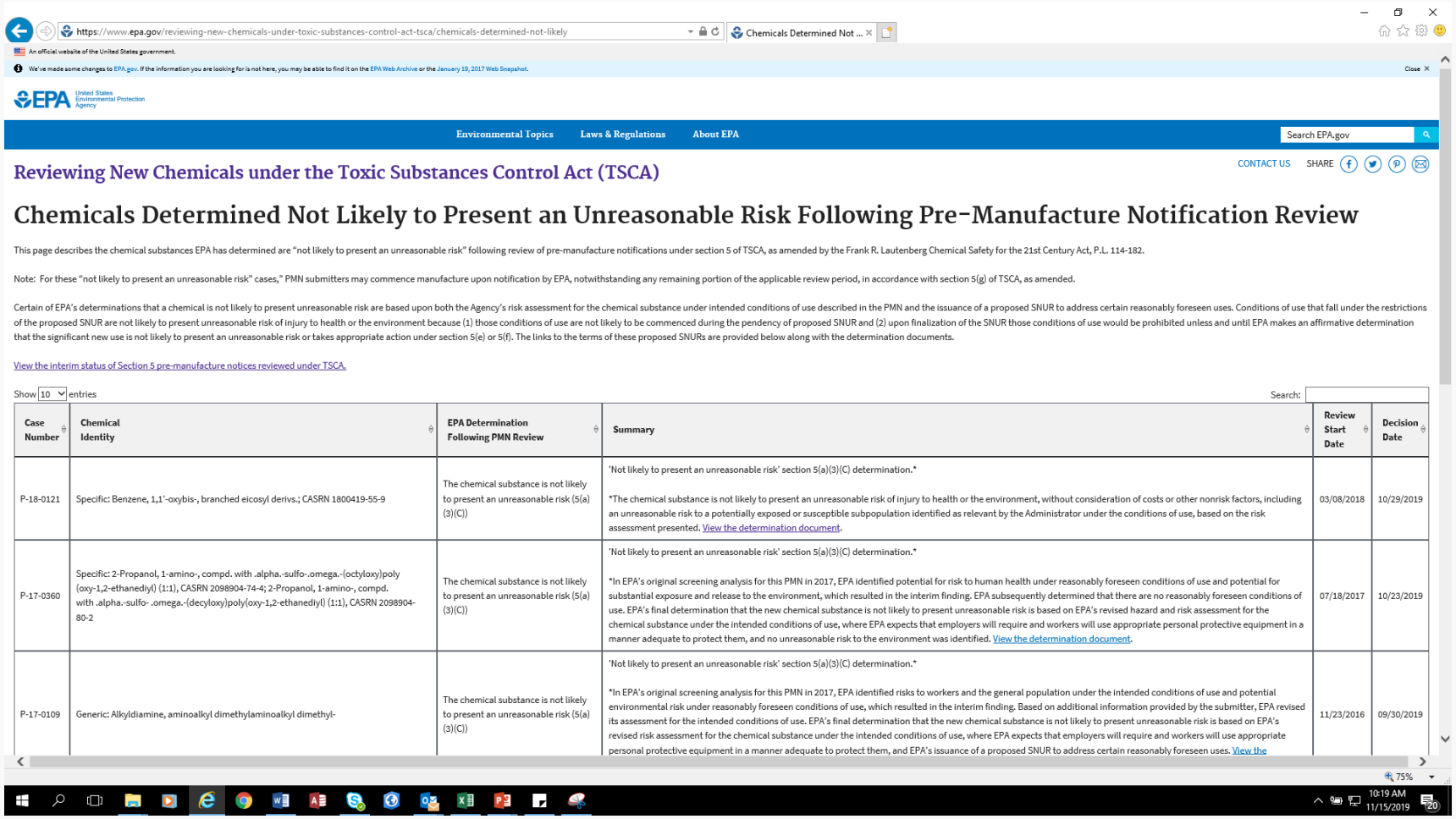
Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and

"Not Likely" Determinations



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

"Not Likely" Determinations



https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely

Chemicals Determined Not ...

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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 5 of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, P.L. 114-182.

Note: For these "not likely to present an unreasonable risk" cases," PMN submitters may commence manufacture upon notification by EPA, notwithstanding any remaining portion of the applicable review period, in accordance with section 5(g) of TSCA, as amended.

Certain of EPA's determinations that a chemical is not likely to present 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 foreseen uses. Conditions of use that fall under the restrictions of the proposed SNUR are not likely to present unreasonable risk of injury to health or the environment because (1) those conditions of use are not likely to be commenced during the pendency of proposed SNUR and (2) upon finalization of the SNUR those conditions of use would be prohibited unless and until EPA makes an affirmative determination that the significant new use is not likely to present an unreasonable risk or takes appropriate action under section 5(e) or 5(f). The links to the terms of these proposed SNURs are provided below along with the determination documents.

View the interim status of Section 5 pre-manufacture notices reviewed under TSCA.

Show 10 entries | Search:

Case Number	Chemical Identity	EPA Determination Following PMN Review	Summary	Review Start Date	Decision Date
P-18-0121	Specific: Benzene, 1,1'-oxybis-, branched eicosyl derivs.; CASRN 1800419-55-9	The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))	'Not likely to present an unreasonable risk' section 5(a)(3)(C) determination.* *The chemical substance is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, based on the risk assessment presented. View the determination document.	03/08/2018	10/29/2019
P-17-0360	Specific: 2-Propanol, 1-amino-, compd. with .alpha.-sulfo-.omega.-(octyloxy)poly (oxy-1,2-ethanediyl) (1:1), CASRN 2098904-74-4; 2-Propanol, 1-amino-, compd. with .alpha.-sulfo- .omega.-(decyloxy)poly(oxy-1,2-ethanediyl) (1:1), CASRN 2098904-80-2	The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))	'Not likely to present an unreasonable risk' section 5(a)(3)(C) determination.* *In EPA's original screening analysis for this PMN in 2017, EPA identified potential for risk to human health under reasonably foreseen conditions of use and potential for substantial exposure and release to the environment, which resulted in the interim finding. EPA subsequently determined that there are no reasonably foreseen conditions of use. EPA's final determination that the new chemical substance is not likely to present unreasonable risk is based on EPA's revised hazard and risk assessment for the chemical substance under the intended conditions of use, where EPA expects that employers will require and workers will use appropriate personal protective equipment in a manner adequate to protect them, and no unreasonable risk to the environment was identified. View the determination document.	07/18/2017	10/23/2019
P-17-0109	Generic: Alkyldiamine, aminoalkyl dimethylaminoalkyl dimethyl-	The chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))	'Not likely to present an unreasonable risk' section 5(a)(3)(C) determination.* *In EPA's original screening analysis for this PMN in 2017, EPA identified risks to workers and the general population under the intended conditions of use and potential environmental risk under reasonably foreseen conditions of use, which resulted in the interim finding. Based on additional information provided by the submitter, EPA revised its assessment for the intended conditions of use. EPA's final determination that the new chemical substance is not likely to present unreasonable risk is based on EPA's revised risk assessment for the chemical substance under the intended conditions of use, where EPA expects that employers will require and workers will use appropriate personal protective equipment in a manner adequate to protect them, and EPA's issuance of a proposed SNUR to address certain reasonably foreseen uses. View the	11/23/2016	09/30/2019

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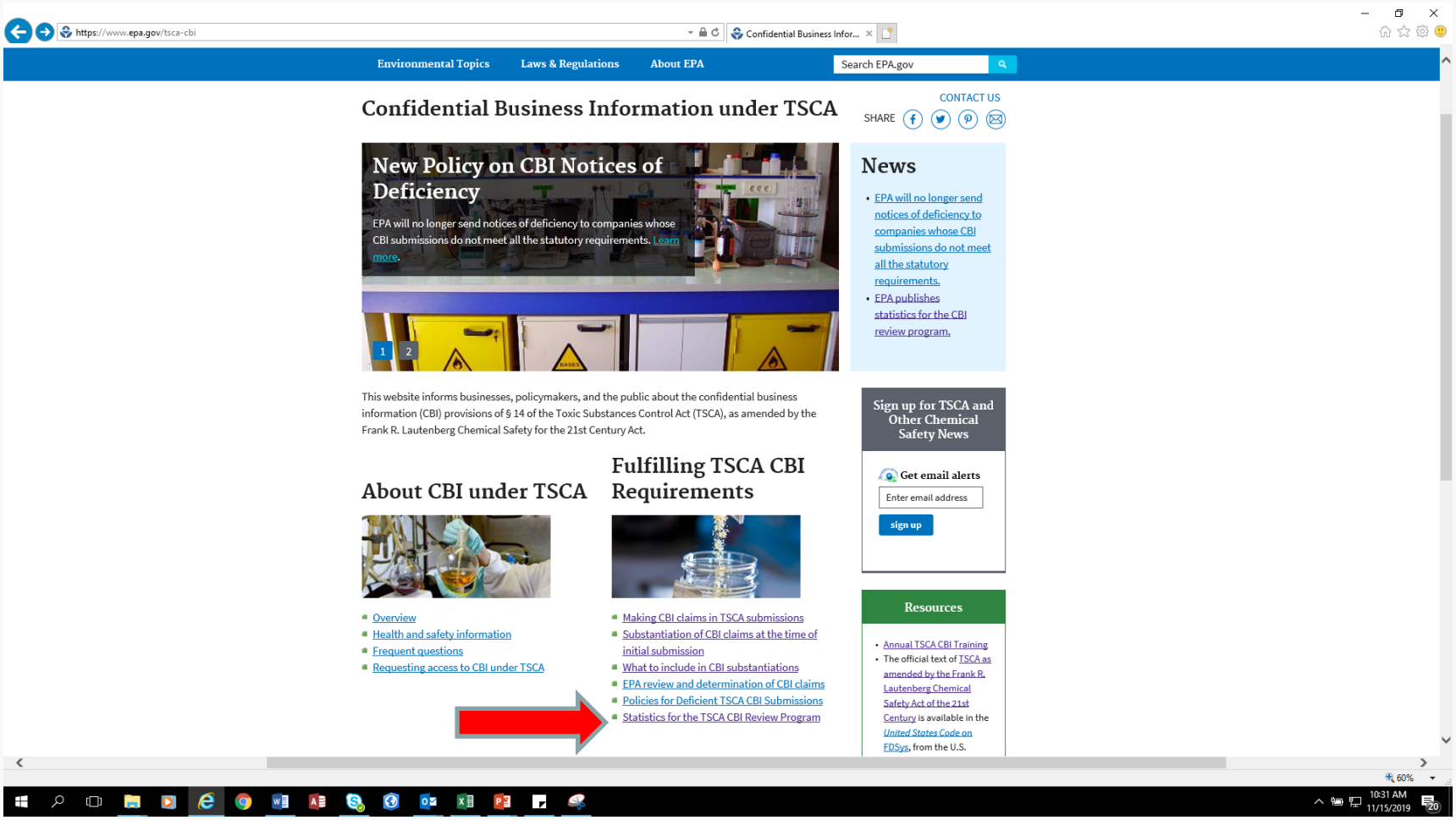
Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely

TSCA CBI Site: Review Statistics



Source: https://www.epa.gov/tsca-cbi

TSCA CBI Site: Review Statistics

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(g). 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)	
Cases in which the specific chemical identity is subject to CBI review	2,495
Cases in which information other than the specific chemical identity is subject to CBI review	2,324
Cases in which both the specific chemical identity and information other than the specific chemical identity is subject to CBI review	677
Total cases subject to CBI review	**5,496**

Cases resulting in final CBI determinations	
Cases with all CBI claims subject to review, approved	609
Cases with all CBI claims subject to review, denied	15
Cases with CBI claims subject to review, approved-in-part/denied-in-part	43
Total cases resulting in final CBI determinations	**667**

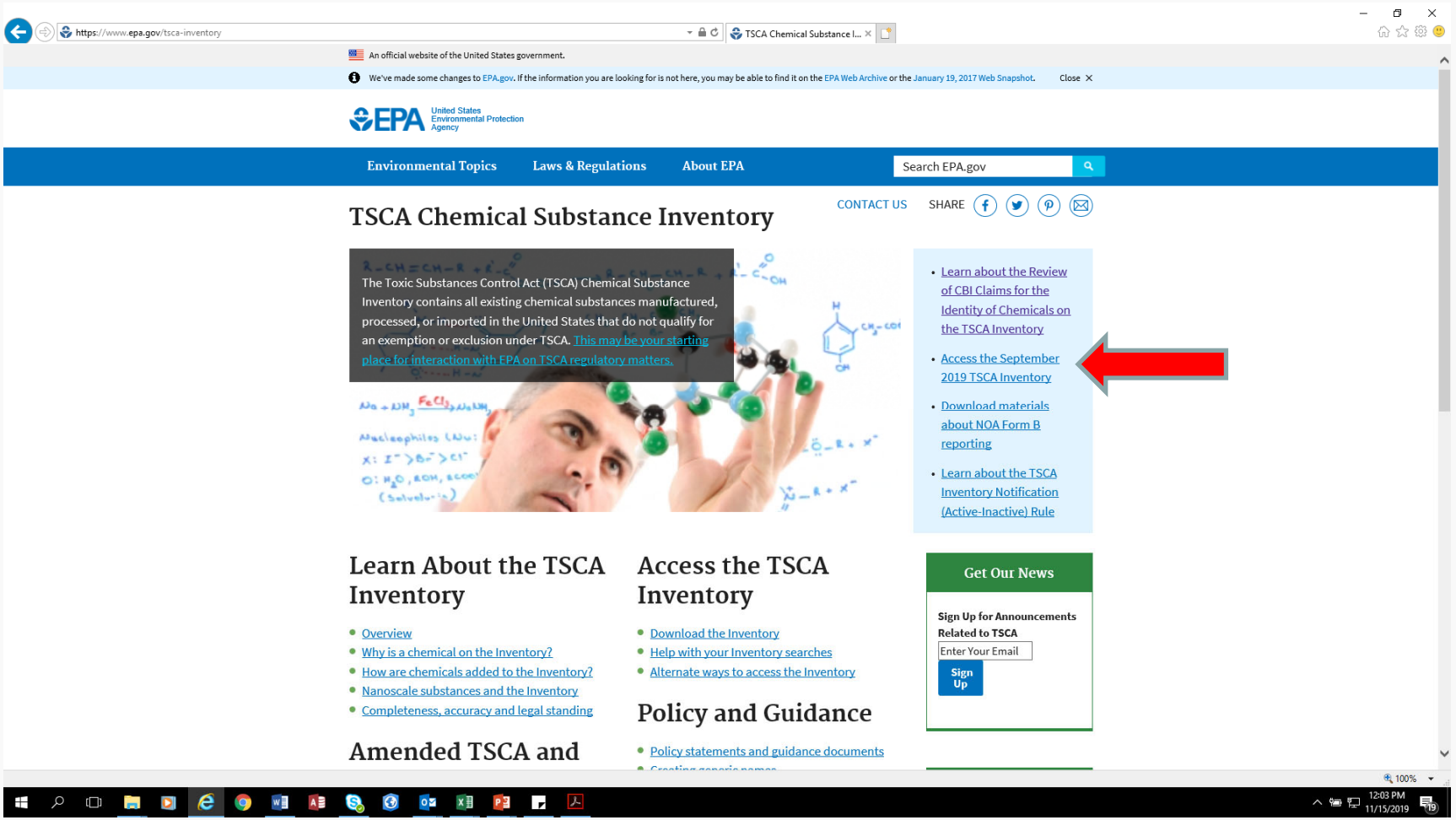
* "Denial - appeal period pending" cases are those for which a CBI determination denying one or more CBI claims in a case has been issued to the submitter of the information, but for which the required 30-day notification period following receipt of the determination under TSCA section 14(g)(2)(B) has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

Cases reviewed with no final CBI determination necessary	
Cases with all CBI claims screened and found to be exempt from review	1,071
Cases with all CBI claims withdrawn by submitter	433
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)	1,220
Total cases reviewed/screened with no final CBI determination necessary	**2,724**

Cases currently undergoing CBI review	
Cases currently undergoing CBI review	**2,105**

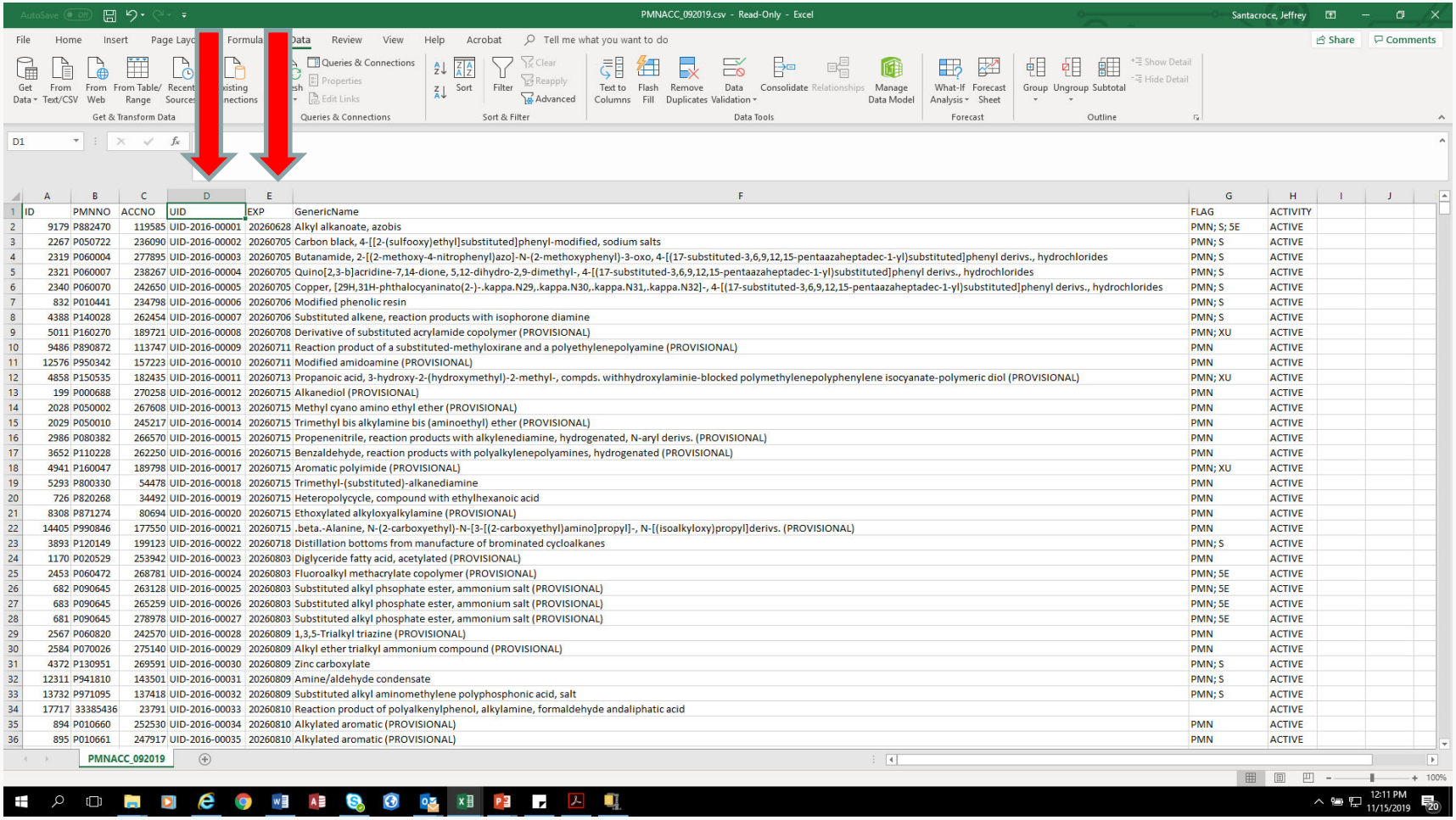
Source: https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program

TSCA Inventory Site: Inventory w/ IUD



Source: https://www.epa.gov/tsca-inventory

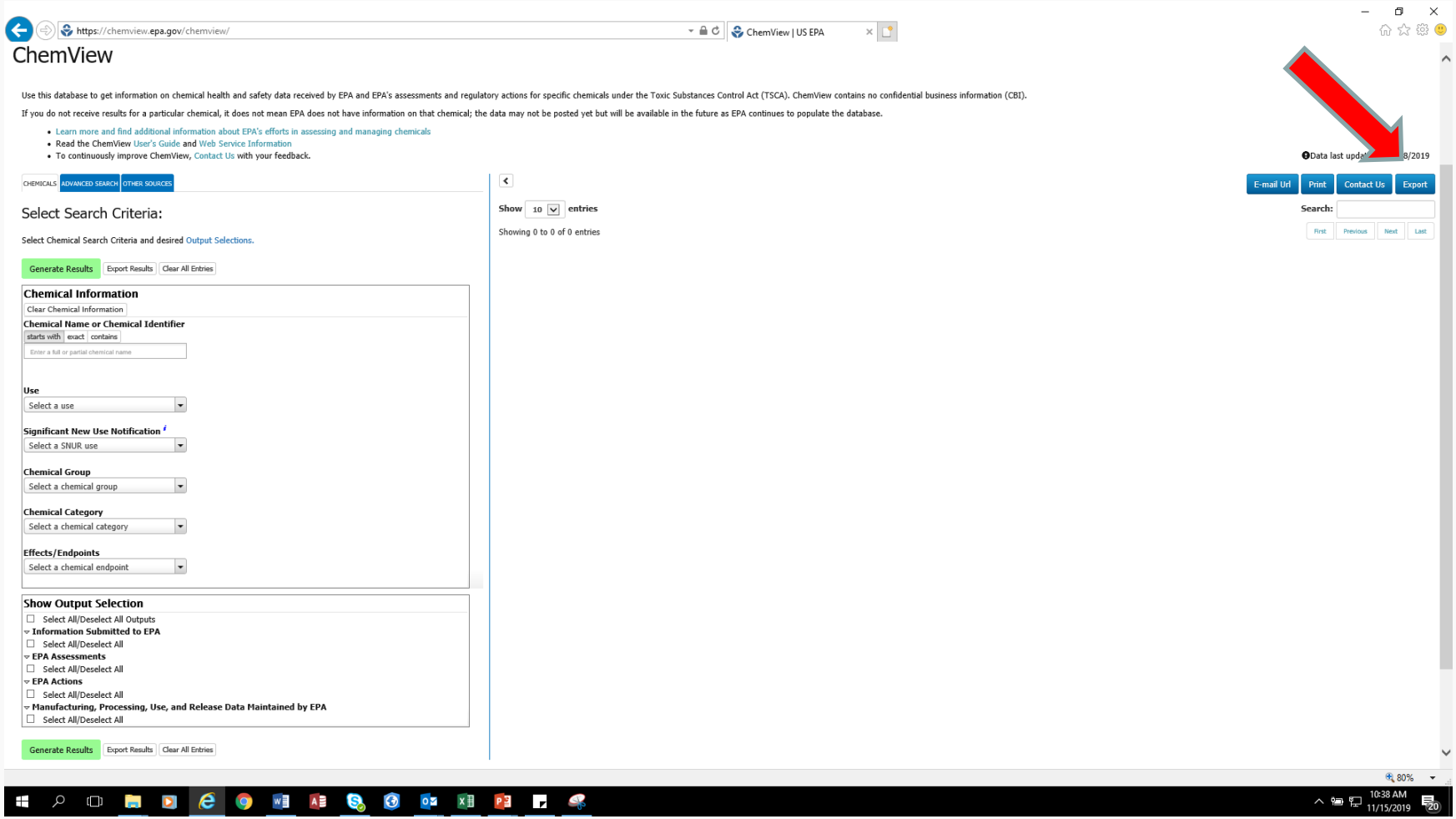
TSCA Inventory Site: Inventory w/ IUD



PMNACC_092019.csv - Read-Only - Excel

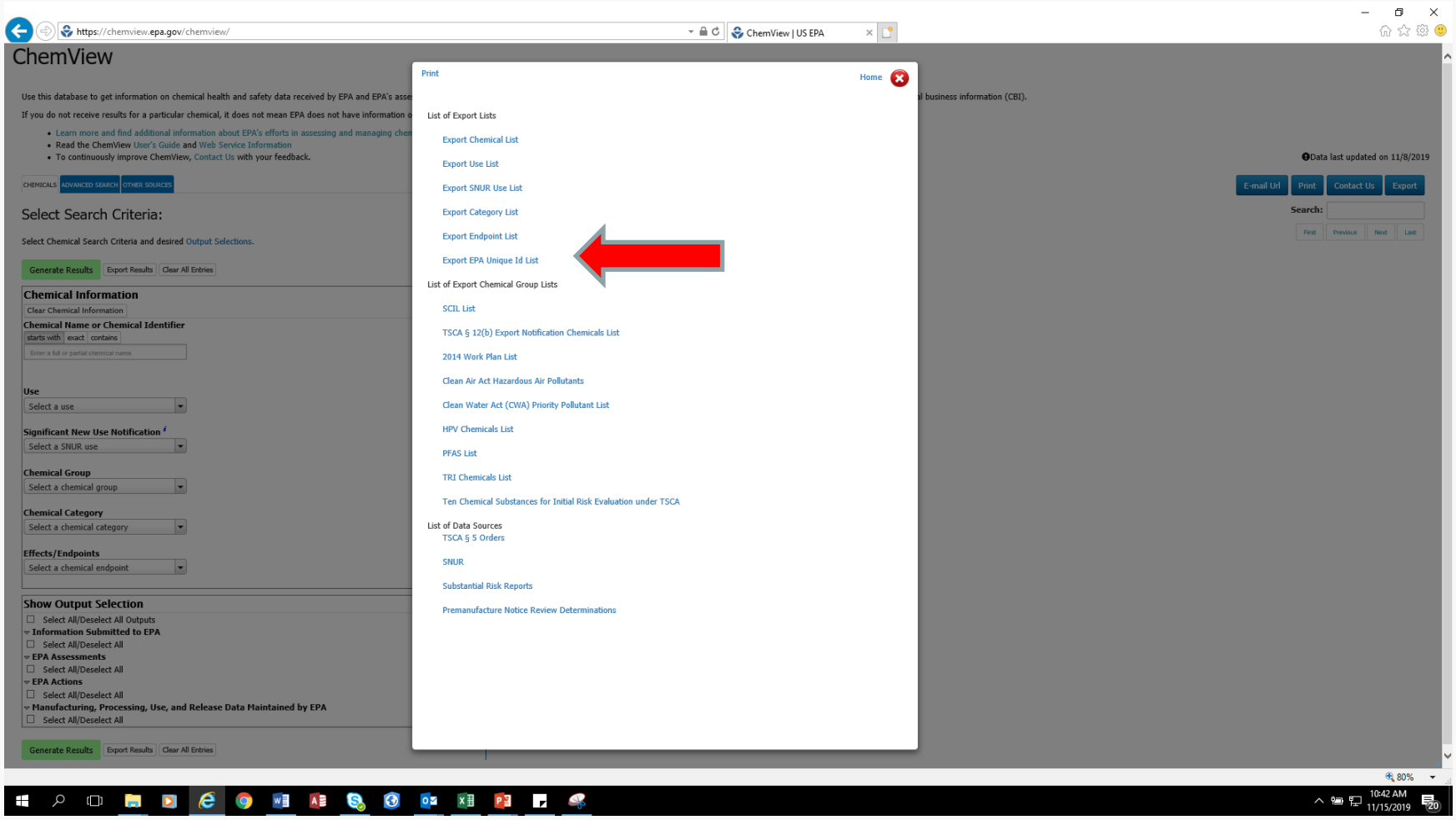
ID	PMNNO	ACCNO	UID	EXP	GenericName	FLAG	ACTIVITY
9179	P882470	119585	UID-2016-00001	20260628	Alkyl alkanoate, azobis	PMN; S; SE	ACTIVE
2267	P050722	236090	UID-2016-00002	20260705	Carbon black, 4-[[2-(sulfooxy)ethyl]substituted]phenyl-modified, sodium salts	PMN; S	ACTIVE
2319	P060004	277895	UID-2016-00003	20260705	Butanamide, 2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxo, 4-[(17-substituted-3,6,9,12,15-pentaazaheptadec-1-yl)substituted]phenyl derivs., hydrochlorides	PMN; S	ACTIVE
2321	P060007	238267	UID-2016-00004	20260705	Quino[2,3-b]acridine-7,14-dione, 5,12-dihydro-2,9-dimethyl-, 4-[(17-substituted-3,6,9,12,15-pentaazaheptadec-1-yl)substituted]phenyl derivs., hydrochlorides	PMN; S	ACTIVE
2340	P060070	242650	UID-2016-00005	20260705	Copper, [29H,31H-phthalocyaninato(2-)-.kappa.N29,.kappa.N30,.kappa.N31,.kappa.N32]-, 4-[(17-substituted-3,6,9,12,15-pentaazaheptadec-1-yl)substituted]phenyl derivs., hydrochlorides	PMN; S	ACTIVE
832	P010441	234798	UID-2016-00006	20260706	Modified phenolic resin	PMN; S	ACTIVE
4388	P140028	262454	UID-2016-00007	20260706	Substituted alkene, reaction products with isophorone diamine	PMN; S	ACTIVE
5011	P160270	189721	UID-2016-00008	20260708	Derivative of substituted acrylamide copolymer (PROVISIONAL)	PMN; XU	ACTIVE
9486	P890872	113747	UID-2016-00009	20260711	Reaction product of a substituted-methyloxirane and a polyethylenepolyamine (PROVISIONAL)	PMN	ACTIVE
12576	P950342	157223	UID-2016-00010	20260711	Modified amidoamine (PROVISIONAL)	PMN	ACTIVE
4858	P150535	182435	UID-2016-00011	20260713	Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, compds. withhydroxylaminie-blocked polymethylenepolyphenylene isocyanate-polymeric diol (PROVISIONAL)	PMN; XU	ACTIVE
199	P000688	270258	UID-2016-00012	20260715	Alkanediol (PROVISIONAL)	PMN	ACTIVE
2028	P050002	267608	UID-2016-00013	20260715	Methyl cyano amino ethyl ether (PROVISIONAL)	PMN	ACTIVE
2029	P050010	245217	UID-2016-00014	20260715	Trimethyl bis alkylamine bis (aminoethyl) ether (PROVISIONAL)	PMN	ACTIVE
2986	P080382	266570	UID-2016-00015	20260715	Propenenitrile, reaction products with alkylenediamine, hydrogenated, N-aryl derivs. (PROVISIONAL)	PMN	ACTIVE
3652	P110228	262250	UID-2016-00016	20260715	Benzaldehyde, reaction products with polyalkylenepolyamines, hydrogenated (PROVISIONAL)	PMN	ACTIVE
4941	P160047	189798	UID-2016-00017	20260715	Aromatic polyimide (PROVISIONAL)	PMN; XU	ACTIVE
5293	P800330	54478	UID-2016-00018	20260715	Trimethyl-(substituted)-alkanediamine	PMN	ACTIVE
726	P820268	34492	UID-2016-00019	20260715	Heteropolycycle, compound with ethylhexanoic acid	PMN	ACTIVE
8308	P871274	80694	UID-2016-00020	20260715	Ethoxylated alkyloxyalkylamine (PROVISIONAL)	PMN	ACTIVE
14405	P990846	177550	UID-2016-00021	20260715	.beta.-Alanine, N-(2-carboxyethyl)-N-[3-[(2-carboxyethyl)amino]propyl]-, N-[(isoalkyloxy)propyl]derivs. (PROVISIONAL)	PMN	ACTIVE
3893	P120149	199123	UID-2016-00022	20260718	Distillation bottoms from manufacture of brominated cycloalkanes	PMN; S	ACTIVE
1170	P020529	253942	UID-2016-00023	20260803	Diglyceride fatty acid, acetylated (PROVISIONAL)	PMN	ACTIVE
2453	P060472	268781	UID-2016-00024	20260803	Fluoroalkyl methacrylate copolymer (PROVISIONAL)	PMN; SE	ACTIVE
682	P090645	263128	UID-2016-00025	20260803	Substituted alkyl phsophate ester, ammonium salt (PROVISIONAL)	PMN; SE	ACTIVE
683	P090645	265259	UID-2016-00026	20260803	Substituted alkyl phosphate ester, ammonium salt (PROVISIONAL)	PMN; SE	ACTIVE
681	P090645	278978	UID-2016-00027	20260803	Substituted alkyl phosphate ester, ammonium salt (PROVISIONAL)	PMN; SE	ACTIVE
2567	P060820	242570	UID-2016-00028	20260809	1,3,5-Trialkyl triazine (PROVISIONAL)	PMN	ACTIVE
2584	P070026	275140	UID-2016-00029	20260809	Alkyl ether trialkyl ammonium compound (PROVISIONAL)	PMN	ACTIVE
4372	P130951	269591	UID-2016-00030	20260809	Zinc carboxylate	PMN; S	ACTIVE
12311	P941810	143501	UID-2016-00031	20260809	Amine/aldehyde condensate	PMN; S	ACTIVE
13732	P971095	137418	UID-2016-00032	20260809	Substituted alkyl aminomethylene polyphosphonic acid, salt	PMN; S	ACTIVE
17717	33385436	23791	UID-2016-00033	20260810	Reaction product of polyalkenylphenol, alkylamine, formaldehyde andaliphatic acid		ACTIVE
894	P010660	252530	UID-2016-00034	20260810	Alkylated aromatic (PROVISIONAL)	PMN	ACTIVE
895	P010661	247917	UID-2016-00035	20260810	Alkylated aromatic (PROVISIONAL)	PMN	ACTIVE

ChemView: UID List



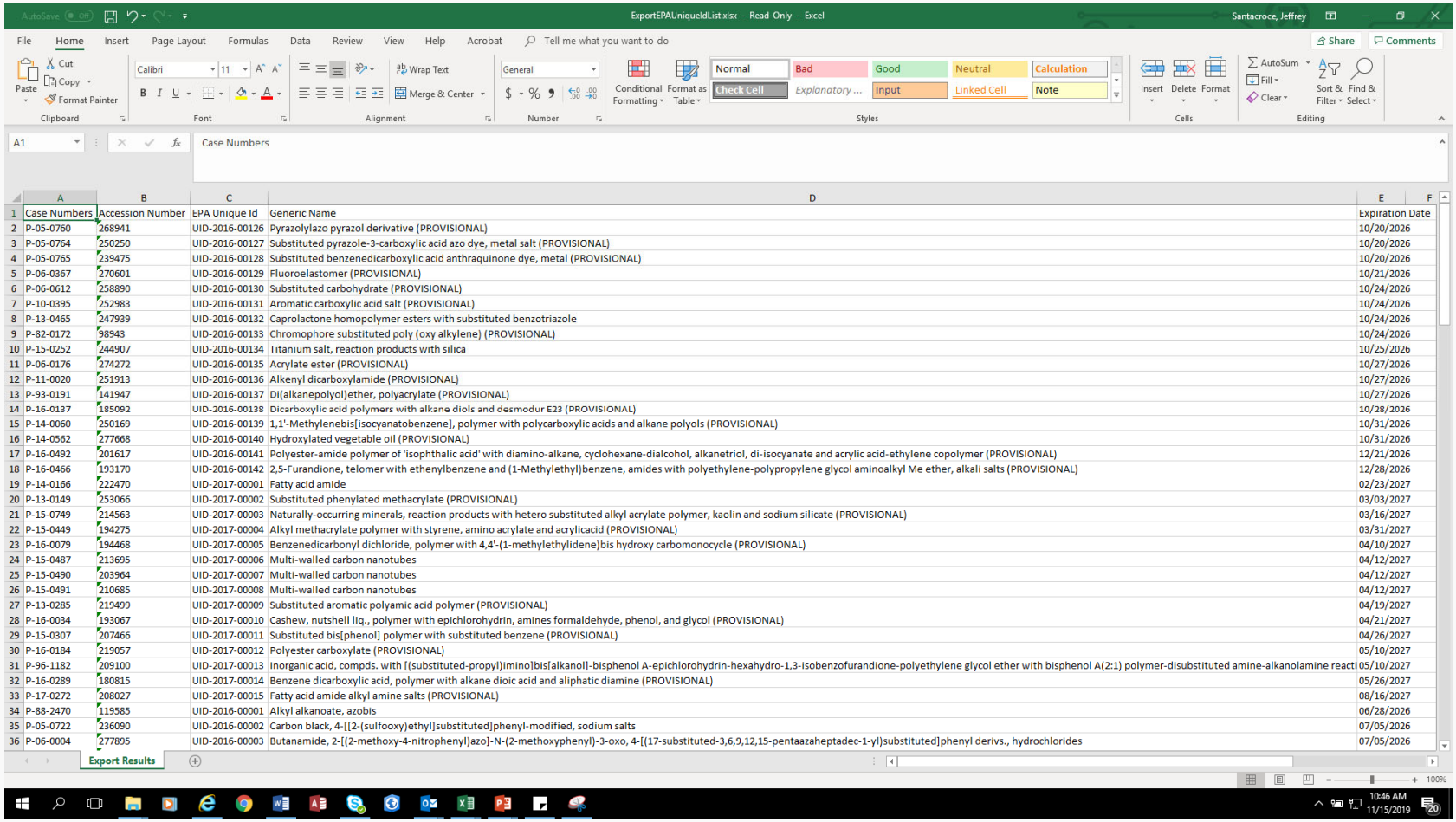
Source: https://chemview.epa.gov/chemview/

ChemView: UID List



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

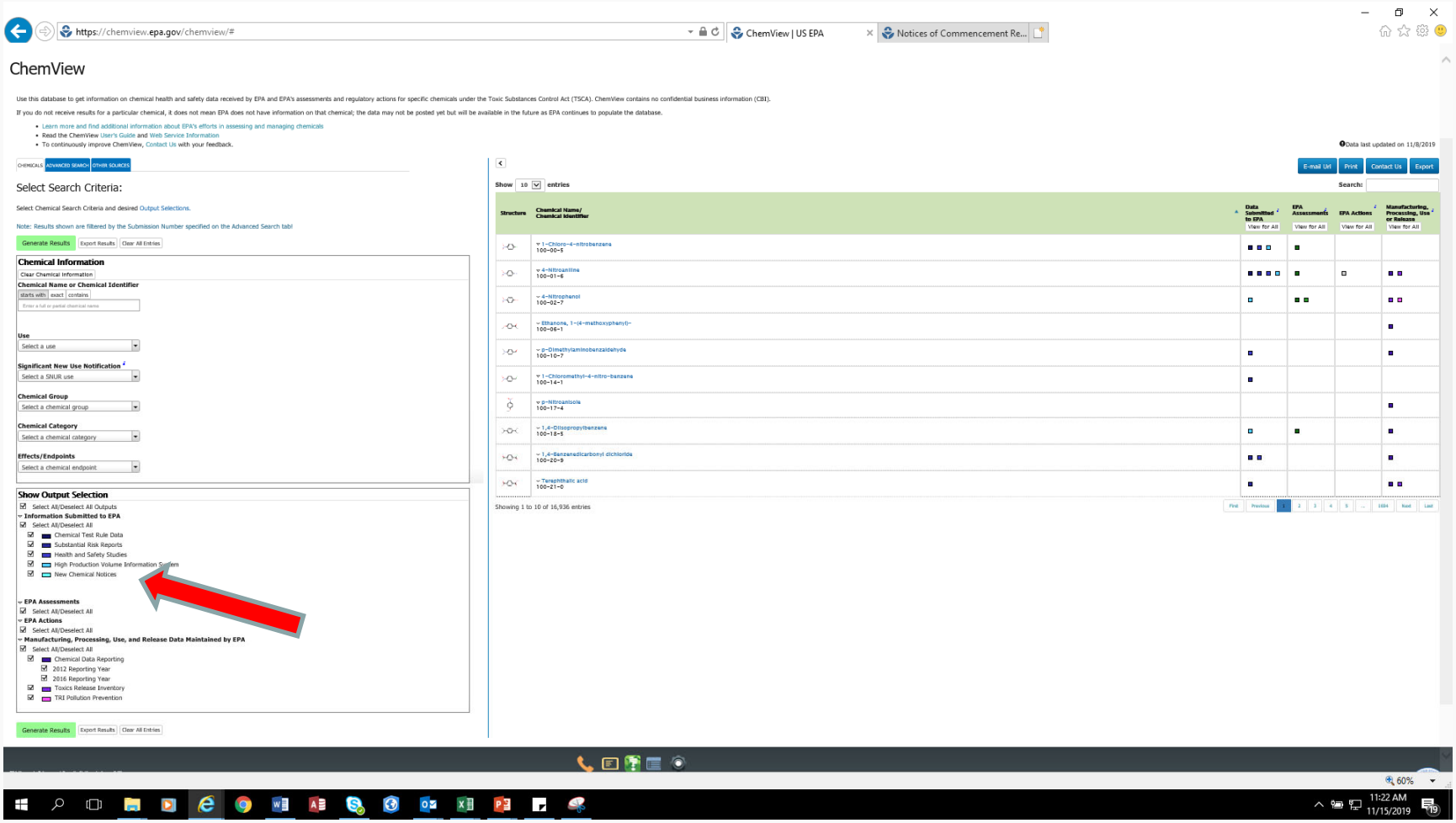
ChemView: UID List



Case Numbers	Accession Number	EPA Unique Id	Generic Name	Expiration Date
P-05-0760	268941	UID-2016-00126	Pyrazolylazo pyrazol derivative (PROVISIONAL)	10/20/2026
P-05-0764	250250	UID-2016-00127	Substituted pyrazole-3-carboxylic acid azo dye, metal salt (PROVISIONAL)	10/20/2026
P-05-0765	239475	UID-2016-00128	Substituted benzenedicarboxylic acid anthraquinone dye, metal (PROVISIONAL)	10/20/2026
P-06-0367	270601	UID-2016-00129	Fluoroelastomer (PROVISIONAL)	10/21/2026
P-06-0612	258890	UID-2016-00130	Substituted carbohydrate (PROVISIONAL)	10/24/2026
P-10-0395	252983	UID-2016-00131	Aromatic carboxylic acid salt (PROVISIONAL)	10/24/2026
P-13-0465	247939	UID-2016-00132	Caprolactone homopolymer esters with substituted benzotriazole	10/24/2026
P-82-0172	98943	UID-2016-00133	Chromophore substituted poly (oxy alkylene) (PROVISIONAL)	10/24/2026
P-15-0252	244907	UID-2016-00134	Titanium salt, reaction products with silica	10/25/2026
P-06-0176	274272	UID-2016-00135	Acrylate ester (PROVISIONAL)	10/27/2026
P-11-0020	251913	UID-2016-00136	Alkenyl dicarboxylamide (PROVISIONAL)	10/27/2026
P-93-0191	141947	UID-2016-00137	Di(alkanepolyol)ether, polyacrylate (PROVISIONAL)	10/27/2026
P-16-0137	185092	UID-2016-00138	Dicarboxylic acid polymers with alkane diols and desmodur E23 (PROVISIONAL)	10/28/2026
P-14-0060	250169	UID-2016-00139	1,1'-Methylenebis[isocyanatobenzene], polymer with polycarboxylic acids and alkane polyols (PROVISIONAL)	10/31/2026
P-14-0562	277668	UID-2016-00140	Hydroxylated vegetable oil (PROVISIONAL)	10/31/2026
P-16-0492	201617	UID-2016-00141	Polyester-amide polymer of 'isophthalic acid' with diamino-alkane, cyclohexane-dialcohol, alkanetriol, di-isocyanate and acrylic acid-ethylene copolymer (PROVISIONAL)	12/21/2026
P-16-0466	193170	UID-2016-00142	2,5-Furandione, telomer with ethenylbenzene and (1-Methylethyl)benzene, amides with polyethylene-polypropylene glycol aminoalkyl Me ether, alkali salts (PROVISIONAL)	12/28/2026
P-14-0166	222470	UID-2017-00001	Fatty acid amide	02/23/2027
P-13-0149	253066	UID-2017-00002	Substituted phenylated methacrylate (PROVISIONAL)	03/03/2027
P-15-0749	214563	UID-2017-00003	Naturally-occurring minerals, reaction products with hetero substituted alkyl acrylate polymer, kaolin and sodium silicate (PROVISIONAL)	03/16/2027
P-15-0449	194275	UID-2017-00004	Alkyl methacrylate polymer with styrene, amino acrylate and acrylicacid (PROVISIONAL)	03/31/2027
P-16-0079	194468	UID-2017-00005	Benzenedicarbonyl dichloride, polymer with 4,4'-(1-methylethylidene)bis hydroxy carbomonocycle (PROVISIONAL)	04/10/2027
P-15-0487	213695	UID-2017-00006	Multi-walled carbon nanotubes	04/12/2027
P-15-0490	203964	UID-2017-00007	Multi-walled carbon nanotubes	04/12/2027
P-15-0491	210685	UID-2017-00008	Multi-walled carbon nanotubes	04/12/2027
P-13-0285	219499	UID-2017-00009	Substituted aromatic polyamic acid polymer (PROVISIONAL)	04/19/2027
P-16-0034	193067	UID-2017-00010	Cashew, nutshell liq., polymer with epichlorohydrin, amines formaldehyde, phenol, and glycol (PROVISIONAL)	04/21/2027
P-15-0307	207466	UID-2017-00011	Substituted bis[phenol] polymer with substituted benzene (PROVISIONAL)	04/26/2027
P-16-0184	219057	UID-2017-00012	Polyester carboxylate (PROVISIONAL)	05/10/2027
P-96-1182	209100	UID-2017-00013	Inorganic acid, compds. with [(substituted-propyl)imino]bis[alkanol]-bisphenol A-epichlorohydrin-hexahydro-1,3-isobenzofurandione-polyethylene glycol ether with bisphenol A(2:1) polymer-disubstituted amine-alkanolamine reacti	05/10/2027
P-16-0289	180815	UID-2017-00014	Benzene dicarboxylic acid, polymer with alkane dioic acid and aliphatic diamine (PROVISIONAL)	05/26/2027
P-17-0272	208027	UID-2017-00015	Fatty acid amide alkyl amine salts (PROVISIONAL)	08/16/2027
P-88-2470	119585	UID-2016-00001	Alkyl alkanoate, azobis	06/28/2026
P-05-0722	236090	UID-2016-00002	Carbon black, 4-[[2-(sulfooxy)ethyl]substituted]phenyl-modified, sodium salts	07/05/2026
P-06-0004	277895	UID-2016-00003	Butanamide, 2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxo, 4-[(17-substituted-3,6,9,12,15-pentaazaheptadec-1-yl)substituted]phenyl derivs., hydrochlorides	07/05/2026

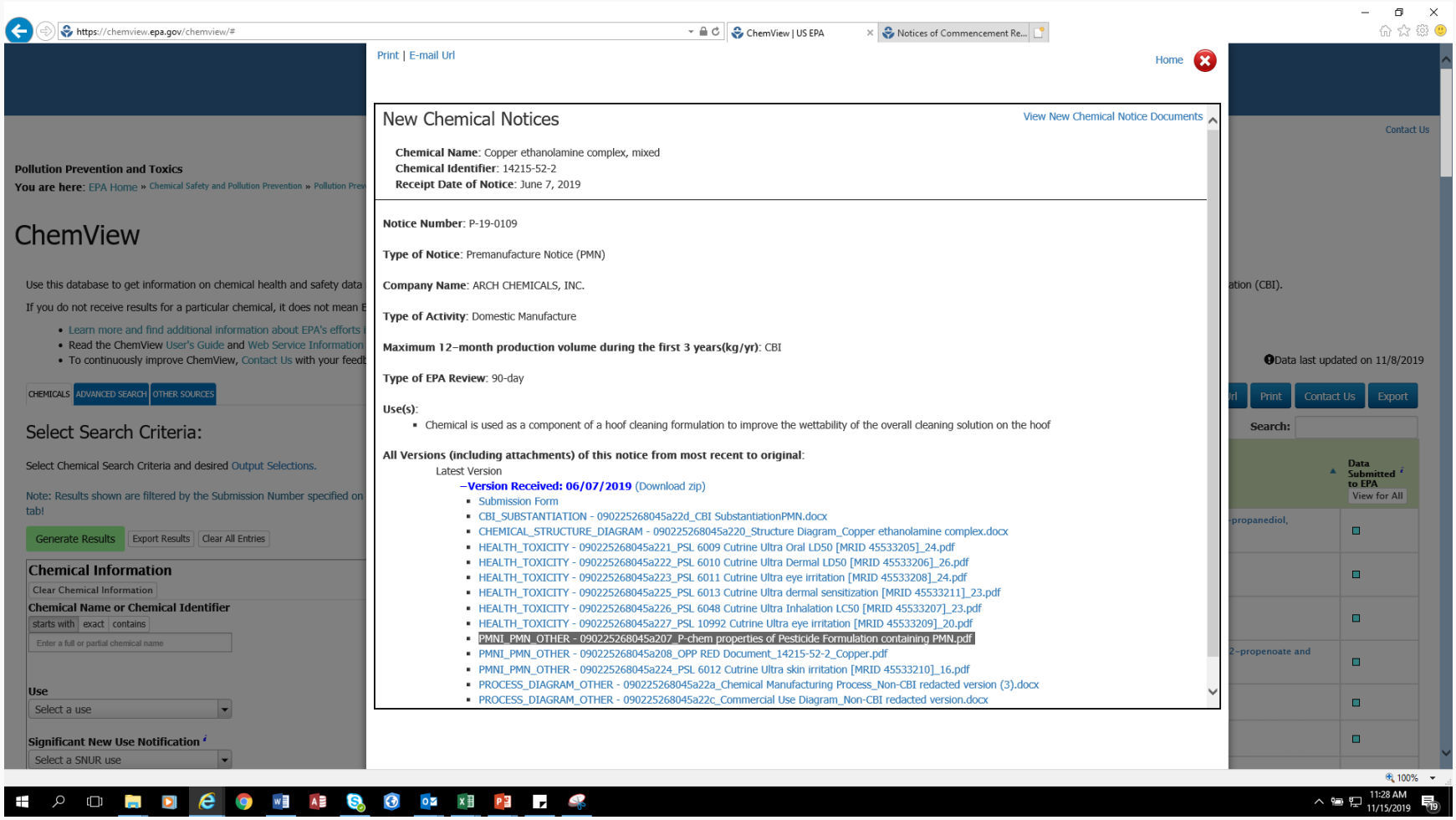
Source: https://chemview.epa.gov/chemview/

ChemView: New Chemical Notices



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

ChemView: New Chemical Notices



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ChemView: New Chemical Notices

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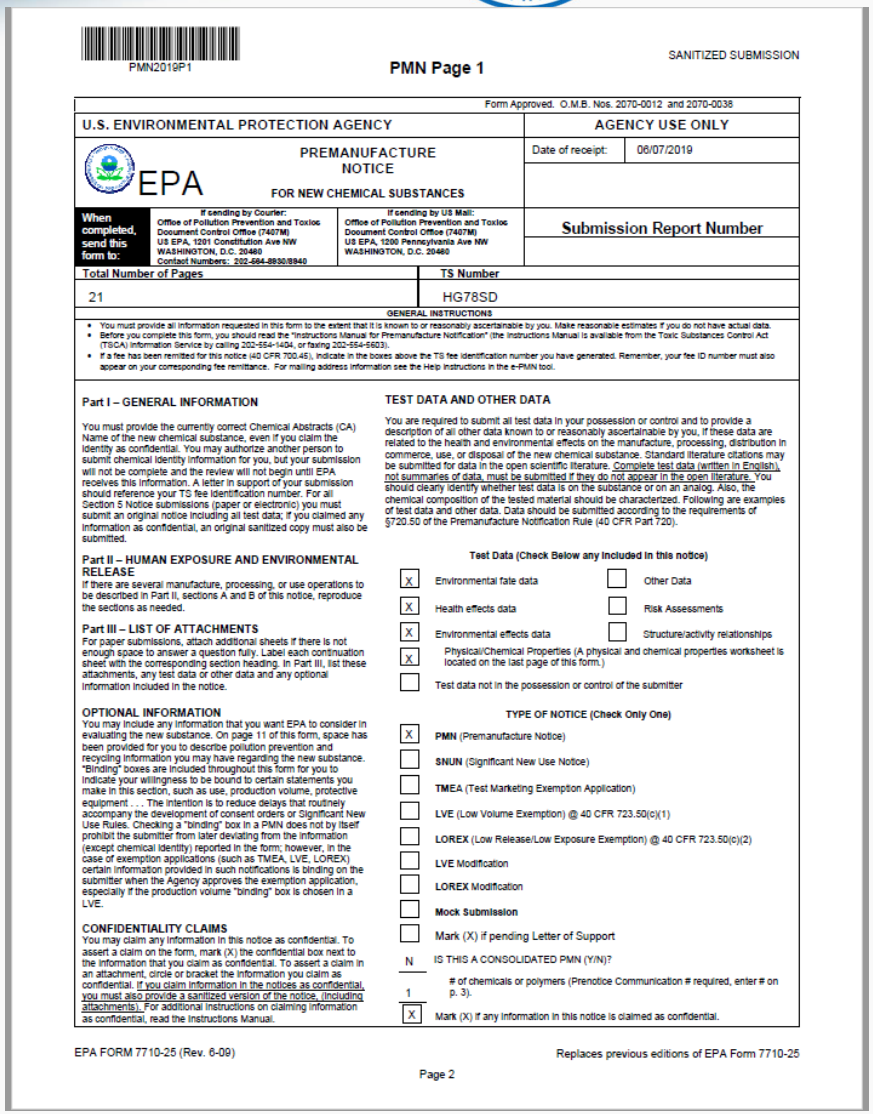


PMN2019P1

PMN Page 1

SANITIZED SUBMISSION

Form Approved. O.M.B. Nos. 2070-0012 and 2070-0038

U.S. ENVIRONMENTAL PROTECTION AGENCY | **AGENCY USE ONLY**

EPA

PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

Date of receipt: 06/07/2019

When completed, send this form to:

If sending by Courier:
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
US EPA, 1201 Constitution Ave NW
WASHINGTON, D.C. 20460
Contact Numbers: 202-564-8930/8940

If sending by US Mail:
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
US EPA, 1200 Pennsylvania Ave NW
WASHINGTON, D.C. 20460

Submission Report Number

Total Number of Pages	TS Number
21	HG78SD

GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).
- If a fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS fee identification number you have generated. Remember, your fee ID number must also appear on your corresponding fee remittance. For mailing address information see the Help instructions in the e-PMN tool.

Part I – GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS fee identification number. For all Section 5 Notice submissions (paper or electronic) you must submit an original notice including all test data; if you claimed any information as confidential, an original sanitized copy must also be submitted.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

Part III – LIST OF ATTACHMENTS

For paper submissions, attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.

OPTIONAL INFORMATION

You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance. "Binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . The intention is to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Checking a "binding" box in a PMN does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form; however, in the case of exemption applications (such as TMEA, LVE, LOREX) certain information provided in such notifications is binding on the submitter when the Agency approves the exemption application, especially if the production volume "binding" box is chosen in a LVE.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notices as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (Check Below any included in this notice)

[X]	Environmental fate data	[ ]	Other Data
[X]	Health effects data	[ ]	Risk Assessments
[X]	Environmental effects data	[ ]	Structure/activity relationships
[X]	Physical/Chemical Properties (A physical and chemical properties worksheet is located on the last page of this form.)		
[ ]	Test data not in the possession or control of the submitter		

TYPE OF NOTICE (Check Only One)

- [X] **PMN** (Premanufacture Notice)
- [ ] **SNUN** (Significant New Use Notice)
- [ ] **TMEA** (Test Marketing Exemption Application)
- [ ] **LVE** (Low Volume Exemption) @ 40 CFR 723.50(c)(1)
- [ ] **LOREX** (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)
- [ ] **LVE** Modification
- [ ] **LOREX** Modification
- [ ] **Mock Submission**
- [ ] Mark (X) if pending Letter of Support

N — IS THIS A CONSOLIDATED PMN (Y/N)?

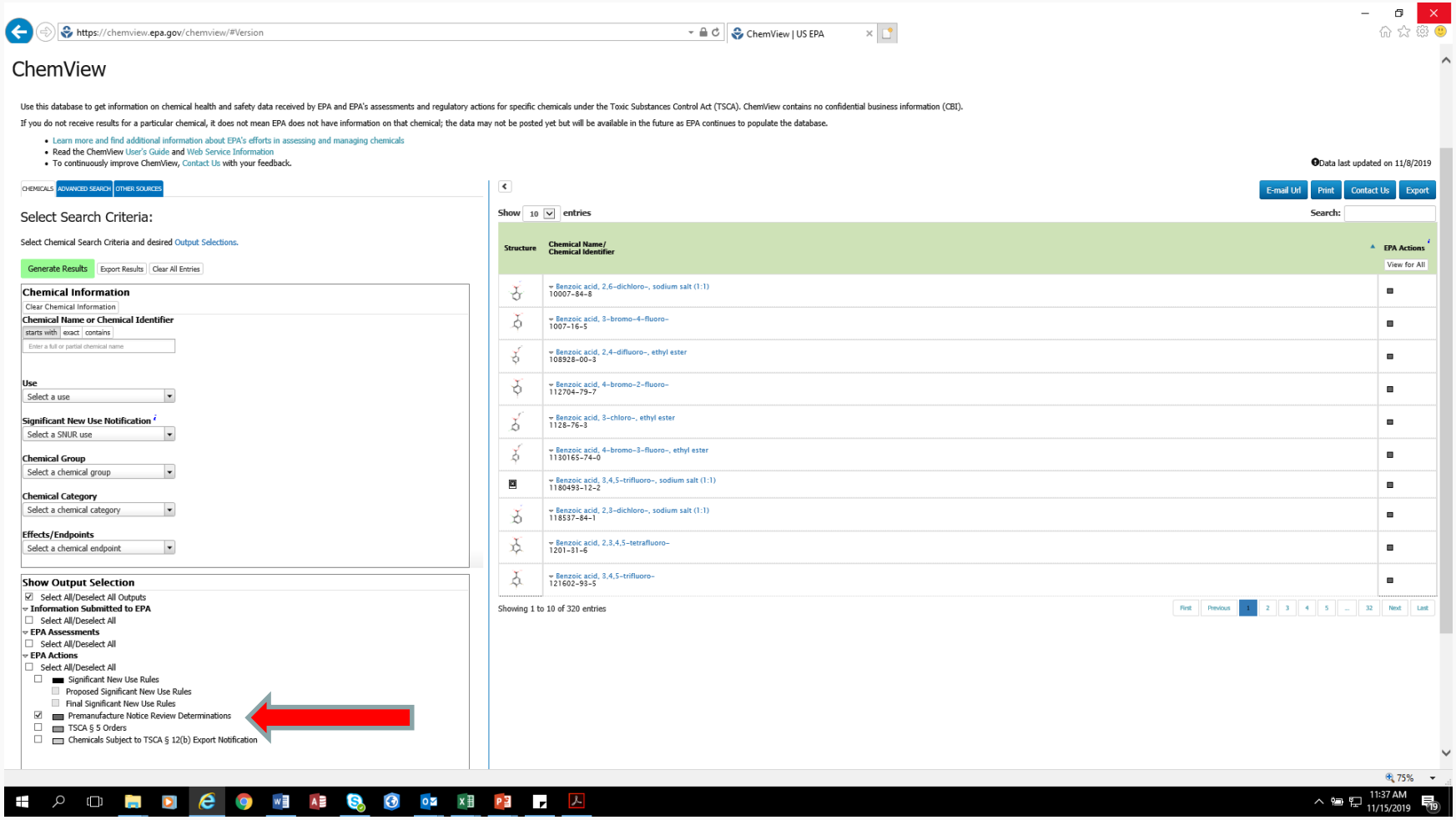
1 — # of chemicals or polymers (Prenotice Communication # required, enter # on p. 3).

[X] Mark (X) if any information in this notice is claimed as confidential.

EPA FORM 7710-25 (Rev. 6-09) Replaces previous editions of EPA Form 7710-25

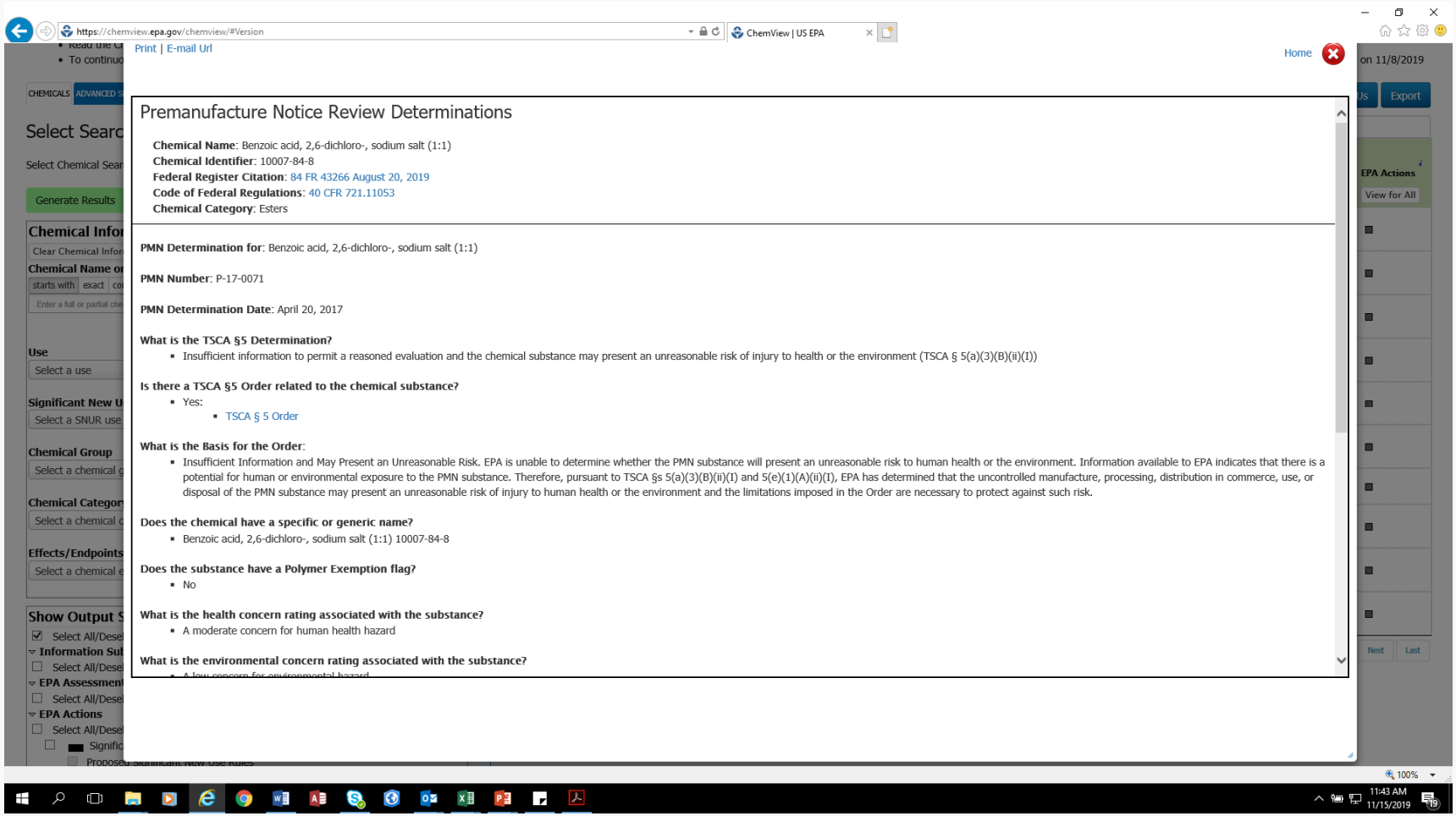
Page 2

ChemView: PMN Review Determinations



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

ChemView: PMN Review Determinations



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