

REACH Workshop Pre-Registration in Practice

Helena Huttunen ECHA Guidance & Helpdesks Brussels, 14 April 2008

Steps for Pre-Registration for Phase-in Substances





Examples of Actions for Phase-in Substances

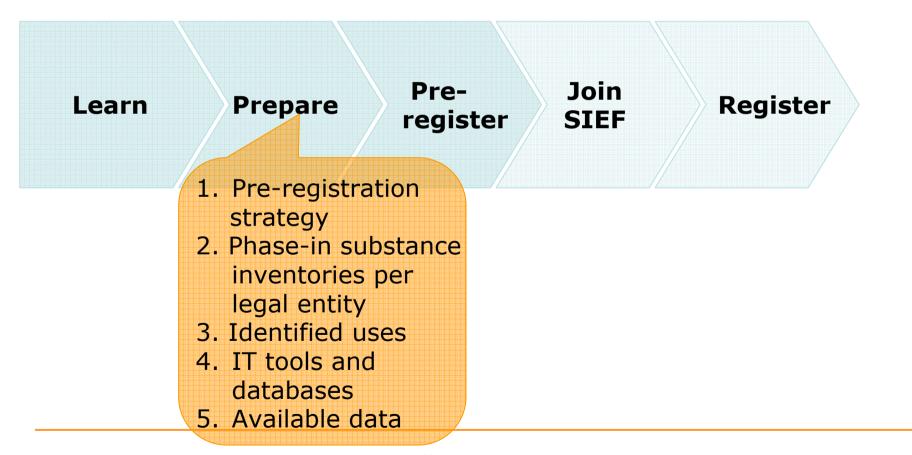




- 1. Know REACH regulation
- 2. Know company and its roles
- 3. Know substances
- 4. Know suppliers and recipients

Examples of Actions for Phase-in Substances





Pre-registration Data Requirements



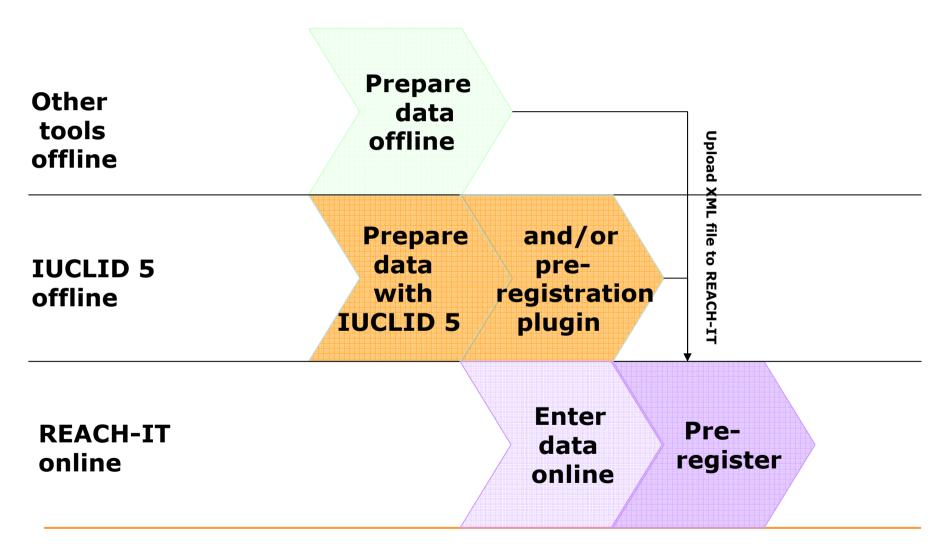
Learn Prepare Pre-register SIEF Register

REACH:

- 1. Substance identity: EC-#, CAS-#, names
- 2. Contact person of the registrant (company and 3rd party if needed)
- 3. Envisaged deadline for the registration and the tonnage band
- 4. Similar substances

Options to Pre-Register





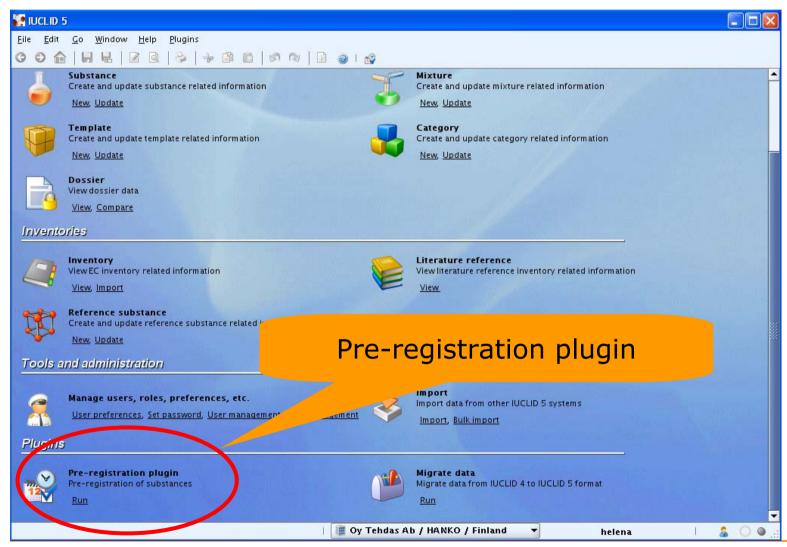
Steps for Preparing Data with IUCLID 5 and Pre-Registration Plugin European Chemicals Agency

- 1. Optional: create substances in IUCLID 5 database for each legal entity (recommended for saving the data for later uses)
- 2. Create a pre-registration list in plugin tool
- 3. Add/create substances to the pre-registration list
- 4. Validate your data
- 5. Export the bulk/single xml files (per legal entity)
- Upload the pre-registration XML files to REACH-IT (per legal entity)

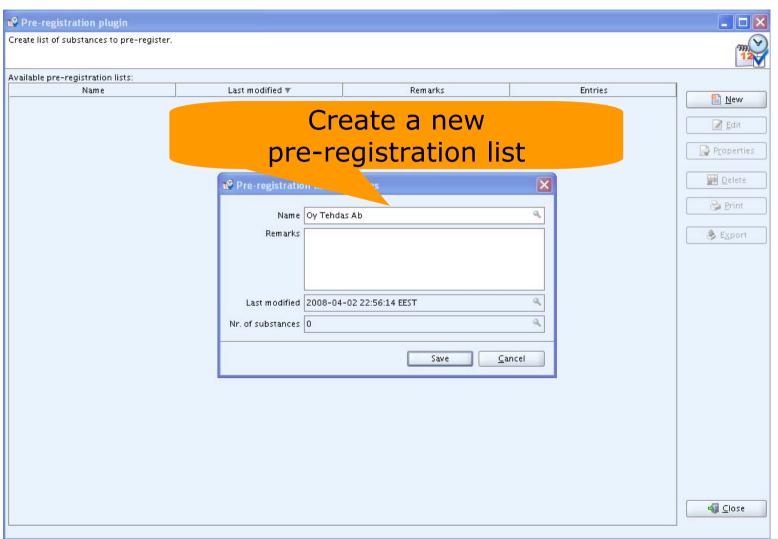


Legal Entity	Role	Substance (EC, CAS, name)	Envisaged Deadline and Tonnage Band	Contact	Similar Substances for Read- Across Purpose
One company can have several legal entities and roles					



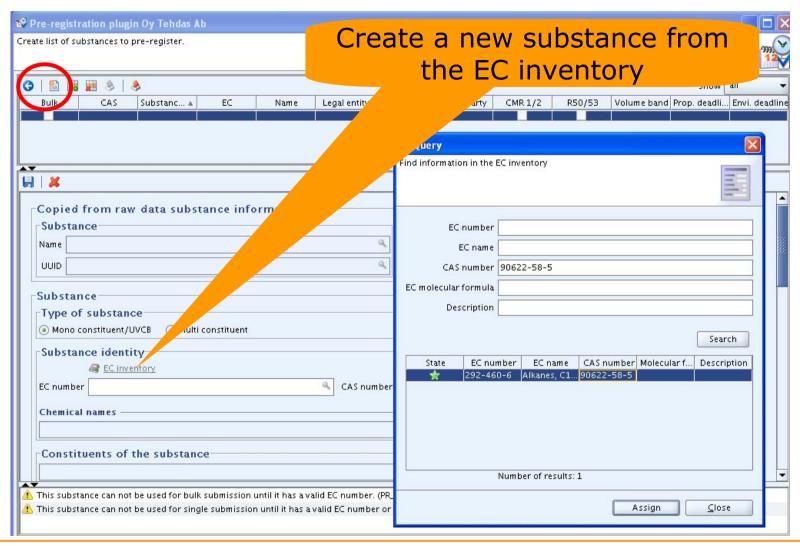




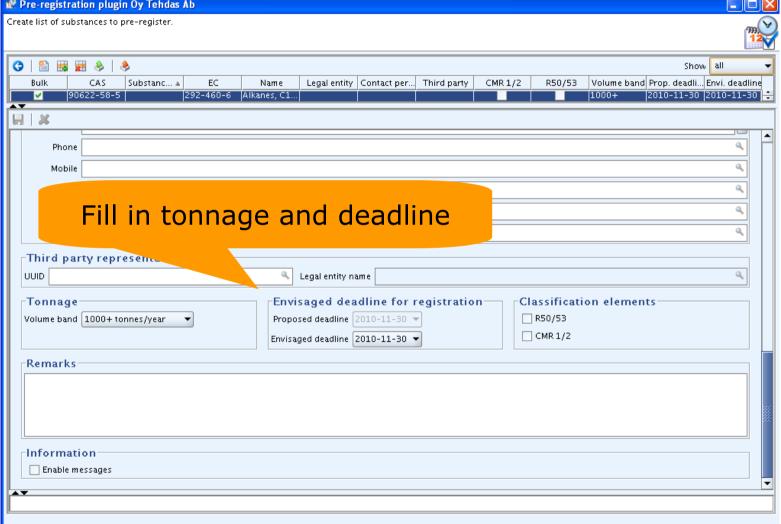


Example: Pre-Registration Plugin (4) ECHA



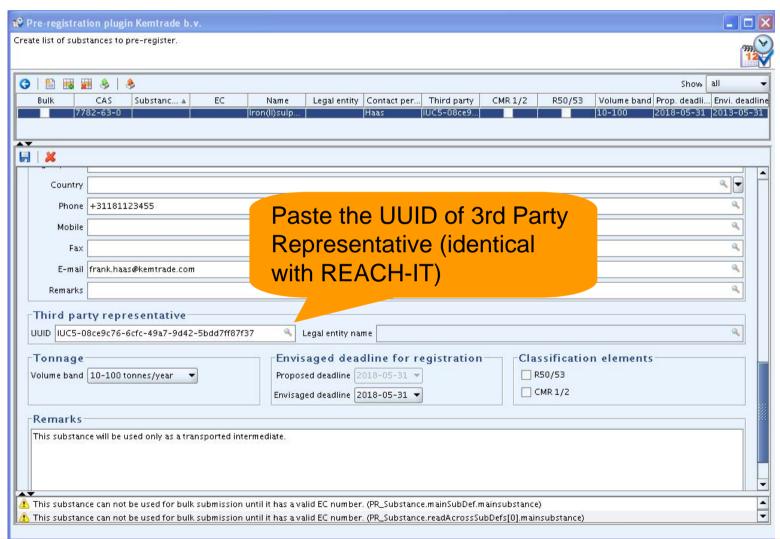


Example:Pre-Registration Plugin & ELHA European Chemicals Agency Pre-registration plugin 0y Tehdas Ab Create list of substances to pre-register.



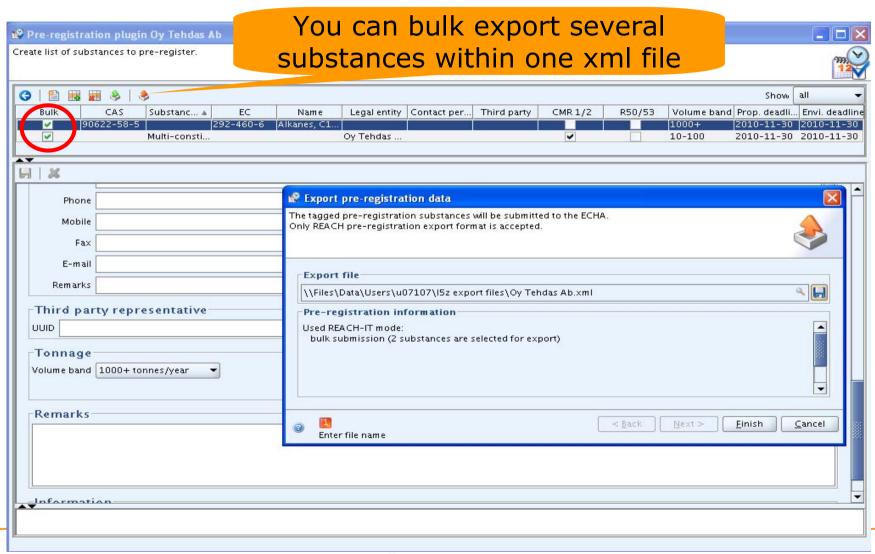
Example: Pre-registration Plugin (ECHA





Example: Bulk Export from Pre-Registration Plugin





Recommendations for IUCLID 5



- Pre-registrations must be submitted per legal entity
- A legal entity can identify a 3rd party representative by typing its UUID (should be equal to REACH-IT)
- Bulk pre-registration of several phase-in substances as one XML file requires EC-#s. Special cases without EC-# can be exported as single XML files from IUCLID or encoded directly online via REACH-IT.
- Contact information can be entered in REACH-IT or in IUCLID 5
- More detailed user guidance is available on http://echa.europa.eu/iuclid

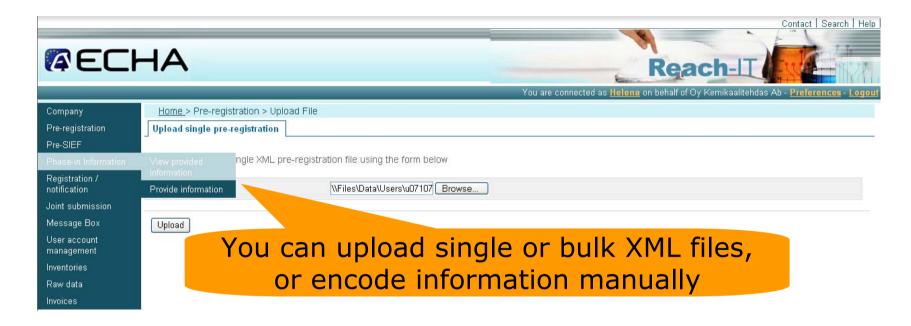
Steps for Pre-Registering with REACH-IT



- 1. Create a company in sign-up
 - Create a REACH-IT account for your legal entity (login & password)
 - Import or enter company information
 - Enter billing information
 - Add contact persons
 - Check the information you have entered and validate it
- 2. Add data and submit pre-registration
 - Encode or upload pre-registration data
 - Validate and submit
 - System generates the pre-registration number (e.g. 05-1234567-12-0000)
- 3. PRE-SIEF formation
 - Shows pre-registrants of the same substance
- 4. Publication of list of pre-registered substances

Example: Upload of XML file to REACH-IT





Recommendations for REACH-IT



- Fill in company contact information (at least) here
- Import/create 3rd Party Representative UUIDs first here (for reference to IUCLID 5 users)
- Phase-in substances without EC-# need to be single imported/encoded online in REACH-IT
- Bulk submissions will have one submission # per batch but one pre-registration # per substance
- Any other data than company and substance identity can be edited later (also in pre-SIEF)
- A pre-registration can be de-activated later
- In case of uncertain substance identity, a conservative preregistration strategy is recommended (esp. multiconstituent substances)

List of Pre-Registered Substances



- Will be published by ECHA by 1.1.2009
- Data holders join in and start indicating their available data
- They cannot see the participants in the pre-SIEF, but can be contacted by the participants

Options to Pre-Register



