



First experiences from industry on REACH enforcement  
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# Agenda

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- **Cefic enforcement working group**
- **First experiences**
  - REACH-EN-FORCE projects
  - Customs involvement
- **How to prepare**
  - Essenscia self assessment tool

# Enforcement working group

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- **Under the Cefic dossier compliance platform**
  - Supported by REN
- **Scope and potential issues**
  - Comparable enforcement in EU
  - Same penalties in EU
  - Import must be included in the enforcement

# Enforcement working group

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- **Objectives**
  - Adequate enforcement is needed
    - A pro-active approach is necessary
    - Warning system must be organised so that Cefic is warned in an early stage that something somewhere goes wrong
    - Organise that all points are treated by the Forum
    - What to do if one of us breaches the rules
  - Cefic must become the « preferential partner » of the Forum to discuss problems of enforcement of REACH

# First experience

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- **Central role for member states**
  - To maintain an official system of control (art 125)
  - To establish penalties for infringements (art 126)
- **Coordination in the FORUM (art 86)**
  - REACH-EN-FORCE projects
  - Unfortunately doesn't mean harmonised enforcement
    - France notice enforcement on SVHC in articles: 'once an article, always an article'

# REACH-EN-FORCE 1

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- **First coordinated inspection campaign**
  - 1 singular inspection manual (incl. checklist)
  - 25 MS participated
  - May – December 2009
- **Key concepts**
  - Check compliance with:
    - (pre) registration - No data no market (art 5)
    - SDS obligations (art 31.1 – 31.5 – 31.6)
  - Appoint national coordinators
- **Report available on ECHA website**
  - [http://echa.europa.eu/doc/about/organisation/forum/ref\\_1\\_facts\\_report.pdf](http://echa.europa.eu/doc/about/organisation/forum/ref_1_facts_report.pdf)

# REACH-EN-FORCE 2

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- **Check compliance of formulators**
  - SDS
  - To raise awareness: ECHA fact sheet SDS and ES for DU
- **Timing:**
  - Announced dec 2009
  - Preparation in 2010
  - On-site inspections scheduled in 2011

# Customs involvement

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- Sub-group of the ECHA Forum working on involvement of customs in REACH enforcement
- Proposal under preparation to include REACH information in the new customs declaration format
  - Inclusion of the registration number under discussion
- Joint Cefic-EM paper with support from other industry associations (EFPIA, FECC, etc.)



# Customs involvement: Cefic-EM position



## Main points:

- Check of REACH compliance of imports should happen at the '**most appropriate**' place, i.e. not necessarily exclusively at the border, but rather at the importer's premises.
- **Harmonisation among EU countries** with regards to the Customs involvement is crucial
- **Blockage of goods should be avoided** at borders
- Companies holding an **Authorised Economic Operator (AEO)** certificate, the control on REACH should be carried out on a procedural mode rather than on an individual transaction basis.
- The **inclusion of the registration number** in the customs declaration is neither useful nor workable
- A **self-declaration** could be used instead by companies to provide information on REACH compliance. This can be used as a screening tool by customs authorities to identify suspicious cases for which further enforcement actions may be required

# Industry experience first inspections

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- **Scope:**
  - full substance portfolio of a company vs. 1 substance
  - pre-registration aspects / REACH general compliance / supply chain communications duties / SDS ...
- **Process/approach:**
  - some inspectors still under training process
  - Different national inspectorates involved
    - Sometimes coordinated inspection
  - Templates inspection manuals sometimes available
  - Few unannounced inspections
  - Sometimes check of the REACH compliance via other channels (e.g. health or food safety authorities)
  - Final inspection reports usually not provided

# Industry experience first inspections

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- **Outcome**
  - A few blockage of goods at ports and airports (pre-registration)
  - Few legal issues related to enforcement procedure (e.g. protection of CBI) identified for the time being
  - No exchange/dispute with authorities on legal interpretations for the time being
- **Disparities among MSs:** e.g.
  - in terms of flexibility
  - In terms of public notice of the results of an inspection

# Industry experience first inspections

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- **Central organisation of REACH team**
  - Link with operational teams in plants
  - Availability of information/experts
    - language
  - Difficulties for REACH experts to have expertise in national administrative laws and of national court remedies
- **Overlaps (contradiction) between REACH & other legislations**
  - > overlap (contradiction) on enforcement?

# National inspectorates



## Overview on ECHA website



European Chemicals Agency

- HOME
- SIEF
- REACH
- DATA SHARING
- ENFORCEMENT  
National inspectorates  
Forum
- CONSULTATIONS
- ECHA CHEM
- REACH-IT
- CLP
- GUIDANCE

### Enforcement of REACH and CLP – national inspectorates

Select country by clicking a flag or the name:

- |               |           |            |                |             |                |        |
|---------------|-----------|------------|----------------|-------------|----------------|--------|
| Belgium       | Bulgaria  | Cyprus     | Czech Republic | Denmark     | Estonia        | France |
| Germany       | Greece    | Hungary    | Iceland        | Ireland     | Italy          | Latvia |
| Liechtenstein | Lithuania | Luxembourg | Malta          | Netherlands | Norway         | Poland |
| Portugal      | Romania   | Slovakia   | Spain          | Sweden      | United Kingdom |        |

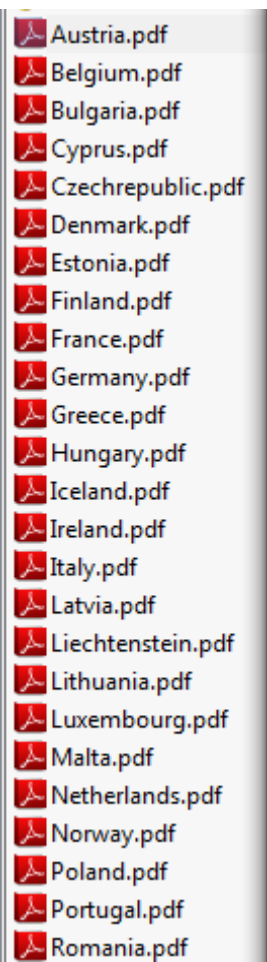
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# National penalties



[http://ec.europa.eu/environment/chemicals/reach/enforcement\\_en.htm](http://ec.europa.eu/environment/chemicals/reach/enforcement_en.htm)



## BELGIUM

### Federal law

#### 1. Provisions in place in the Member States on REACH penalties

The table below has been compiled on the basis of the information provided in the legislation sent by Belgium in its notification to the European Commission. This table indicates briefly which REACH articles are covered in the federal legislation.

When there is a star (\*) next to the country name, it means that the country applies what is called a “catch-all” provision, meaning that there is a provision in the law indicating that any infringement of the REACH Regulation can be sanctioned under national law.

Country	BELGIUM
Article	
5	X
6(1)	X
6(2)	
6(3)	X
7(1)	X
7(2)	X
7(3)	X

# How to prepare?

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

# REACH self assessment tool

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- **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

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- **developed by the essenscia Product Policy Working Group**
- **available for members/VLARIP/WALRIP on essenscia's extranet**
  - Release of the first version: July, 2009
  - New version 1.1 December 2010
  - Being adapted for Cefic members
- **takes into account the REACH articles referred to in the Belgian legal framework**
  - to be checked for other countries
- **content of the registration/authorisation dossier itself not included**
  - Use Technical Completeness Check (TCC)

# REACH self assessment tool

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- **Xls met 6 sheets where companies can add comments**
  - Version
  - Introduction
  - Self assessment tool
  - REACH documents
  - Recommended documents
  - abbreviations

# 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 REACH text	K Assessment ?	L Evidence	M Availability of the evidence
<p>subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or 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.</p>	<p>Are the substances <b>manufactured and/or imported</b> by the company registered ?</p>	<p>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.</p>	<p>1) within reasonable time (documentation and expert knowledge may not be available in that time inspection e.g. is registration in the HQ or a consultant)                  2) immediate                  3) immediate                  4) within reasonable time                  5) within reasonable time (documentation and expert knowledge may not be available in that time inspection e.g. is registration in the HQ or a consultant)</p>

# How to use the tool?



## use filters and sort. Multiple filters can be combined.

- per title, chapter, or article of the REACH regulation (column A "title in REACH", column B "chapter in REACH" or column C "REACH article")
- per date of entry into force (column D "Entry into force")
- per penalty (column E "Penalty")
- if a warning procedure is foreseen or not (select "yes" or "no" in the column F "Warning Procedure")
- REACH key words (columns S to Z with REACH subjects) the requirements related to that subject (orange columns)

	A	B	C	D	E	F	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB
1	REACH tit	Chapter	Article in REACH	Entry into force	Penalty	Warning procedure: Y/N (art 17)	applicable for the LE			Manufacturer importer	Downstream user	Registration	Authorisation	Notification to the EU	SDS C&L	Communication upst	Communication dow	Inventory (substance)	RMM	Reach r	

# How to use the tool?



## Write your own remarks

- Per LE (column N "Applicable for the legal entity" )
- Per role (columns O to R with REACH roles) (blue columns)
- Per department (columns AA to AD with responsible departments) (green columns)

**multiply and rename the assessment sheet to keep track of the assessment for different Legal Entities, different substances, ...**

C	D	E	F	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	AC	AD	A
Article in REACH	Entry into force	Penalty	Warning procedure: Y/N (art 17)	applicable for the LE	Manufacturer	Importer	Downstream user	Registration	Authorisation	Notification to the EC	SDS C&L	Communication upstream	Communication downstream	Inventory (substance)	RMM	Reach responsible	Purchasing	Sales	SDS re		
6.3	1/06/2008	light	N		x	x		x				x		x							

Navigation tabs: Versions, Introduction, self assessment tool, REACH Documentation, recommen...

# REACH documentation



## Documents required in the REACH regulation

- Safety data sheets
- Registration dossier
- ....

## List if/where they are available

	A	B	C	D
	Documentation	Comment	relevant for the LE (Y/N)	available
9	identification of the LE in REACH-IT	UUID for each LE for each role in case of multiple roles		
10	preregistration + preregistration number	Evidence of the preregistration (submission report, preregistration number) needs to be available at the LE. At least preregistration number needs to be available at the producing/importing plant. When the complete dossier is not available at the producing/importing site, the site needs to provide the point of contact.		
11	Registration dossier + registration number	Evidence of the registration needs to be available at the LE. At least registration number needs to be available at the producing/importing plant. When the complete dossier is not available at the producing/importing site, the site needs to provide the point of contact. For substances that you don't have to register because the conditions of 'already registered substances' are met (eg. reimport (art. 2.7c), monomers in polymers (art. 6.3), recycled substances (art. 2.7d), the registration number needs to be available at the registering site.		
12	Authorisation dossier + authorisation number	The authorisation dossier needs to be available at the LE. At least authorisation number needs to be available at the producing/importing plant. When the complete dossier is not available at the producing/importing site, the site needs to provide the point of contact.		
13	Notification dossier (art. 7)	The notification dossier needs to be available at the LE. At least notification number needs to be available at the producing/importing plant. When the complete dossier is not available at the producing/importing site, the site needs to provide the point of contact.		

# Recommended documents



## Documents not mentioned in the REACH regulation, but recommended

- Chemicals inventory
- Company structure, REACH roles, procedures, ...
- Justification of borderline cases ....
- Document all actions, contacts ECHA, ...

## List if/where they are available

	A Documentation	B Comment	C relevant for the LE (Y/N)	D available
8	Inventory of substances and mixtures	A good inventory contains all purchased and produced substances and mixtures detailed to the level of the substance. For each substance, as such, as a monomer in polymer, in a mixture or in an article, indicate the tonnage per year as well as the origin (own productions, purchase from EU supplier, purchase from non EU supplier...). For each substance indicate in the inventory also the classification (min. CMR, environmental toxicity) The inventory needs to be updated on a regular basis. Keep in mind that late preregistration needs to be done within 6 months of start of production or import >1 t.		

# General remarks for the documentation

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- **keep history records of living documents on crucial dates (eg REACH deadlines)**
- **keep information for 10 years after last production/import (art 36)**
- **"available" means that the documentation can be shown in hard copy or electronic version at the time of the assessment.**
  - the documents don't have to be stand alone documents, but can be part of an electronic system
  - Evidence relating to operations taking place at the production site should be immediately available on site.
  - For the more administrative regulatory aspects, often centrally organised, the evidence should be provided within reasonable time, to be discussed with the inspection authority.



# General remarks for the documentation

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- **the documents and knowledge on the content of the dossier may be available external to the LE (e.g. headquarters, consultant).**
  - Make sure REACH contact/procedure is known
  - Announced inspections
  - Required evidence not available on the site needs to be available to the inspections within a reasonable time
- **most REACH documentation only available in English**
  - Enforcement officers supposed to understand English.
  - Many guidance documents (till first quarter 2010), industry manuals and software are only available in English.
  - English is the preferred communication language of ECHA.

# conclusion

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- **REACH compliance**
  - Document all actions & decisions
  - Check compliance regularly
  - Make sure REACH contact/procedure is known within the company
  - Be cooperative towards the different enforcement officers
- **REACH enforcement**
  - Harmonisation necessary
  - Create level playing field



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



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