

Enforcement of the REACH and CLP Regulations in EU Member States

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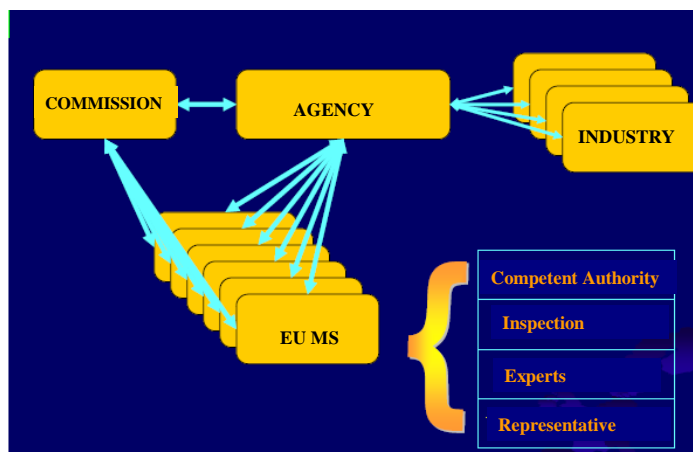


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REACH Organisation



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Registration & Testing Costs

REACH Regulation (1907/2006)

Type of REACH obligation	Annual Quantity	Number of substances	Registration Costs**	Estimated testing costs***
Evaluation (level 2)	≥ 1000 t (& SVHC)	15,000	€24,000-31,000	€ 200,000
Evaluation (level 1)	≥ 100 t	4,500	€ 8,600 - 11,000	€ 160,000
Registration (CSR)*	≥ 10 t	6,000	€ 3,000 - 4,000	€ 40,000
Registration (base set)	≥ 1 t	26,000	€ 1,200 - 1,600	€ 12,000
Out of REACH	≥ 100 kg & < 1 t	???	Not applicable	Not applicable
Out of REACH	≥ 10 kg & < 100 kg	???	Not applicable	Not applicable

* Excluding Chemical Safety Report

** Depending on size of the company and consortium Participation. Costs are per registrant!

*** Average costs



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Base Set (REACH ANNEX VII) > 1 tonne/year

- ✓ chemical identity
- ✓ production information
- ✓ physical chemical properties information
- ✓ skin & eye irritation studies
- ✓ *in vitro* mutagenicity study
- ✓ acute oral toxicity study
- ✓ acute ecotoxicological (Daphnia) studies
- ✓ degradation studies



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Conditions for Enforcement

- Effective implementation of environmental and chemicals legislation can be guaranteed only if its requirements (permits, notification, proper labelling...) are enforced in an appropriate and effective way.
- This is facilitated if the legislation is clear and the responsibilities of industry and government are specified.
- There are various European networks in which national authorities are working together to reach harmonized working methods in the enforcement of environmental and chemicals legislation.



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European Enforcement Networks

Environmental Legislation: IMPEL
Implementation and Enforcement of Environmental Law network

Chemicals Legislation: CLEEN
Chemicals Legislation European Enforcement Network



ECHA FORUM

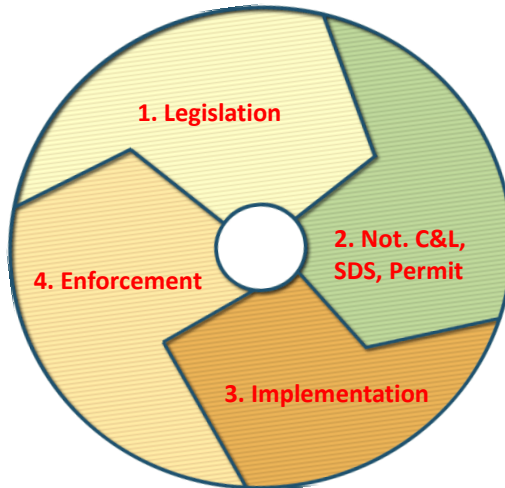


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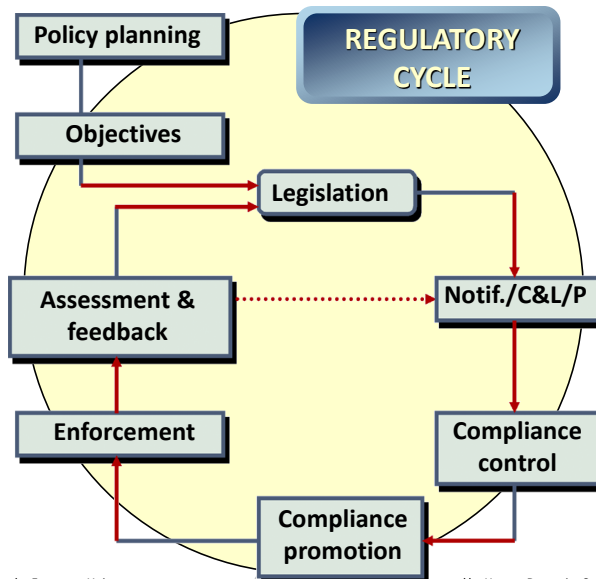
Enforcement: Regulatory Cycle



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Lessons learned

Past initiative Chemicals Legislation - CLEEN

NONS (*Notification of New Substances*), 1995 – 1996

- Scope: Notification of New Substances Dir. 67/548/EEC and 92/32/EEC
- Focus: Dyestuffs

SENSE (*Solid Enforcement of Substances in Europe*), 1996 - 1997

- Scope: Notification of New Substances, C&L and MSDS of Substances Dir. 67/548/EEC and 92/32/EEC
- Focus: Photochemicals, paints, intermediates, dyestuffs, paper industry chemicals

EUREX (*European Enforcement Project on Existing Chemicals*), 1997 – 1999

- Scope: Existing Substances Regulation Reg. (EEC) 793/93
- Focus: Art. 3 and 4 (data submission)

ECLIPS (*European Classification and Labelling Inspections of Preparations, including Safety Data Sheets*), 2002-2003

- Scope: European legislation on classification and labelling of chemical products and on Safety Data Sheets.



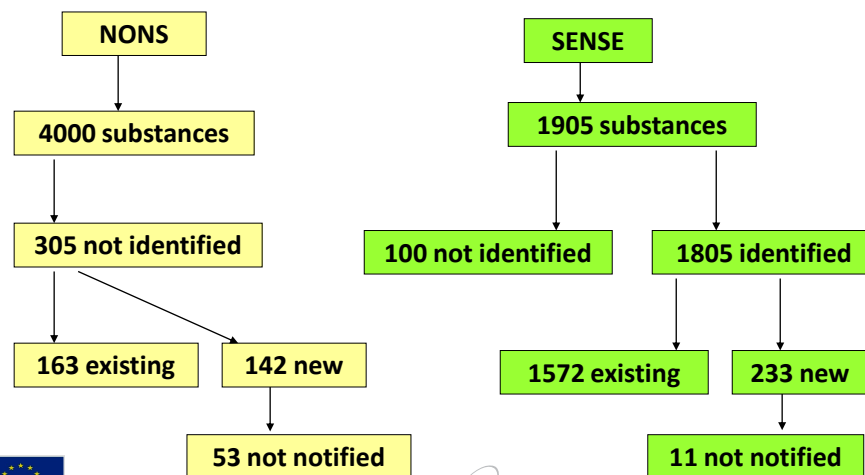
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Lessons learned

Past initiative Chemicals Legislation - Notification



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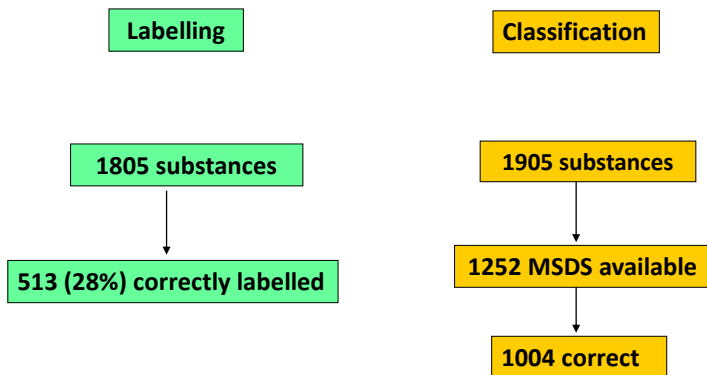


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Lessons learned

Past initiative Chemicals Legislation – C&L and MSDS

SENSE Project



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What should we expect from REACH?

REACH Enforcement Network (Title X)

- Enforcement of REACH will have to be harmonized. This process will be covered by the establishment of the Forum (art.86).
 - ✓ This Forum is established by the Agency (Finland)
 - ✓ Each Member State shall appoint one member to the Forum
- This Forum will be responsible for exchanging experience on enforcement to reach a harmonization in the European enforcement of the REACH regulation



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What should we expect from REACH?

Enforcement (Title XIII & XIV)

- Competent Authorities of Member States are responsible for REACH enforcement (art. 121 and 125) :
 - ✓ Different inspections (labour, environment, health) will have to work together to avoid duplication
 - ✓ Penalties for non-compliance will have to be notified to the Commission before December 2008
- Member States have to report their enforcement activities to the European Commission (art. 127):
 - ✓ every 5 years this report will have to be submitted to the Commission (art.117)
 - ✓ first report to be submitted by June 2010



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What should we expect from REACH?

Dutch Example (1)

- Various inspectorates have been trained in REACH.
- Env. Insp. is co-ordinating enforcement
- Water, Goods, Health & Labour Insp. will have to share expertise to avoid duplication of inspections
- Penalties are published in Dutch Parliament
- Infringements will be punished according to Law for Economic Offences
- Penalties will be “light” or “heavy” depending on the infringement



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What should we expect with REACH?

Dutch Example (2) - Quiz

Infringements and the related penalties in The Netherlands:

- Art. 5: “No data no market” HEAVY
- Art. 7-2: Obligation to notify the Agency for the production or importing of articles. LIGHT
- Art. 22-1: Obligation to update the registration. LIGHT
- Art. 31-1: Obligation to provide Safety Data Sheet to the recipient of the substance or preparation. HEAVY



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Inspection – An impression of the field work



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CHECKLIST FOR THE INSPECTIONS 1

Former Chemicals legislation

Preparation of the inspection

- selection of involved authorities and training of involved inspectors
- involve other relevant organisations
- selection of companies to be visited
- ask notification unit for detailed information about the selected companies
- announcement of visit

Inspection of the company

Follow up of the inspection



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CHECKLIST FOR THE INSPECTIONS 2

Former Chemicals legislation

Preparation of the inspection

Inspection of the company

- collecting information about organization and documentation (system)
- selection of substances (selection criteria)
- selection of substances which are placed on the EU market
- determine chemical identity of each of the selected substances
- is the substance listed in EINECS
- if not listed in EINECS: has the substance been notified by the firm?
- if notified: check the allowed quantities for notified substances (compliance?)
- h, i, j, k, l, m, n, o will follow next sheet



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Follow up of the inspection

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CHECKLIST FOR THE INSPECTIONS 3

Former Chemicals legislation

Preparation of the inspection

Inspection of the company

a,b,c,d,e,f,g in previous sheet

- h. if not listed in EINECS and not notified: check market quantities for new substances which were marketed in the EEA
- i. are any exemptions applicable, eg. R&D
- j. check if exempted substance is toxic, carcinogenic or mutagenic
- k. are "Annex 1" substances traded
- l. is the labelling of Annex 1 substances correct
- m. check Material Safety Data Sheets (MSDS)
- n. sampling of substances
- o. finishing of the visit



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Follow up of the inspection

public sector consulting

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CHECKLIST FOR THE INSPECTIONS 4

Former Chemicals legislation

Preparation of the inspection

Inspection of the company

Follow up of the inspection

- a. ask the company for additional information
- b. check additional information
- c. check analysis, does it comply with the given chemical structure
- d. evt: take sanctions/actions
- e. report the conclusion



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human
dynamics
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Time needed per company inspection 1

Selection of company and preparation of inspection: 4 days
 Inspection: 1 day
 Follow-up actions: 4 days

Differences due to:
 ✓ in-depth or fast check
 ✓ administered time
 ✓ facilities (eg. EINECS on CD Rom)
 ✓ quality of company records



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Time needed per company inspection 2

Country	Time needed per inspection
Belgium, Denmark, Finland, Netherlands, Sweden	Less than 3 days
Germany, Greece, Italy, Norway, United Kingdom	3 - 9 days
Austria, France, Ireland, Portugal, Spain	More than 9 days



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Competent authorities (CA) and enforcement authorities (EA) chemicals legislation

Country	CA	EA
Austria	MoE	Nine Fed. States
Denmark	MoE	Chemicals Inspectorate
Sweden	MoE Nat.Ch. Insp	Nat. Chem. Insp
Spain	MoH	Health. Dep. 17 comm
Italy	MoH	MoH
Netherlands	MoE/MoS/MoH	Env./Lab/ Cons. Goods Insp
United Kingdom	HSE	HSE Insp



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CHECKLIST FOR THE INSPECTIONS – REACH (1) - Manufacturer

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Preparation of the inspection

- selection of involved authorities and training of involved inspectors
- involve other relevant organisations
- selection of companies to be visited
- exchange information from various inspectorates
- ask Agency for detailed information (including chemical safety reports; CSR) of the selected companies
- announcement of visit

Inspection of the company

Follow up of the inspection



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CHECKLIST FOR THE INSPECTIONS –

REACH (3)

Preparation of the inspection

Inspection of the company:

- a. collect information about organisation and documentation (system)
- b. selection of substances (selection criteria)
- c. selection of substances which are placed on the EU market
- d. **selection of tonnage band of each substance (>1t/y, >100 t/y, etc.)**
- e. determine chemical identity of each of the selected substances
- f. **is the substance registered (ECHA, Helsinki, Finland)?**
- g. ~~is the substance listed in EINECS?~~
- h. ~~if not listed in EINECS: has the substance been notified by the firm?~~
- i. ~~if notified: check the allowed quantities for notified substances (compliance?)~~
- h, i, j, k, l, m, n, o will follow next sheet



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Follow up of the inspection



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CHECKLIST FOR THE INSPECTIONS –

REACH (4)

Preparation of the inspection

Inspection of the company (a,b,c,d,e,f,g in previous sheet)

- ~~h. if not listed in EINECS and substance and/or use are not registered: check if there are any exemptions applicable, eg. R&D~~
- i. check if there is Restriction or Authorisation for use if substance is toxic, carcinogenic or mutagenic, PBT, vPvB or of equivalent concern
- j. (producers/importers only) is the Chemical Safety Report (CSR) available?
- k. is the labelling according the information in the CSR?
- l. compare information Extended Safety Data Sheets (ESDS) on intended use, risk reduction measurements to CSR information
- m. sampling of substances
- n. finishing of the visit



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Follow up of the inspection



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CHECKLIST FOR THE INSPECTIONS – REACH (5)

Preparation of the inspection



Inspection of the company



Follow up of the inspection

- a. ask the company for additional information
- b. check additional information
- c. check analysis, does it comply with the given chemical structure
- d. evt: take sanctions/actions
- e. report the conclusion



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Differences between inspection under current/former chemicals legislation and inspection under REACH

Emphasis on registration information:

- ✓ EINECS / ELINCS information will fade out
- ✓ registration of substance and intended uses
- ✓ Authorisation necessary if Substances of Very High Concern (SVHC) are used

Differences between MS will have to fade out over time due to information exchange in Forum between enforcement experts of various MS



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Results of the Forum coordinated REACH enforcement project on registration, pre-registraion and safety data sheets (REACH –ENFORCE -1 project) - 2010

Factual background

- ✓ 25 Member States of the EEA participated
- ✓ The participating inspectors inspected almost 1,600 companies.
- ✓ The inspected companies in the Member States, which were **manufacturers, importers, downstream users and only representatives**, were selected on the basis of different criteria and selection methods.



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(REACH –ENFORCE -1 project) - 2010

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Results

- ✓ **Non compliance regarding the (pre-)registration** obligations was found in **8%** of the inspected companies.
- ✓ **11 % of the required SDSs was non compliant with obligation to have a SDS** and
- ✓ **20% did not comply with the obligation for the right language** and the necessary headings in the SDS.
- ✓ Only representatives were not always in compliance with Article 8* of REACH.

Note: The results on the required SDSs must be seen with caution, as the scope of the SDS checks in the project was quite limited. Previous surveys of the content of SDSs made by the Inspectorates under CLEEN (ECLIPS) projects were much more advanced and detailed. Since the REACH-EN-Force-1 project checked only the basic and formal requirements of the SDSs, its results cannot be considered as an improvement of compliance for the SDSs.

*OR obligations: sufficient background and up to date information on quantities imported



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REACH-EN-FORCE 2 Project Report (2013)

Obligation of *downstream users* - *formulators of mixtures*

Background

The project was carried out by 29 Member States¹ with the inspection phase lasting from May 2011 until March 2012. The survey addressed the conduct of companies with regard to the registration (REACH) and notification (CLP) of substances and concerning their duties of providing information down the supply chain and implementing risk reduction measures on site. Particular attention was paid to the quality and management of the downstream users' own safety data sheets (SDSs).

Inspections of 1 181 enterprises of four size categories were reported with checks on approximately 6 900 substances, 4 500 mixtures and the evaluation of 4 500 SDSs.

Although the majority of the visited companies were downstream users, more than 50% were also active in additional roles, e.g. as manufacturers, importers, only representatives.

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Results

Two thirds of the surveyed enterprises (67%) violated provisions of the chemicals legislation to various extents of concern. Non-compliance included registration and notification contraventions, failing to sufficiently provide information on hazardous chemicals downstream and deficient implementation of risk management measures.

Some findings of non-compliance have been:

- 269 enterprises acting as manufacturers, importers or only representatives were proven by inspectors to actually be required to (pre-)register substances, of which 8% failed to fulfil their legal obligations. More than 50% of this non-compliant group were non-SME companies (57%).
- 275 enterprises acting as manufacturers, importers or only representatives were proven by inspectors to actually be required to notify their substances to the classification and labelling inventory at ECHA, of which 15% failed to fulfil this legal obligation.
- 52% of the checked SDSs have shown defects in the information of various types and to various extents within the sections of the SDSs that have been investigated.



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Some Improvements in Compliance

The required SDSs have been available on site in 97% of 1 118 inspected companies signaling a somewhat improved compliance compared to the previous REF-1 project (87%).
Such a slight improvement in compliance has also been observed for 86% of the companies with regard to the national language and formats used for the SDSs. REF-1 project (80%)



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REACH- ENFORCE- 3

Forum's third coordinated enforcement project (REF-3) focuses on checking the registration obligations of manufacturers, importers and only representatives in close cooperation **with customs authorities**.

The project is organised in two phases. The first phase finished in 2013 with the second phase just starting in February 2014. During this plenary meeting, the members discussed the draft report of the first phase, in which 28 countries participated.

Results show that inspectors checked 528 companies and 3 065 substances across European countries. 3% of the checked companies did not register any of the substances which they were supposed to register and 14% of companies were in compliant only with some registration duties. Non-compliance was found most frequently among only representatives and least frequently among manufacturers.

The final report of the first phase of REF-3 has been published in 2014.



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REACH- ENFORCE- 3

Results Phase 1

The overall conclusion of the REACH-EN-FORCE-3 project is that there is a considerable number of noncompliant companies that do not fully observe REACH registration obligations.

It has been confirmed that **importing companies** need more attention as they are less compliant than manufacturers.

The project has identified **only representatives** as a group specifically at risk of non-compliance with their registration duties.

For this reason the Forum and Member States have decided to extend the enforcement project with further inspections in 2014.



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PwC Study on Development of Enforcement Indicators for REACH and CLP (ENFIND) 2015*

Level	Category	# of indicators proposed	Total
Member State	Discovery of non-compliance	5	16
	Official controls	2	
	Training	2	
	Duties	2	
	Enforcement actions	5	
Forum	Information and standards	4	16
	Training	4	
	Enforcement projects	4	
	IT Tools	2	
	Exchange of inspectors	1	
	Stakeholder opinion	1	
EU	Compliance	4	12
	Enforcement actions	3	
	Training	1	
	Forum	2	
	Harmonised enforcement	1	
	Overall enforcement ²	1	

*http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8280&lang=nl



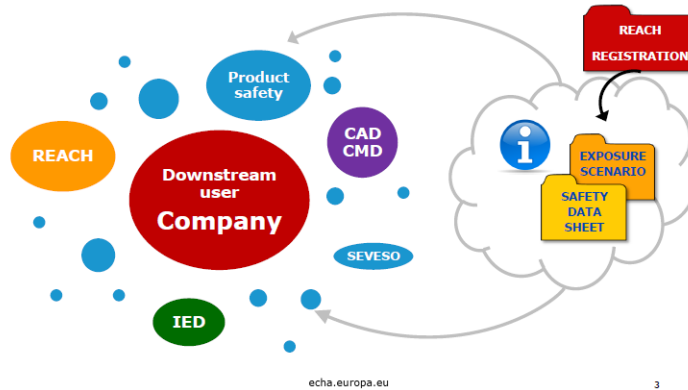
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Safe use of chemicals at industrial sites



echa.europa.eu

3

Elina Karhu: http://echa.europa.eu/view-article/-/journal_content/title/workshop-on-the-use-of-reach-clp-information-at-industrial-sites



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