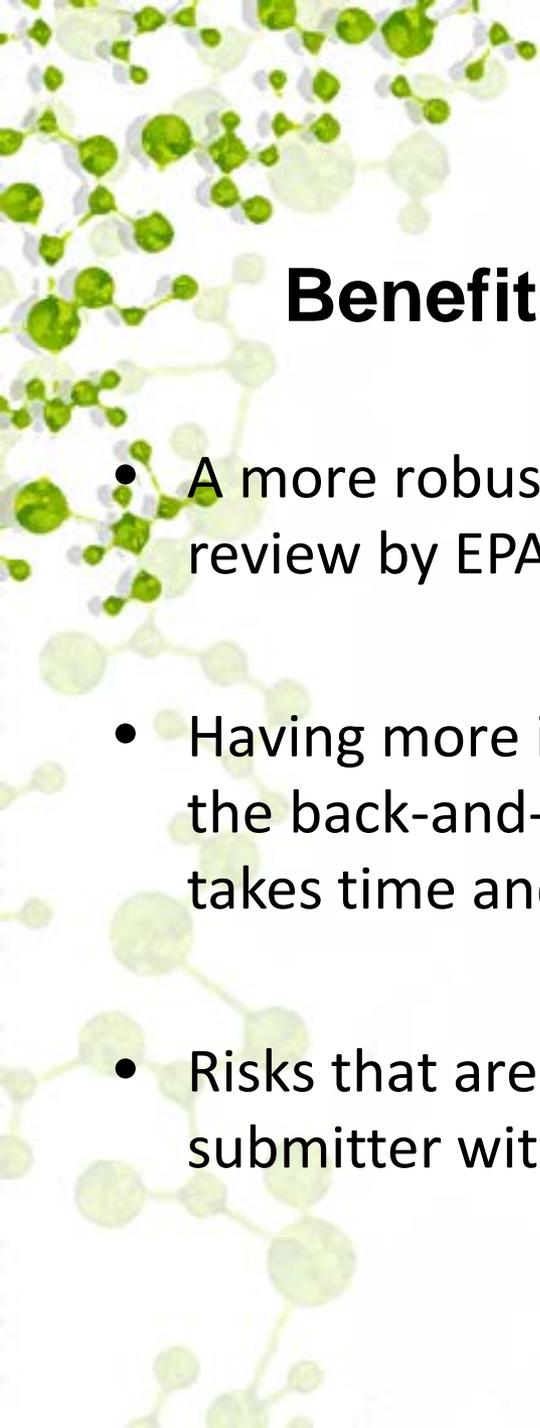


How to Make the Review Process More Efficient

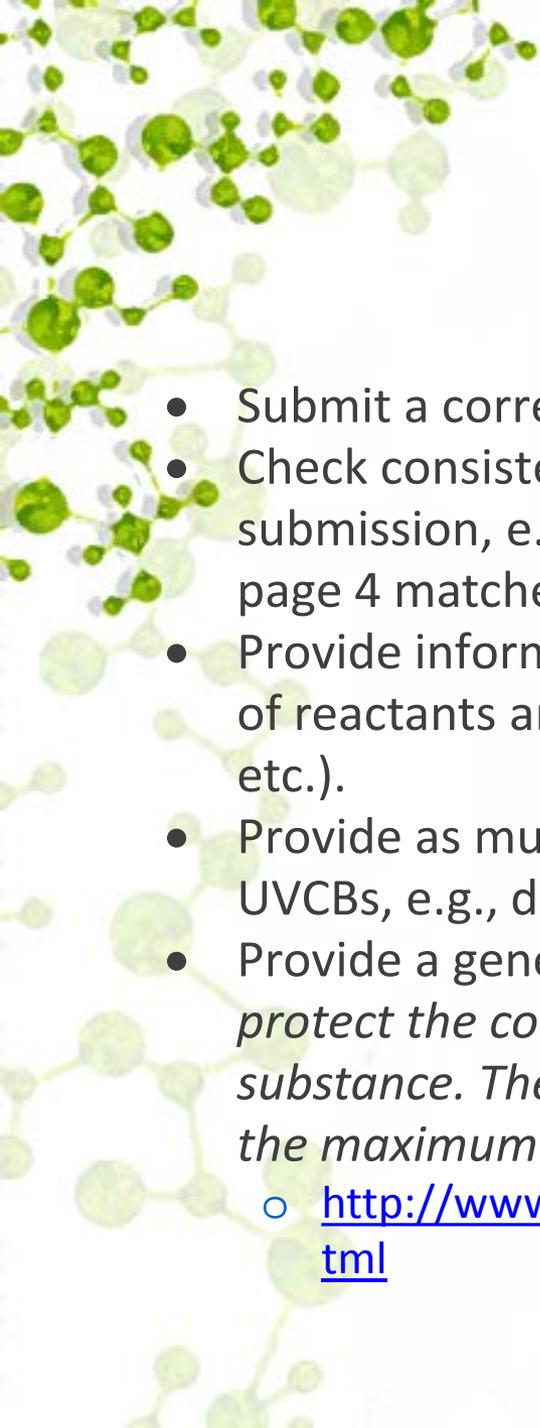
Greg Schweer
Chief, New Chemicals Management Branch
Office of Pollution Prevention and Toxics

December 14, 2016



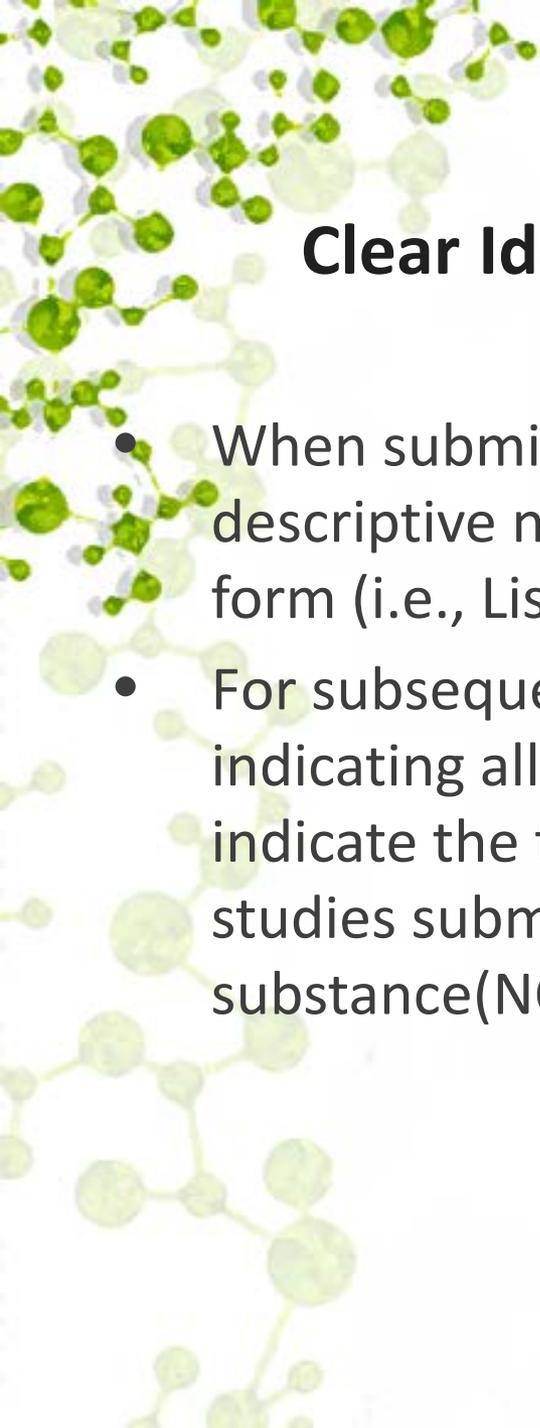
Benefits of a Robust PMN Submission

- A more robust PMN submission can result in a more efficient review by EPA.
- Having more information in the PMN submission will decrease the back-and-forth between EPA and the submitter, which takes time and resources.
- Risks that are identified can often be addressed by the submitter with more detailed information.



Chemical Identity

- Submit a correct CA Index name
- Check consistency of the chemical identity information provided in a submission, e.g., make sure that the chemical identity on PMN form page 4 matches the manufacturing diagram
- Provide information on polymers on PMN form page 5 (i.e., identities of reactants and residuals, lowest number average molecular weight, etc.).
- Provide as much structurally descriptive information as possible for UVCBs, e.g., describe the extent of the variable components
- Provide a generic name that that is *“only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible”* (40 CFR 720.85(a))
 - <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/policy.html>



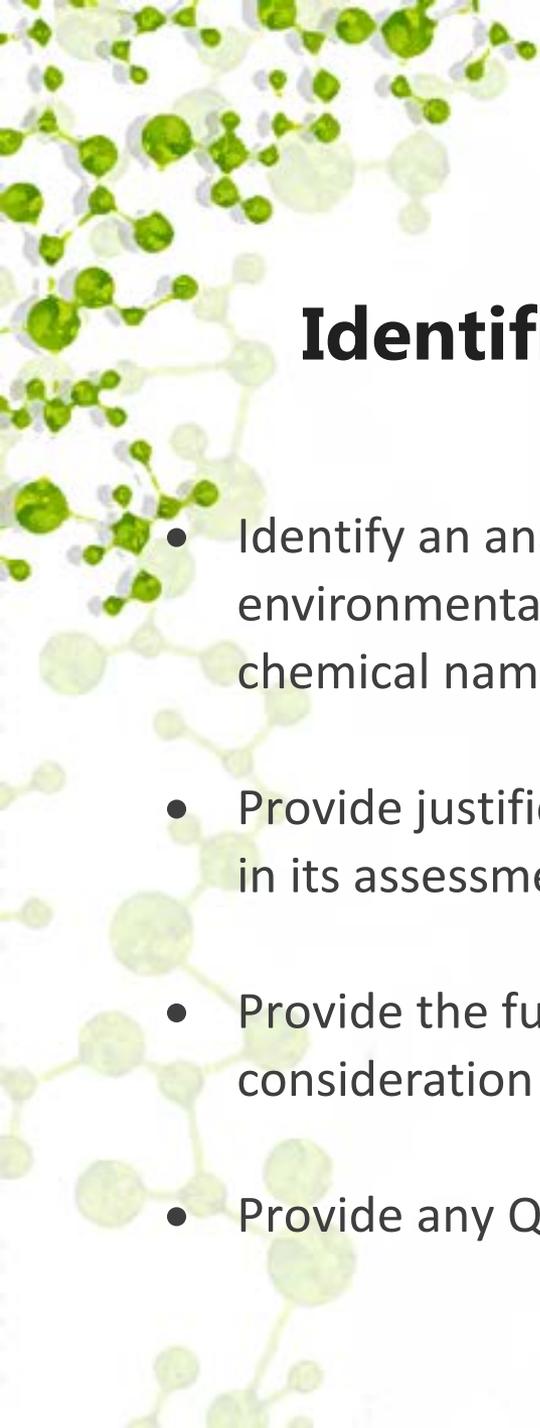
Clear Identification of Submitted Materials

- When submitting the PMN form, provide clear and descriptive names for attachments on page 12 of the PMN form (i.e., List of Attachments).
- For subsequent submissions of information, attach a table indicating all materials submitted. In this table, clearly indicate the test substance/chemical structure for any studies submitted (whether for the new chemical substance(NCS) or an analog).



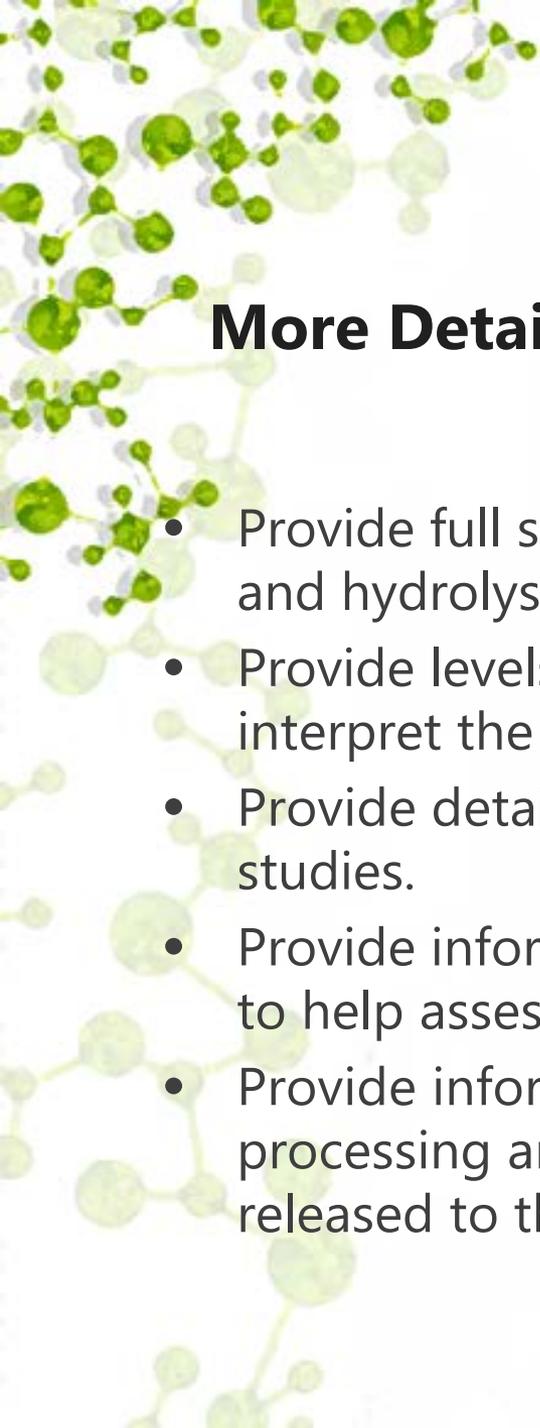
Physical-Chemical Property Information

- Provide measured values for at least the basic physical/chemical properties of the NCS (water solubility, vapor pressure, melting point, octanol/water partition coefficient, boiling point).
- Provide particle size distribution analysis data if NCS is manufactured as a particulate.



Identification of Appropriate Analogs

- Identify an analog(s) for any endpoint – p/chem property, environmental fate, ecotoxicity, human health effects. Provide chemical name and CAS numbers.
- Provide justification for recommending that EPA consider the analog in its assessment.
- Provide the full studies on the endpoint(s) to better ensure consideration by EPA.
- Provide any QSAR Toxicity Analysis reports (e.g., DEREK)



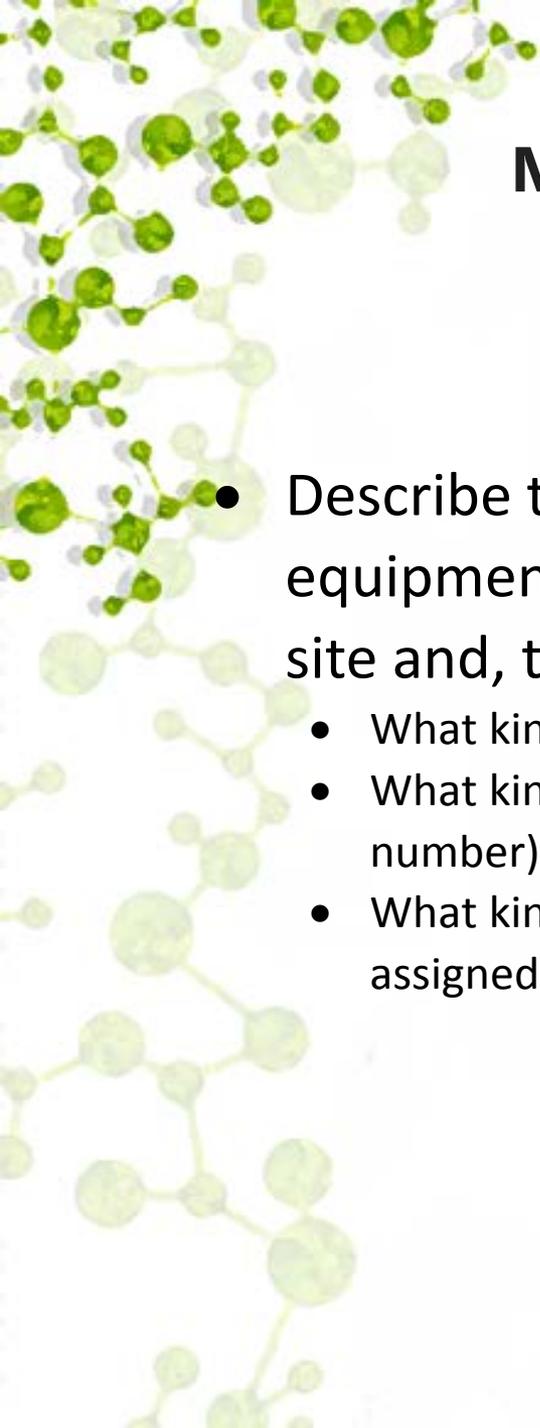
More Detailed Information on Environmental Fate

- Provide full studies on Ready and/or Inherent Biodegradability and hydrolysis on the NCS or analog.
- Provide levels of residuals/starting materials in NCS to help interpret the results of fate studies.
- Provide detailed information on analytical methods used in the studies.
- Provide information on UV/Vis spectrum on the NCS or analog to help assess potential for photolysis.
- Provide information on chemical transformation during mfg, processing and use to help identify the form of the NCS released to the environment.



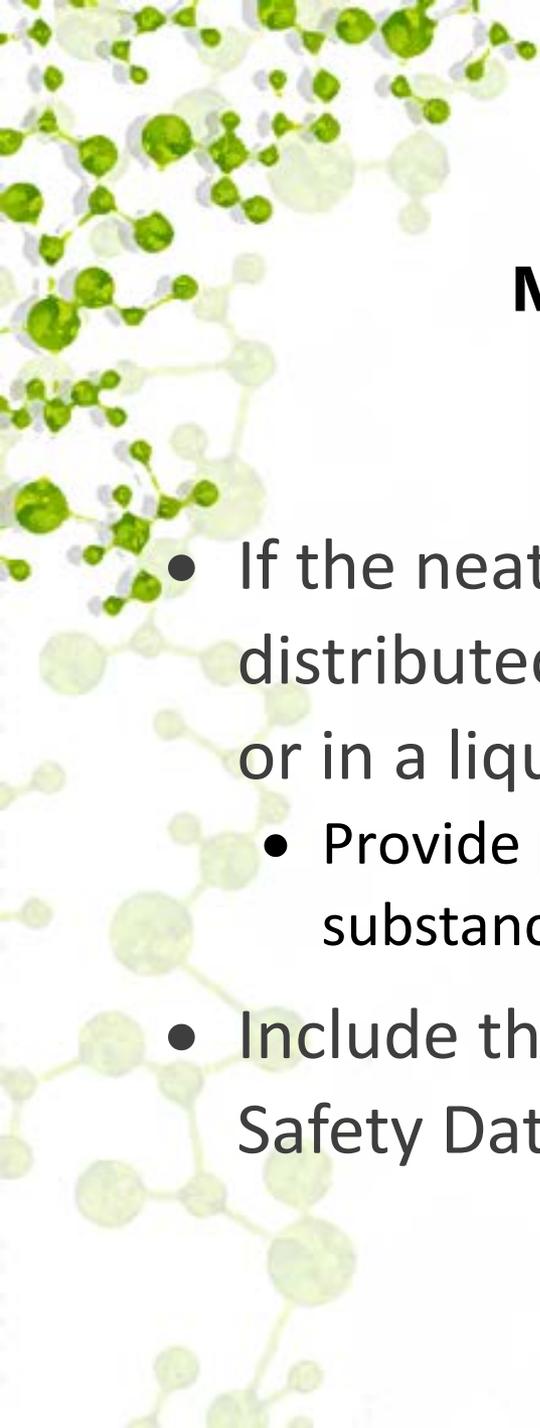
More Detailed Information on Worker Exposure

- Detailed descriptions of the manufacturing/processing/use operations and processes that identify:
 - What are the worker activities?
 - What is the frequency and duration of each worker activity?
 - How (dermal and/or inhalation) and during which activities is worker exposure expected?
 - If worker exposure is not expected, why not?
 - How many workers are exposed during these activities?



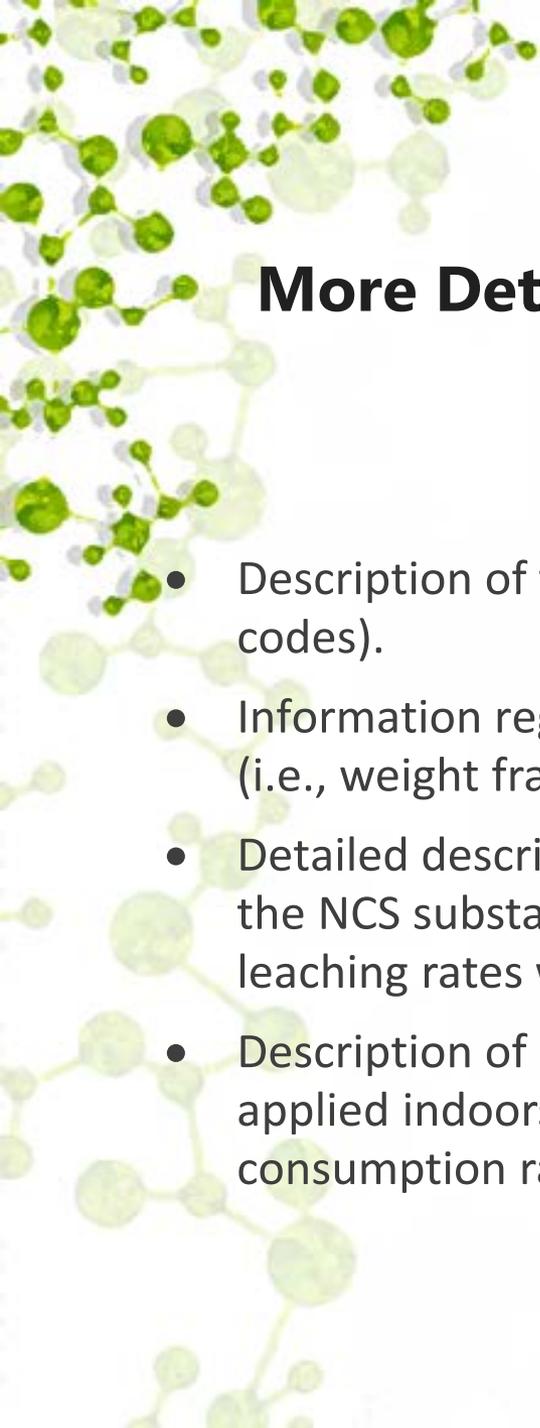
More Detailed Information on Worker Exposure

- Describe the specific type of personal protective equipment (PPE) that will be used at the manufacturing site and, to the extent known, at processing and use sites.
 - What kind of gloves (i.e., material composition, name/model number)?
 - What kind of protective clothing and goggles (i.e., name/model number)?
 - What kind of respirator (i.e., name/model number, cartridge type, assigned protection factor (APF))?



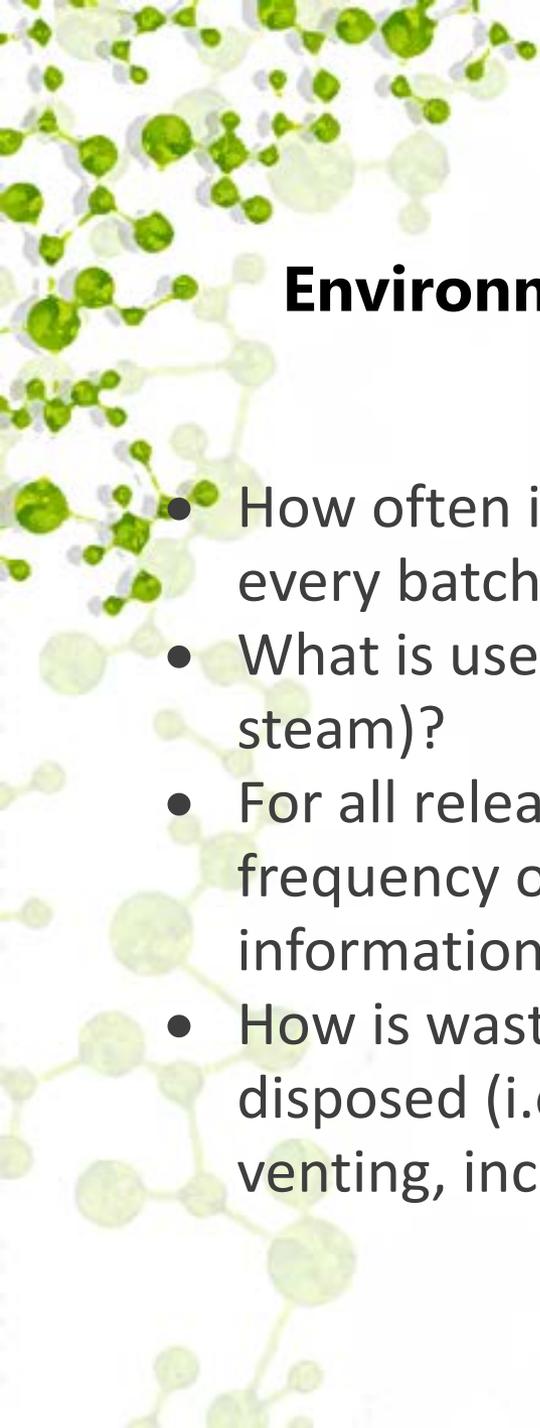
More Detailed Information on Worker Exposure

- If the neat NCS substance is a solid, will it be distributed to processors and users in a solid form or in a liquid or paste form?
 - Provide particle size distribution analysis data if substance is manufactured as a particulate.
- Include the Safety Data Sheet (SDS) or Materials Safety Data Sheet (MSDS).



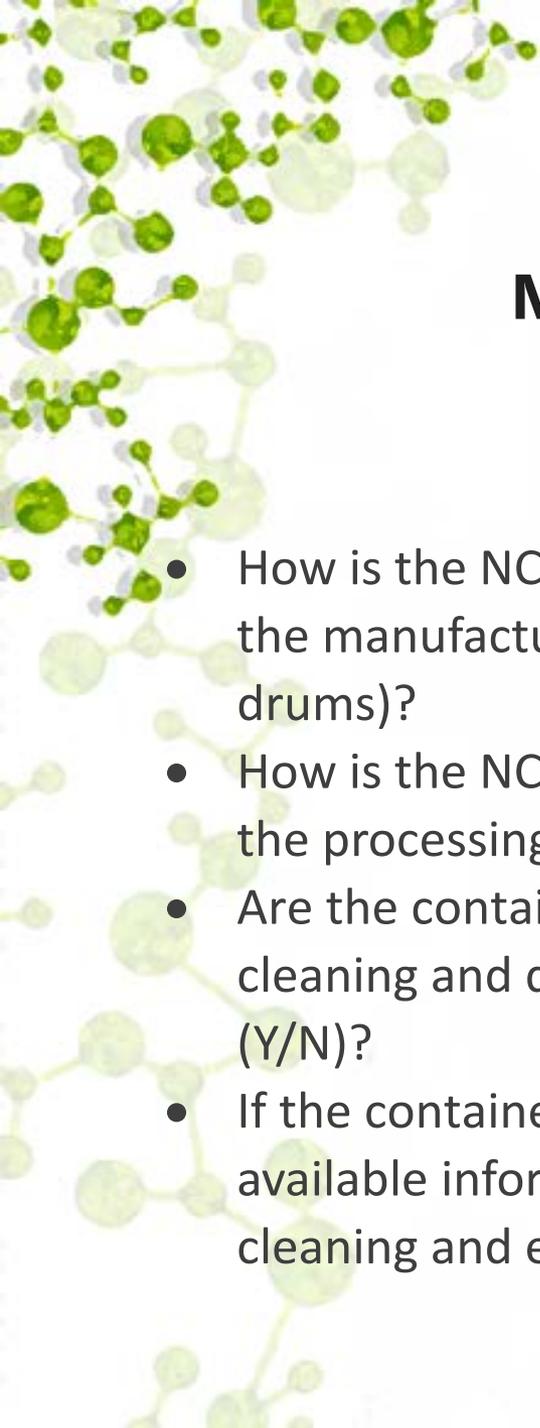
More Detailed Information on Commercial and Consumer Exposure

- Description of the functional use of the NCS in products (e.g., OECD use codes).
- Information regarding quantity of the NCS in potential product or formulation (i.e., weight fraction, volume percent).
- Detailed description of the types of products or articles that will incorporate the NCS substance (e.g., household cleaners, plastic articles) including leaching rates where applicable.
- Description of how and where a potential product would be used (e.g., spray applied indoors, brushed on outdoor surface) including information regarding consumption rates, frequency and duration of use.



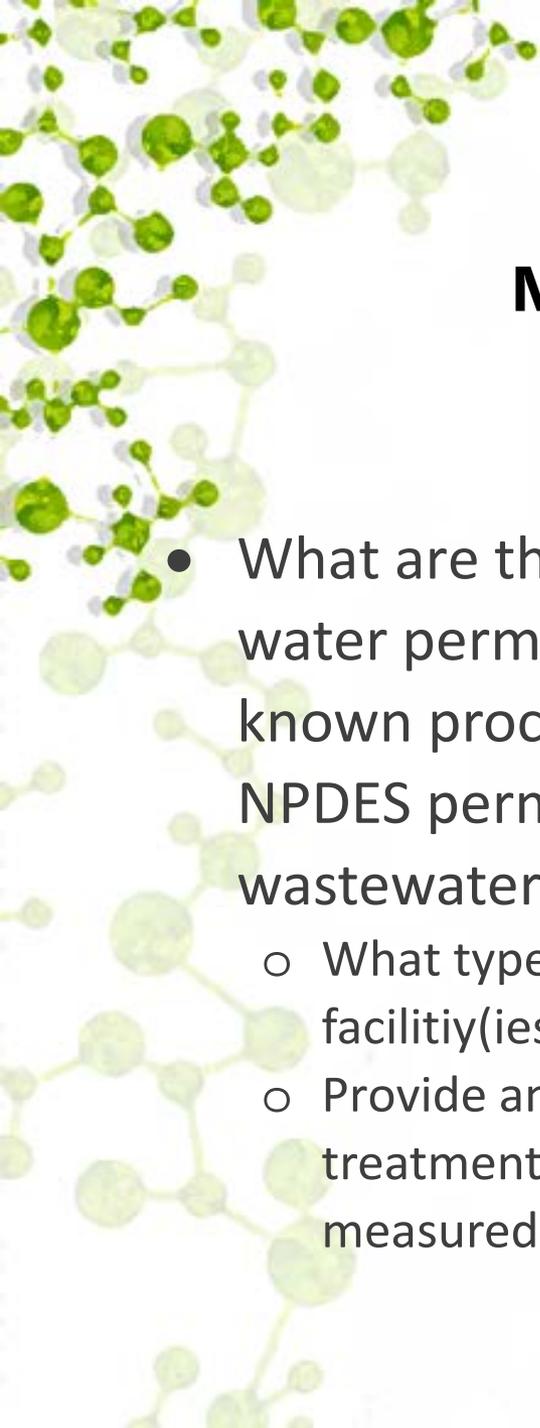
Environmental Releases from Manufacturing, Processing and Use Sites

- How often is the equipment cleaned (e.g., every day, after every batch, once a year)?
- What is used to clean the equipment (e.g. water, solvent, steam)?
- For all releases, provide estimates of the amount and the frequency of releases. Be sure to include detailed information on the basis for each estimate.
- How is waste (including cleaning and process waste) disposed (i.e., on-site waste water treatment, POTW, venting, incineration, landfill, etc.)



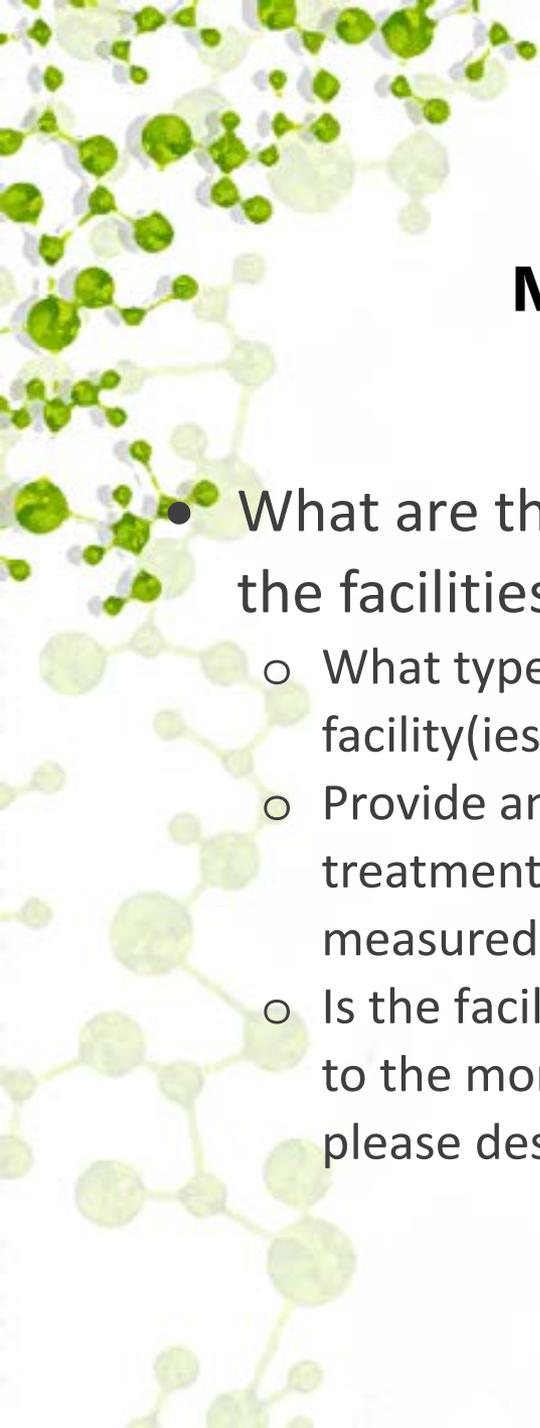
More Detailed Information on Transport and Disposal

- How is the NCS or the product containing the NCS transported from the manufacturing site(s) to the processing sites (e.g., totes, tank cars, drums)?
 - How is the NCS or the product containing the NCS transported from the processing sites to further processing and/or use site(s)?
 - Are the containers used to store / transport the NCS dedicated? Is the cleaning and disposal of the transport containers under your control (Y/N)?
 - If the containers are cleaned or disposed of off-site, please provide available information including the cleaning methods, frequency of cleaning and estimated amount released per cleaning.



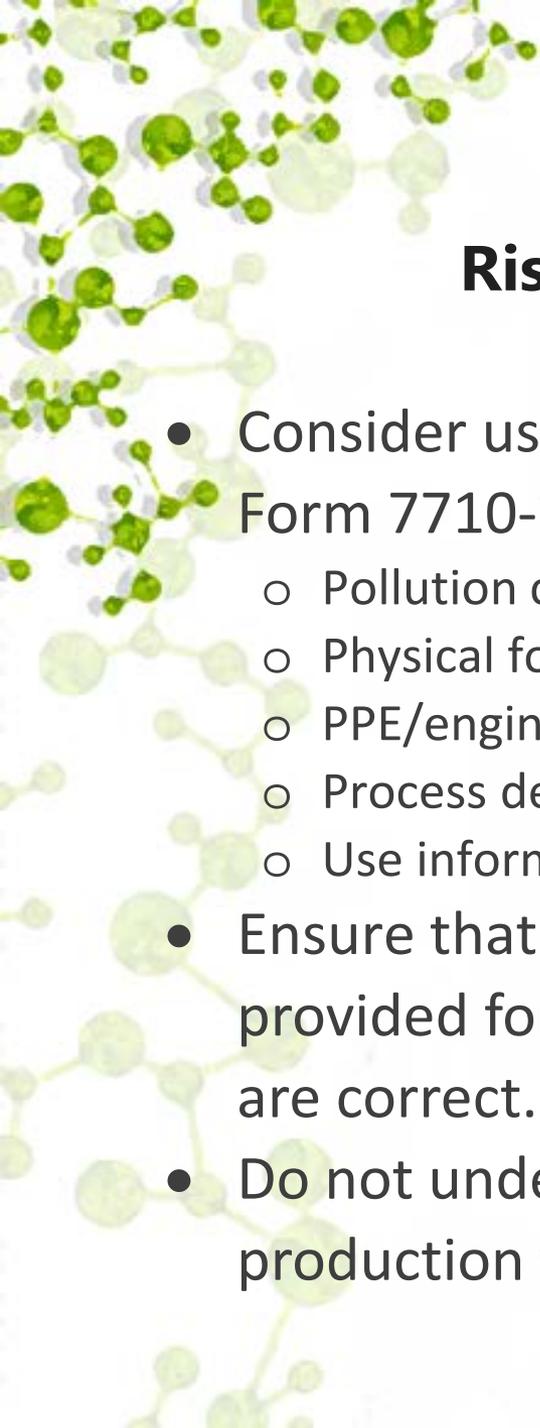
More Detailed Information on Transport and Disposal

- What are the NPDES permit numbers (i.e., non-storm water permit numbers) for the manufacturing site(s), known processing site(s), and known use site(s) or the NPDES permit numbers for the POTWs receiving wastewater from the facility(ies)?
 - What type of wastewater treatment technologies are used at the facility(ies)?
 - Provide any removal efficiency information for your onsite treatment unit operations? Is the information estimated or measured?



More Detailed Information on Transport and Disposal

- What are the Clean Air Act operating permit numbers for the facilities with expected releases to air?
 - What type of air pollution control technologies are used at the facility(ies)?
 - Provide any removal efficiency information for your onsite treatment unit operations? Is the information estimated or measured?
 - Is the facility under a Leak Detection and Repair program (relates to the monitoring and management of fugitive releases). If “yes”, please describe the program.



Risk Management Considerations

- Consider using the “binding option” in the PMN form (EPA Form 7710-25):
 - Pollution control technology and efficiency
 - Physical form(s) of the PMN substance
 - PPE/engineering controls
 - Process description
 - Use information
- Ensure that the phone numbers and email addresses provided for the technical contact and authorized official are correct.
- Do not underestimate your maximum 12-month production volume estimate.



Risk Management Considerations

- Good practice to inform your EPA Program Manager (email, fax or phone message) that you have electronically submitted an amendment or document via CDX.
- When a suspension of more than 15 days appears to be needed, we encourage you to submit a written request for suspension thru CDX for the longer time period.
- Become familiar with the TSCA Section 5(e) Consent Order “Boilerplate” on EPA’s website (<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-program-boilerplates>).