



Pre-registration: feedback from industry

Echa's First Stakeholders' Day

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Content



- **Pre-registration in the REACH IT**
- **Availability of the IT system**
- **Practical issues**
- **Cefic REACH structure**
- **Concerns**
- **Industry activities for next steps in REACH**
- **Working in SIEF**



Although several REACH IT functionalities were not available at start of pre-registration, Cefic recognises ECHA's effort to support industry in reducing the inconvenience to a maximum possible in the given situation.

Pre-registration in the REACH IT



- **On-line in the REACH-IT portal**
- **Single Upload to the REACH-IT portal**
 - XML file created with the IUCLID5 Pre-registration Plug-in
- **Bulk Upload to the REACH-IT portal**
 - XML file created with the IUCLID5 Pre-registration Plug-in
 - OR
 - XML file created with the Cefic/CONCAWE Excel Tool

Pre-registration in the REACH IT Industry feedback



- **On-line**
 - Easy to use
 - Gives immediate access to pre-SIEF
- **Single upload**
 - Does not allow to update the registrant
 - Not so useful as it is only shortcut to on-line
- **Bulk upload**
 - Format of XML not fully consistent with REACH IT
 - Cefic/Concawe XML tool
 - Will generate XML file from excel
 - User guide with examples
 - Video tutorial

Pre-registration in the REACH IT Industry feedback



- **Bulk upload is the most efficient option for pre-registering many substances**
- **Pre-registrations can be easily updated**
- **The 6-hours quarantine period is a bit frustrating**
- **The maximum of 10.000 substances per LE is supported by industry**
- **In last few weeks delays noticed in pre-registration**

Availability of REACH IT system at start of pre-registration



Industry managed to deal with the situation and minor problems were encountered:

- Legal entity registration: per role required, leading to many extra LE and subsequent administration
- Submission Registration dossiers via registered mail
- PPORD notification

Late knowledge of what will be available:

- Pre-registration planning of companies to change
- Resource planning difficult with no firm dates (vacation period)

Practical issues



The availability of limited functions in the REACH IT system at start of pre-registration was of great concern for industry:

- Planning bulk submission
- Temporary procedures
- PORD submission
- Company resource planning

The change in OR position

- Change of company strategy
- Company resource planning

Practical issues



Late availability of draft documents and involvement of industry in major topics

- Limited time for commenting
- Difficult to consult members

In July bulk pre-registration became available:

- Cefic/Concawe XML tool
- No major issues encountered

Since few weeks major delays with REACH IT system

- Long delays with pre-registration files
- Concern about system capacity

Practical issues



Double pre-registration:

Commission/ECHA advise to:

- Pre-register monomers for polymers
 - Re-imported monomers of polymers
 - Re-imported substances
 - Substances in articles
 - Recovered waste
- Unnecessary burden for industry: pre-registration and SIEF follow up work

Cefic position: in case of doubt that your supplier will pre-register, do a pre-registration. However when you can be confident that your supplier will pre-register, no need for double pre-registration.

Practical issues



Communication registration number:

- Full registration number, including last 4 digits
- Supplier easy to trace
- Normally > 1 supplier for substances. This means for each batch administration of registration number
- For preparations with multiple suppliers for same substance, hard to keep track of registration numbers

Cefic: The last 4 digits given to the registration number are not part of the registration number. Including these will lead to an unworkable situation.

Practical issues



Disclosure LE name in case of TPR at registration.

M/I may nominate TPR to not disclose name of M/I to other SIEF participants

However at registration the name of the LE will be disclosed to other SIEF participants.

Cefic: also at registration TPR as contact for lead registrant and other SIEF members. TPR can communicate to M/I

Practical issues



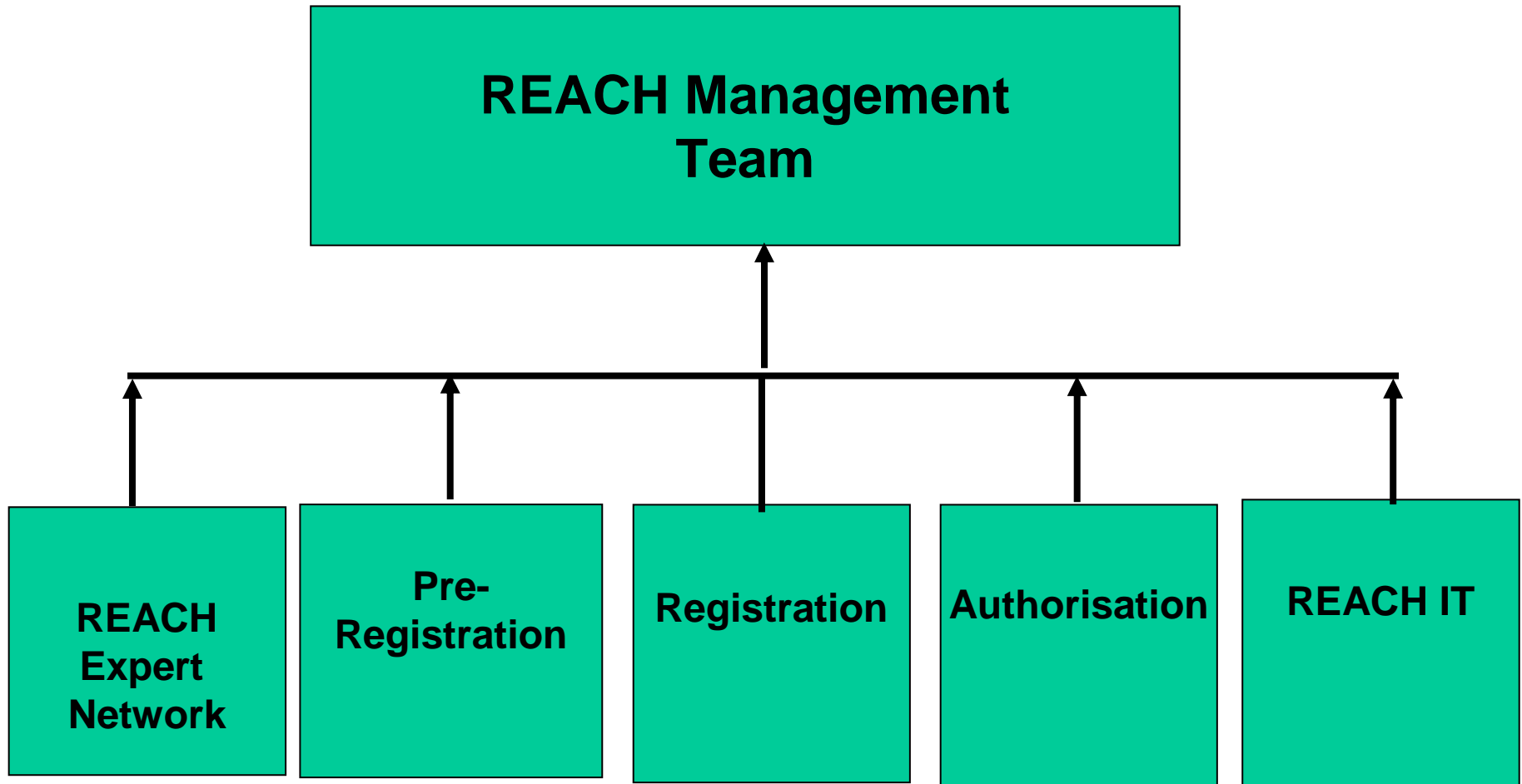
Only Representative and TPR nomination:

TPR can only be nominated by EU manufacturer or importer. Only Representative cannot nominate TPR.

- Non-EU manufacturer, formulator or article producer may want his own experts to communicate in the SIEF as TPR

Cefic: Only Representative may appoint TPR

Cefic REACH structure



Industry Preparation



- REACH Implementation Workshops
- REACH IT workshops
- Industry Preparation Newsletters
- Special editions of newsletters on pre-registration and data sharing
- REACH IT newsflashes
- Supply chain communication tools and standard documents
- Tools and practical guides

Concerns



- **Limited awareness of REACH specifically outside EU**
- **Knowledge within smaller companies to prepare Registration dossiers**
- **Late availability of IT tools to support the creation of the registration dossier**
- **Many 'ghost' pre-registrants leading to unnecessary activities in SIEF**
- **Late availability of documents and systems, limited time for commenting**

Industry facilitating next steps in REACH



- **Newsletters on:**
 - **working in SIEF**
 - **Supply Chain Communication**
 - **ES/CSA/CSR**
 - **Authorisation**
- **Guidance documents on:**
 - **Strictly Controlled Intermediates**
 - **Polymers**
- **Papers on:**
 - **Only Representative**
 - **Importers**

Industry Facilitating next steps in REACH



ES/CSA/CSR

(in close cooperation with VCI)

- Additional guidance on Generic Exposure and Specific Exposure scenarios
- Use of existing data like ESR, HPV
- Simplified guidance (VCI)
- Proposal for industry portal for standard libraries, supply chain communication, exposure estimating tools, etc

- Workshop on ES/CSA/CSR
 - 27 – 28 Oct Brussels

Working in SIEF



The working in SIEF is an industry responsibility:

Cefic and 5 national Federations (German VCI, French UIC, English CIA, Spanish FEIQUE and Italian FEDERCHIMICA) have taken the initiative of developing an IT tool to facilitate the SIEF process:

SIEFreach

- **Practical tools to help in the SIEF process**
- **Released in Aug 2008**
- **Small fee required**





Thank you