

Ensuring operational compliance
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Agenda



- **Update on Enforcement activities**
- **Organise operational compliance SDS**
- **How to prepare for an inspection**

Enforcement



REACH-EN-FORCE1 on SDS & pre-registration (extended):

Infringements found:

- registration obligation: 4%
- SDS missing/partial: 9%
- SDS deficiencies: 21 %
- In general non compliance in 20% of visited companies (decrease from 24%)

Facts report on prolongation phase has just been published

REACH-EN-FORCE2 on DU & formulators:

- Paints and detergents as focus group
- Report foreseen by summer 2012

Enforcement



REACH-EN-FORCE3 on customs (will start next year)

- Will cover imports and OR
- Enforcement of restrictions (imported articles)

→ In addition, some MS are working on the enforcement of intermediates

Supporting systems:

- **RIPE**: REACH Information Portal for Enforcement
- **EIES**: Electronic information exchange system

Enforcement



ECHA forum with stakeholders in October:

- Different stakeholders gave presentations on main industry difficulties including supply chain issues, OR& SDS, specific sectors' problems, etc
- Industry willing to give input and be involved in Forum discussions to ensure harmonisation and efficient enforcement
- Consistent enforcement across EU

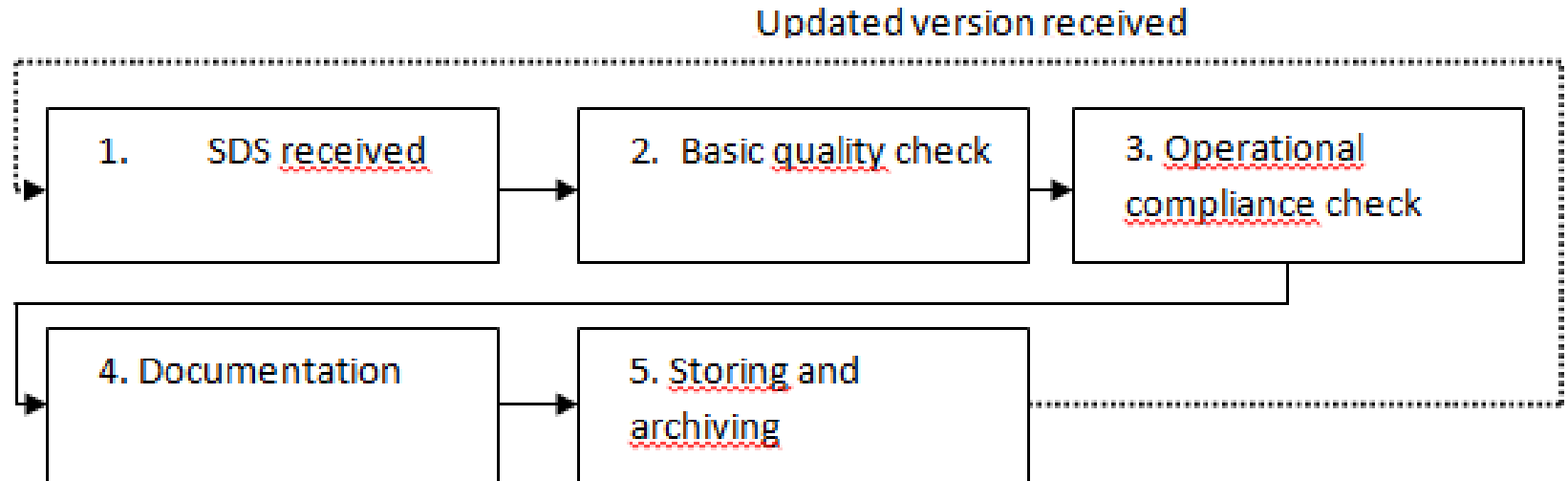
EC conference on 1 March 2012 in Helsinki:

- Industry would like contribute to share experiences and expectations
- Key message to pass: Need a level playing field

Operational compliance SDS



Organisational Process after receiving SDS:



1. Receiving the SDS



- SDS arrive to different places in the company e.g. purchasing department, HSE, plant, etc.
→ *consider installing a specific e-mail address for SDS income*
- SDS apply not only to raw materials, but also to maintenance products, laboratory products, cleaning products, lubricants, etc.
→ *necessary processes have to be put in place for such products too*
- Make sure that everyone in the company knows the process for how to handle incoming SDSs
→ *recommended to have this process described in an internal document*

2. Basic quality check



- This check includes the basic elements that can be quickly verified upon receiving the SDS
- This task can be carried out by the receiving person if they are properly trained
- If the outcome of this check is that the company decides that the SDS can not be accepted, the SDS should be returned to the supplier

→ *Specify what you found to be non compliant*

3. Operational compliance check



Check-list with potential follow-up action per section e.g.

- Information is consistent with the label
- Industrial Hygiene Services and 1st aid responders / emergency responders
- Storage tanks and pipes are labeled or wear warning signs
- All the described measures are covered
- Training of emergency responders conducted
- Fire Protection resource to confirm that the unsuitable media cannot accidentally be used
- Safe handling precautions are followed
- Workplace concentrations are lower than the documented limit values
- If you have new information on hazardous properties, you must inform your supplier

Check-list operational compliance



Section	Information that must be in this section	Potential actions
SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1 Product identifier	<p>In the case of a substance: -Name (EC or CAS or ...) and -Identification Number (EC or CAS or ...)</p> <p>In the case of a mixture: Trade Name or Designation</p>	<p>→ Check if this information is consistent with the label</p> <p>→ If there is a truncated Registration number (Example: 01 - 1234567890 - 11 - xxxx), make sure you have a template to request your supplier the full number in case an inspector requests it. See Cefic available letter: http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/</p> <p>→ Note that not all SDS will have registration numbers (Please consult Cefic paper on SC Comm for more information: http://www.cefic.org/Documents/IndustrySupport/Communication_January2011_final.pdf)</p>
		<p>→ If there is a registration number (truncated or not), check if there are Exposure Scenarios in the annex. If so, you have 12 months to comply with the OCs/RMMs.</p>
1.2 Relevant identified uses of substance or mixture and uses advised against	Identified uses (what the substance or mixture is intended to do)and/or uses advised against (must only be filled out if applicable)	<p>→ Check with area use(s) & if not concurrent => Contact your supplier</p> <p>→ If an Exposure Scenario is included – CHECK FOR CONSISTENCY Please consult the Cefic paper on checking the ES in extended SDS for more information: http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/</p> <p>→ If the use is as an “intermediate” under Strictly Controlled Conditions (SCC) → check if you have confirmed SCC to the supplier and check if appropriate documentation for SCC is available</p>
1.3 Details of the supplier of the SDS	Identity/name of producer or importer or only representative or distributor Complete address incl. phone number! Contact regarding SDS information (email address)	<p>→ Check if all required info is there.</p>

To be published soon!

4&5. Final steps



4. Documentation:

The outcome of the operational compliance check, needs to be documented including Action plan / follow-up

5. Storing and archiving:

Different system per company: from a basic printing and filing to a sophisticated document management system:

- retrieve the latest version of the SDS within a reasonable time
- make information available to workers in a suitable format
- record the receiving and acceptance date of an SDS
- search for the relevant SDS according to different criteria
- store all SDSs for the same product, received from different suppliers
- keep old versions of SDS

Q&As



- SDS come in different languages, if the assessment is done in a centralised team, it may help to have another language e.g. English version. How to handle this language consideration?
- Different suppliers for the same substances → different SDS sometimes with major differences in RMM. What if one supplier has an ES and another supplier has not?
- What if the ES is not available in the local language? Does the clock start ticking?

How to prepare for an inspection?



- **Document and keep documents available**
- **Internal protocols**
 - Internal 'audits' on site
 - Trainings (e.g. to national operational teams/ to product divisions at EU level / to EU legal team)
- **REACH self assessment tool:**
 - Checklist to help companies check REACH compliance
 - to prepare for enforcement visits
 - Record evidence/place where evidence is stored

REACH self assessment tool



- **Listing of REACH provisions with penalties for infringements**
- **Questions to better understand the REACH requirements**
- **Suggestion of possible evidence the company could use to proof compliance**
 - Record evidence/place evidence is stored

REACH self assessment tool'



Per REACH article

- Assessment questions
- Suggested evidence
- Availability of the evidence

Write down
your self assessment
in column N

Different filter options

J	K	L	M
REACH text	Assessment ?	Evidence	Availability of the evidence
Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.	Are the substances manufactured and/or imported by the company registered ?	<p>essencia: Evidence that could be collected to show compliance with the requirement</p> <ol style="list-style-type: none"> 1) assessment of what the substance is + assessment that the substance is subject to registration 2) calculation of the tonnage band for the LE 3) Either evidence of the preregistration (preregistration number) or evidence of the registration (registration number) 4) In case of import where the non EU supplier appointed a OR: written evidence of the non EU supplier, and preferably also of the OR, that the quantity of the substance from this supplier is covered in the OR agreement. 5) In case no EINECS nr available : proof of the phase-in status of the substance. 	<ol style="list-style-type: none"> 1) within reasonable time (documentation and expert kr may not be available in that ti inspection e.g. is registration i the HQ or a consultant) 2) immediate 3) immediate 4) within reasonable time 5) within reasonable time (documentation and expert kr may not be available in that ti inspection e.g. is registration i the HQ or a consultant)

How to prepare for an inspection?



Introduction about company structure including REACH organisation

Keep documents available (e.g. old SDS, outcome of check...)

- can be part of an electronic system
- For the more administrative regulatory aspects, often centrally organised, the evidence should be provided within reasonable time, to be discussed with the inspection authority
- Make sure you have everything in your systems (information may be with consultants, Headquarters, etc...)
- Some documents are only available in English

Announce inspection to the staff

How to prepare for an inspection?



Ensure you can show evidence supporting your decisions/actions e.g. SIEF communication, ECHA letters, result of internal SDS compliance check, etc.

Ask for (timely) feedback on inspection

Be aware of ECHA Forum documents:

- Strategies for Enforcement of REACH and CLP (March 2011)
- Minimum Criteria for REACH and CLP Inspections (March 2011)



**Thank you for your attention!
Any questions?**

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