



Bona Fide Notices

Randy Yakal
Chemist

New Chemicals Division
Office of Pollution Prevention and Toxics

Global Chem Conference
PMN Workshop
March 25, 2024



Bona Fide Intent to Manufacture or Import

What does Bona Fide mean?

law : made in **good faith** without fraud or deceit

| a *bona fide* offer to buy a farm



What is the EPA's Bona Fide process?

- The Bona Fide process is a way to verify if a chemical substance is on the TSCA Inventory.
- If a chemical is ON the Inventory, it can be manufactured or imported in the U.S. without prior notification to EPA.
- If a chemical is not on the Inventory, it is considered a new chemical substance and requires a PMN to be submitted to EPA before it can be manufactured or imported in the U.S. for non-exempt TSCA purpose.



How do I know if I need to submit a Bona Fide?

- First, ensure that you've checked the most up-to-date public (non-CBI) TSCA Inventory, downloadable from EPA's website. This has the most current Inventory information.
- If your chemical cannot be found, having the confidential listings on the Inventory searched via the bona fide process is the next step.



How do I submit a Bona Fide?

- Bona Fides are submitted to EPA via CDX and generally must include:
 1. Specific Chemical Identity, e.g., CA Index name, CASRN if available, structure
 2. Spectrum of substance (not obtained from public sources)
 3. Statement of Commercialization
 4. Other information including description of R&D to date, intended commercial application of the substance, anticipated manufacturing process and facility
- This information can be concise but is required by 40 CFR 720.25.



How do I get my response?

- EPA will respond within 30 days of receipt of a complete submission. After the letter is drafted and reviewed, it is sent directly to the submitter's inbox in their CDX account.
- The response will include the Inventory status and other applicable information including commercial activity status and, if relevant, generic name and accession number, and SNUR status/citation.



Common Mistakes

- Common mistakes to avoid include:
 - Not including all information required (e.g., spectrum)
 - Insufficient Chemical Identity
 - No reactants listed on the chemical information page
 - Marking “Method 1” without including a CAS IES report (see next slide)



Incomplete Submissions

- If a submission has been found to be incomplete, you will be contacted by EPA via email or phone with the reason(s) and the route to correction.
 - Bona fide submissions can be edited in CDX and resubmitted.
- Certain submissions may be rejected outright. In these cases, a new bona fide must be submitted.
- Remember: The EPA 30-day response deadline starts only when a complete submission is received.



Inventory Expert Service

- The Inventory Expert Service (IES) is a CAS commercial fee-for-service you can use to obtain a TSCA Chemical Identity (e.g., CA Index Name and CASRN).
- The IES provides a report with a CA Index name and CASRN (if assigned) appropriate for EPA TSCA purposes.
- If obtained and attached to your bona fide submission, please mark "Method 1." If not available, please mark "Method 2."



Useful Resources

TSCA Bona Fide Regulations

<https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-720/subpart-B/section-720.25>

EPA Bona Fide Web Page

<https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory#bonafide>

Randy Yakal, TSCA Bona Fide Coordinator

yakal.randy@epa.gov // 202-564-4127

CAS IES

<https://www.cas.org/solutions/cas-custom-services/cas-registry-services/inventory-expert-services>