Proactive REACH Compliance: Challenges & Best Practices

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Agenda

• REACH – Important Deadlines
• REACH Requirements and Supply Chain Communication
• ES / SUMI & Best Practices
• 3E Solutions
Third and last registration deadline for phase-in substances

Companies that manufacture/import substances between 1 to 100 tons annually and have pre-registered them

If not pre-registered, late pre-registration may be possible until 31 May 2017
REACH Requirements

- REACH Requirements
- Supply Chain Communication
- Roles & Responsibilities
  - Registrants
    - Manufacturers/Suppliers
    - Importers
  - Downstream Users
    - Formulators
    - Re-fillers
REACH Requirements

Substances

- Registration Dossier
  - CSR (≥ 10 tonnes/a.)
  - Technical Dossier (all substances)
    - Part A
    - Part B (+ES)
REACH Requirement

Formulators

• Mixture is classified as hazardous according to CLP.
• Contains hazardous substances registered under REACH.

Timelines:

• 6 months from the substance registration to DU.
• 12 months to incorporate it into eSDS mixture.
Downstream Users

REACH, Article 31 (7) Paragraph 2:

“Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.”
REACH, Annex I:

“An exposure scenario is the set of conditions, that describe how the substance is manufactured or used during its lifecycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users.”
Substance eSDS Requirements

✓ Exposure scenario (ES) must be attached to the SDS and be an integrated part of the SDS (paging, languages)*

✓ SDS must be consistent with the ES (Sections 1.2, 5, 6, 7, 8, 9, 13)**

*See Annex II of the REACH, Part A - 0.3.2.
REACH ES – Implementation Timeline

- **2008**: Registrants updating documentation (dossiers → eSDS)
- **2010**: Safe use information to DU
- **2013**: Priority setting for reg. action by authorities
- **2014**: Priority setting for reg. action by authorities
- **2015**: Priority setting for reg. action by authorities
- **2016**: Priority setting for reg. action by authorities
- **2017**: Priority setting for reg. action by authorities
- **2018**: Priority setting for reg. action by authorities
- **2019**: Priority setting for reg. action by authorities

- **>1000 tonnes +CMR**
- **100 – 1000 tonnes**
- **1 – 100 tonnes (estimated 70 000 registrations – 3 times more than previous)**

*Estimated registration numbers compared to previous years.*
REACH: Enforcement

• **When**
  – Training for national coordinators Q4 2016
  – Inspections in 2017, Report issued in 2018

• **How**
  – Joint inspections with authorities responsible for occupational safety and health inspections
    • Availability of the eSDS to DU
    • Compliance with the regulations
      – Completeness
      – Consistency within SDS
      – Language requirements met
Supply Chain Communication

- Outside EU Manufacturer
- Outside EU Formulator
- EU Importer
- Formulator
- Distributor
- End Users
Safe Use Information for Mixtures

1) Attachment of the ES(s) for all relevant ingredients as such or ES for a substance in a mixture in concentrations above the thresholds given in Article 14. (eSDS = SDS + nES*N).

2) Integration of ES information resulting from consolidation of various exposure scenarios for substances used in a mixture into the core Sections 1-16 of the SDS. [16-Sections SDS].

3) Append safe use information for the mixture derived from the exposure scenarios of the component substances or product as a whole. (eSDS = SDS + nSUI/SUMI).
ES Estimation Approaches for Mixtures

• **Industry-Specific = “Bottom-up”**
  - Sector groups have developed generic exposure scenarios based on intended uses
  - Existing controls are checked against those recommended in component ES’s
  - Uses existing information on operating conditions and risk management measures that currently allow safe use of mixtures
    (Currently 14 developed and finalized methodologies)

• **Universal = “Top-down”**
  - Done by identification of the ‘Lead Component(s)’ (Cefic/VCI LCID)
  - Requires ES’s for each component that triggers classification of the mixture
    (Only 1 recognized/recommended methodology)
Communication Tool: eSDS for Mixtures

Attach ES for substances to SDS

ES(s) for all relevant substances are attached, may vary according to intended uses.

\( (eSDS = SDS + nES*N) \)

Include information in 16 section SDS

Information consolidated from ES(s) for component substances is integrated into the within main body of mixture SDS.

\( (eSDS = SDS) \)

Append Safe Use information to SDS

Append safe use information for the mixture derived from the exposure scenarios of the component substances or product as a whole.

\( (eSDS = SDS + nSUMI/SUI) \)
eSDS Authoring

- Compilation of Exposure Scenarios for Substances
- Authoring of Safe Use Information for Mixtures
**Exposure Scenario for Communication**

**Are uses (OCs and RMMs) are covered in the received CSR-ES?**

**Yes**

- Transfer relevant CSR-ES into SDS-ES and annex to the SDS
- Check SDS to ensure consistency with CSR (SDS Data in Section 1, 2, 3, 4, 9, 11, 12, 14)
- Check SDS and SDS-ES to ensure consistency between ES and SDS Sections 1.2, 5, 6, 7, 8, 9, 13, 15, 16*

**No**

- Contact the supplier to include the use (conditions of use)
- Implement the conditions of use described in the ES
- Change supplier (to who provides the substance with eSDS that covers relevant uses)
- Find a substitute substance
- Prepare own CSA, unless exceptions apply per Art. 37.4.

Challenges

- Expertise and experience (know what, when, and how)
- Efficiency (smart automation – reducing burden of manual data entry)
- Translations (standardisation of phrases, costs of lengthy documents)
- Quality (compliance, clarity, readability, applicability, relevance)
Related 3E Solutions
3E Solutions

• Consultancy (Regulatory, Practical, Technical)
• Software/MSDgen (Efficiency, Quality)
• Libraries/Translations (ESCom, 3E ES Phrases)
Substance/Base Chemicals

• Substance/Base Chemical Library
  – Compiled by experienced 3E Regulatory Experts and Toxicologists
    • Extensive experience with Global GHS Classifications
  – Methodology
    • Analysis of available data
    • Consideration of existing independent reviews
    • Avoids potential infringement of copyright data
  – Provides not only classification but also supporting documentation for each material
  – Electronic data set for upload to client authoring platforms
Consulting Services

• For both Substances and Mixtures
  – Whether ES/SUI/SUMI is required
  – Which uses are applicable
  – National requirements for the eSDS (if any)

• For Mixtures
  – Identify relevant/applicable methodology
    • Industry specific
    • “Universal” (LCID)
  – Best option for communication
    • Attach ES(s)
    • Incorporate within main body SDS
    • Append SUMI/SUI
Authoring Services

- Authoring Services
  - eSDS
    - Substances
    - Mixtures
      - Including identification of relevant ingredients of the mixture
      - Extraction of the required information from the applicable ESs
      - Choice of the most appropriate approach (industry sector specific, if such exists, or otherwise universal/general approach)
  - SUMI / SUI
    - Information provided on safe use of mixture in concise, readable, and understandable format
  - Authoring platform options
    - Outsourced Authoring, i.e. our authors create a complete eSDS in all requested languages in our authoring platform
    - Co-sourced Authoring, i.e. our authors create a complete eSDS in English in customer’s authoring platform
• ESCom Standard Phrase Catalogue
  – Multi-lingual translation package required
  – 3E offers an alternative that has been subject to rigorous quality evaluation
  • Electronic upload to Authoring Platforms
MSDgen Authoring Software

- SDS, eSDS, ES, SUMI Document Templates
  - Complies with the requirement that ES must be an integrated part of the SDS and have continuous paging
  - Ease of authoring
    - Author once, associate to many
    - Option to import of SUMI/GES from 3E Authoring system for direct association to client’s products
- Multi-lingual libraries for eSDS
- LCID Methodology module
  - Under development
  - Automation identification of Lead Component(s)
    - Factors in priority substances, substance classifications, DNELs, NO(A)ELs, NOAECs, ATEs, LD50s/LC50s, local effects, etc.
  - Complete logging of automatic assessment
Thank You

Q&A

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