

Manual for REACH inspections

Manual Forum Project on pre-registration / registration of phase in substances and SDS

Gisela Holzgraefe

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Background

– IMPEL project 2014 showed:

- Most countries have general guidance for dealing with REACH in inspections in place
 - several countries use the manual / checklist of the FORUM-REACH-EN-FORCE-projects,
 - others have own checklists for REACH in inspections.

Main objective of REACH-EN-FORCE projects: Capacity building by using a step-by-step approach → projects focussed on different duties under REACH / CLP Regulation

→ Manuals of REACH-EN-FORCE projects provide good basis for training for REACH inspections (and for dealing with REACH in IED inspections).

REACH-EN-Force projects

- **REACH-EN-FORCE 1**
 - Project on pre-registration/registration of phase in substances and SDS
- **REACH-EN-FORCE 2**
 - Enforcement of obligations of downstream users – formulators of mixtures
- **REACH-EN-FORCE 3**
 - Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs
- **REACH-EN-FORCE 4** preparatory phase 2015, operational phase 2016
 - Enforcement of classification and labelling of mixtures

REACH-EN-Force projects – objectives

- Building the institutional capacity of enforcement authorities
- Training of inspectors
- Improvement of institutional cooperation of national authorities in enforcement of chemical legislation
- Contribution to achieving equal market conditions and competitiveness for enterprises
- Contribution to coordination and harmonisation (as far as possible) of REACH enforcement in the MS's of the EU and EEA-EFTA states,
- Harmonisation of reporting carried out by the MS

REACH-EN-Force projects

▪ Preparatory phase:

- A Forum expert group makes proposals and some kind of prioritisation by asking: what is needed most?
- The Forum decides on the project.
- A working group is established. In each MS a national coordinator is appointed.
Tasks: elaboration of a manual, developing the reporting tools and regulating the tasks of writing a final report

▪ Training phase

- Forum carries out a training phase – train the trainers of the MS
- Trainers inform the colleagues in their countries in workshops and supervise the project

▪ Operational phase

- authorities carry out inspections and report the results

▪ Project report

project manuals

- The project manuals provide good information on:
 - Description of work methods with advice for the inspector what to do in case of non-compliance (general advice – details may be in national legislation)
 - A questionnaire
 - Report templates
 - REACH / CLP provisions to be inspected and
 - the common understanding of the legal terms
- Manuals are translated into the languages of the participating Member States
- Member States are free to add further information, e.g. REACH-EN-FORCE 1 Germany added:
- Recommendations for preparing inspections and a draft letter, with which operators can be informed about the event beforehand plus supporting examples for filling in the questionnaire.

Focus on REACH-EN-FORCE 1

REACH-EN-Force 1 project - objectives

- Assessment compliance of manufacturers and importers with selected REACH provisions concerning phase in substances as such or in mixtures
- Assessment whether companies define their role (resp. roles) in the supply chain for each substance correctly (manufacturer / importer / downstream user)
- Assessment whether the company are aware of their duties under the REACH Regulation, esp. registration

REACH-EN-Force 1: objectives

- To enforce the principle „no data no market“ in the chemical sector

Article 5 – No data no market

- To assess compliance of manufacturers and importers of substances with REACH provisions on registration of substances as such or in mixtures (except articles)

Article 6: General obligation to register substances on their own or in preparations

- To assess the compliance of manufacturers and importers with REACH provisions on Safety Data Sheets (SDS)

Article 31.1: Availability of SDS

Article 31.5: Language of the SDS

Article 31.6: Content of the SDS, verification if all 16 headings /chapters are present and in the correct order

- To control the existence (not the content) of exposure scenarios

Article 31, par. 7: annex to SDS (if necessary), not main focus of REACH-EN-force 1

REACH-EN-Force 1 – the manual

- **General information** about the project with:
 - legal provisions to be inspected
 - Explanations to the questionnaire, collection of data, analysis of data and reporting
 - **Annex 1:** interpretations by questions and answers (27), examples see next slide
 - **Annex 2:** the questionnaire
 - **Enclosure: Instructions** for filling in and explanations regarding the questionnaire (for each item)
- **IMPORTANT:** Only results of inspections (**company visits**, not desk studies) had to be submitted to the national coordinator

REACH-EN-Force 1 project – Annex 1 interpretation by questions and answers



- **27 questions and answers relevant for the project.** The comprehensive answers are related to the REACH Regulation, the guidance documents and other provisions regulating chemical substances
- 1. How to control the phase-in status of the substance (**question 1**)
- 2. Who can be responsible for the registration? (**question 4**)
Natural or legal person.
Company group consisting of several legal entities (e.g. parent company and its subsidiaries, each of those legal entities has to submit its own registration.
Legal entity has two or more production plants which are not legal entities → one registration by legal entity
- 3. Who is a manufacturer? (**question 5**)
natural or legal entity established and manufacturing within the community
toll manufacturer: manufactures a substance in its own facilities following instructions of a third party. Third party puts substance on the market.

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REACH-EN-Force 1 project – Annex 1 interpretation by questions and answers



- Article 3 no. 9 plus Guidance on Registration: Toll manufacturer considered as „manufacturer“ under REACH. Conditions:
 - he is a legal person
 - he is established within the EU
 - he manufactures a substance or extracts substances in their natural state within the EU
- 4. For which substances the supplier is obliged to compile the SDS? (**question 17**)
- 5. When should an exposure scenario be attached (**question 18**)
(Art. 31)
- 6. How to check if a specific company pre-registered a specific substance (**question 21**) Member States Competent Authority has a list.

Further questions and answers to be found via national helpdesks and ECHA helpdesk

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REACH-EN-Force 1 project – Annex 2 questionnaire (with explanatory notes)



- **Section 1:** General information: authority, contact person, date of inspection
- **Section 2:** Information about the monitored company
 - 2.1 – 5: NACE-code,
 - 2.7 Role of the company acc. to REACH (manufacturer, importer, only representative, downstream user)
- **Section 3:** Company within the Scope of the REACH Regulation: Registration
 - 3.1.1 production / import of phase-in-substances as such or in preparations in quantities of 1 tonne or more per year
 - 3.1.2 / 3: number of manufactured / imported phase-in-substances as such or in preparations in quantities of 1 tonne or more per year
 - 3.1.4: Do exemptions from obligation to register apply?

REACH-EN-Force 1 project – Annex 2 questionnaire (with explanatory notes)

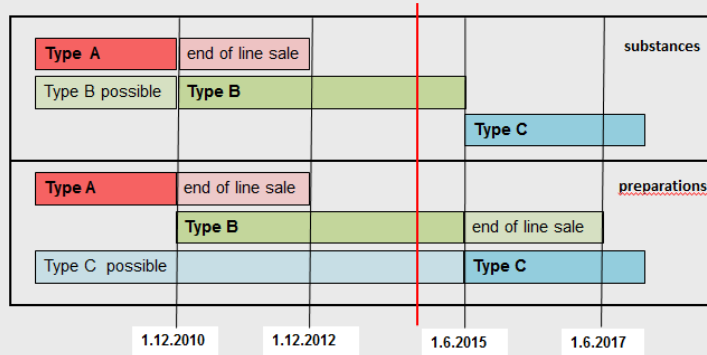


- **Section 4:** Specific Details about the REACH Regulation: Registration
 - 4.1.1 number of pre-registrations as given by the company
Is company Only Representative, for how many substances (pre-)registrations were submitted ?
 - 4.1.2 number of (pre-)registrations submitted by the company to ECHA (homework of authority)
 - 4.1.3 non-compliance with regard to (pre-)registrations found?

REACH-EN-Force 1 project – Annex 2 questionnaire (with explanatory notes)

- **Section 5:** Details regarding Information Obligations in the Supply Chain (Title IV REACH Regulation)
 - 5.1.1: Does company have required safety data sheets for all substances and preparations? (means for all spot-checked substances)
 - 5.1.2: Does company have structures / instruments (e.g. software), which make the preparation of SDS possible?
 - 5.1.3: Do SDS prepared by the company fulfill requirements of Art. 31 par. 5 and 6? Official language of the MS and correct headings and correct order
- **Section 6:** some voluntary questions (DE: IT system or files for SSDS, employee access)
- **Section 7:** Summary / Follow-up Action
 - 7.1 Has non-compliance with REACH obligations been determined
 - 7.2 Measures due to non-compliance (e.g. administrative order, fine ..)
 - 7.3 Measures initiated by the company in case of non-compliance
 - 7.5 Problems

Formats Safety Data Sheets



TYPE A: Annex II to first version of REACH Regulation

TAPE B: Annex I to Regulation 453/2010, amending Annex II to REACH Reg., date: 01.12.2010

TYPE C: Annex II to Regulation 453/2010, amending again Annex II to REACH Reg., date 01.06.2015

Recommendations for preparing inspections

1. Choice of company to be inspected – supporting data and documents

Inventory of companies holding environmental permits
 current permit procedures
 sector / branch specific company lists on the internet
 Information from customs concerning importers

2. Preparation of the inspection:

Company should be informed about the inspection beforehand – purpose:

- person responsible for REACH has to be present and
- the relevant documents must be available on site

Recommendations for preparing inspections

Inspector should collect all relevant information on the company before carrying out the inspection

- Company structure (who is responsible for registration?)
- Activities of the company (which substances / preparations are manufactured / imported)?
- Assessment of the production process (all substances / preparations / intermediates),
- Assessment of product or waste?
- Which exemptions apply? (e.g. cosmetic products, medicinal products, ...)
- Permit applications must contain all relevant information about substances / preparations produced and intermediates, waste
- If necessary, ask company to send an inventory

Recommendations

- Some findings REACH-EN-FORCE Some findings REACH-EN-FORCE
Prioritisation: look first at most harmful substances
- All parties involved should participate in inspections

Some findings REACH-EN-FORCE 1

- 23 MS participated 2009, 19 in the prolongation
- Checked companies: 2/3 with 1 – 10 substances
 - 1/6 with 11 – 100 substances
 - 1/6 with 101 – 1000 substances

Role of the copany	
manufacturer	878
importers	666
Only representatives	83
Downstream user	858

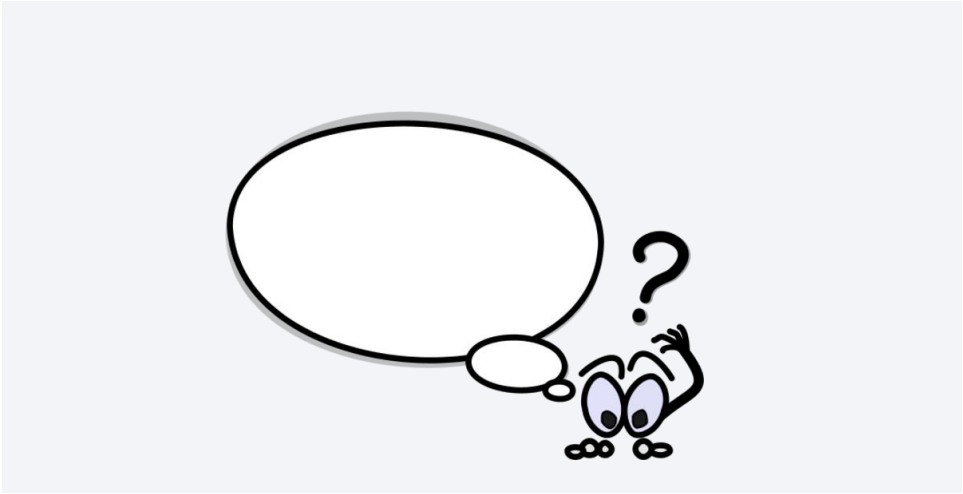
Some findings REACH-EN-FORCE - SDS

- 2009: 5 338 checked, 808 not correct (15 %)
- 2011: 1 711 checked, 366 not correct (21 %)

Measures / follow-up	1 589 companies
Info to the public	3
„Shame and blame	
Warning letter	96
Subsequent order	169
fine	12
Criminal acts	3
other	121

Examples

- **Example 1:** Production of biodiesel (rapeseed oil methylester) from rapeseed oil by-product glycerol – product or waste?
 Company brought the mixture of glycerol / water to a biogas plant treating waste material → waste → no registration
- **Example 2:** Large combustion plant, waste incinerator
 production of gypsum and hydrochloric acid → manufacturers of substances → obligations under REACH
- **Example 3:** Production of biogas in a biogas plant → exemption acc. Annex V REACH Regulation



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Thank you for your attention !!

7-9-2015

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