

Implementing REACH

- Safer chemicals in Europe

5 September 2013
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Outline

- Introduction: REACH in brief and what it means for your business
- Information exchange in the supply chain
- New (Extended) Safety Data Sheets
- Notification duties of substances in articles
- Substances in articles - the consumer's right for information (art. 33)
- Classification Labelling Packaging - in brief
- Recommendations, Tips& Support...
- Conclusions

Introduction: REACH in brief and what it means for your business



REACH

- *Registration, Evaluation, Authorisation & Restriction of Chemicals*
- Piece of European legislation implemented in EU/EEA countries, entry into force in 2007
- to ensure a high level of protection of human health and the environment
- Promote
 - alternative methods of assessment of hazards
 - free circulation of substances on the internal market
 - substituting to less hazardous substances
 - innovation

REACH - not just a Chemical Industry issue!

- Safe handling and use, and availability of quality chemicals relevant for all –cross sectors and society
- Extending the responsibility along the supply chain
- Relevance: availability of chemicals used by your business and access to market

What's new

- Shifting the burden of proof - Industry is responsible for chemical safety
- New approach "substance life-cycle"
- New communication requirements between supply chain actors
- New concept "exposure scenario" describing conditions of safe use

Registration

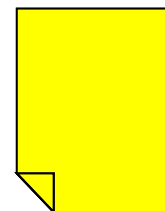
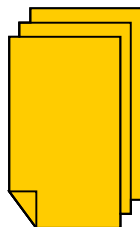
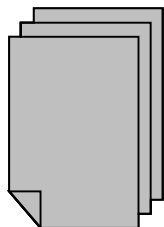
To gather information - Pre REACH lack of information on hazards and risks for majority of substances on the market

- General obligation to register substances on their own or in a mixture
- Registration of substances in articles (where release intended or foreseen)
- Registration > 1 tonne / year
- Different deadlines 2010, 2013 & 2018
- Certain exceptions apply

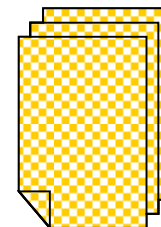
Good quality registration: *essential to ensure safe use!*



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**Registration
dossier**

**Chemical Safety Report
Exposure Scenarios**

**Safety Data
Sheet**

**Exposure
Scenarios**

***Downstream Users
to implement appropriate
risk management measures***

***Promote and support
substitution to less
hazardous substances***

**Safety advice to
customers**

Evaluation

- Dossier Evaluation by ECHA
 - Compliance Checks
 - Examination of Testing Proposals
- Substance Evaluation by Member States
 - Evaluation of the 'substance' as a whole to clarify if a possible risk exists
 - Goes beyond dossier evaluation (simple compliance)
 - Possibility to request information outside standard information requirements

Authorisation

- Authorisation process – to apply for licence to ‘use a substance for certain use’
- Intention to limit (phase out use) the use of specially hazardous substances
- Series of steps...
 - Registry of intention...
 - Identification substance as a ‘*Substance of Very High Concern*’ (SVHC) => Candidate List => *DU obligations apply*
 - Prioritisation step => Inclusion in authorisation list (Annex XIV) => *need to apply for authorisation*

Restriction

- A risk management instrument to address unacceptable risk or risks
- A special condition (restriction) or ban on the use or placing on market of a substance
- When importing articles into the EU it is also important to check list of restrictions for any restrictions that may apply

What REACH means for your business

- Legal responsibilities as (potential) registrant or as downstream user
- Continued access to chemicals
- Restrictions on access to particular chemicals (including articles)
- Access to market
- Increased knowledge on safe use

REACH so far....

- it is on track in achieving its aims
- However...
 - still lack of awareness amongst SMEs and DU and public
- Some examples of incompliance:
 - Incompliant dossiers – information requirements, inadequate CSA
 - articles containing restricted substances on market
 - not providing (compliant) safety data sheets
 - failures by companies to preregister or register
 - Intermediates not applying criteria Strictly Controlled Conditions

Information exchange in the supply chain



Communication in supply chain

- Will substance be registered i.e. available on the market
- Right to inform your supplier on different uses and existing safety precautions in place
- Report up the chain if you are/are not working in line with advice provided in new extended SDS
- Right to request information on presence of SVHC
- Responsibility to provide information on presence of SVHC

Safety Data Sheets & REACH



What's new

- extended safety data sheet
- includes exposure scenario(s)
- Exposure scenarios provide use specific information on operational conditions and RMM that ensure safe use
- Exposure scenarios are based on registrants chemical safety assessment and are forwarded in the supply chain as attachments to the safety data sheets

Extended SDSs for substances and mixtures – experience so far

- Confusion still about:
 - use descriptors
 - short titles of ESs
 - length and level of detail needed, info in ESs vs main body of the SDS
 - SDS for mixtures
 - Best way to communicate safety advice to 'end-users'

Content

- Format for SDS main body 16 headings – Annex II REACH
- Include registration number – stem in case further downstream
- The main technical function of the substance
- Threshold values of the exposure levels
- Physicochemical data
- One or more exposure scenarios containing practical advice on the conditions of safe use

What do you need to do?

- Gather information on how the substance is used by you and your customers (if not already done)
- Check to see whether your uses are covered; & assess if there is a clear mismatch between your uses
- If your uses are covered, compare the conditions of safe use, considering scaling possibilities - assess if there is a clear mismatch between your conditions of use and what is described in the exposure scenarios

What if your use or the conditions of use are not covered?

- Ask your supplier to include your uses in his chemical safety report
- Adapt your activity
- Look for another supplier who provides an exposure scenario covering your use
- Carry out your own chemical safety assessment

Obligation to inform ECHA

You have to report to ECHA when you:

- Need to prepare a downstream user chemical safety report; or
- Wish to benefit from the exemption to prepare a chemical safety report either because:
 - You use the substance in total less than 1 tonne per year; or
 - you use the substance for product and process oriented research
- **You have 6 months** to report to ECHA from the moment you receive an extended safety data sheet with a registration number

What information do you need to provide to ECHA?

- Administrative information
 - identity and that of your supplier's,
 - the substance identity
 - registration number of the substance
- Brief description of the use not covered in the exposure scenario and of the conditions of this use

If your uses are covered

- You have 12 months to implement the measures communicated to you in the extended safety data sheet
- Any changes in resulting risk management measures for mixtures you supply must be reflected in an updated SDS for these mixtures

If your uses are not covered

- You have 12 months to carry out your own chemical safety assessment and to implement the related exposure scenarios
- Any changes in resulting risk management measures for mixtures you supply must be reflected in an updated SDS for these mixtures

How to communicate downstream

- Include this information in the main body of the safety data sheet or in the form of an attached exposure scenario; or
- Forward the exposure scenarios supplied to you your customers, after you have checked their consistency with your safety data sheet

If you receive an extended safety data sheet identifying additional or more severe hazards than previously known, you have to inform your customers of this without delay!

Notification of Substances of very High Concern

*Legal obligations for
importers and producers
of articles*



Do you need to notify?

If these conditions apply...

- Candidate list substance aka SVHC is present in article you produce or import > 1 t/y, at concentration above 0.1% (weight by weight)

Companies are not obliged to notify if...

- No exposure of humans and the environment during normal foreseen terms of use
- Or substance is already registered for that use

When to notify by?

Notifications of substance (SVHC) in articles

- Should be made at latest 6 months after substance has been included in Candidate List

Note that the Candidate List is updated, normally, twice a year - in June and December

Or just ASAP in case of other reasons, change of tonnage in production, import to $> 1\text{t/y}$

What to consider when notifying...

- Does the article contain a Candidate List Substance
- How much of the Candidate list substance does the article contain, weight by weight... is it more than 0.1% w/w, >1t/y

<<*Note differing opinions on "article">>*

- What needs to be notified...
 - the type of article
 - the function
 - description of use...

How to notify?

Two possibilities, either via

- Webform, available on our website (you will need to create REACH-IT account)

Or

- IUCLID software, ver. 5.4 or later, (also freely available from IUCLID webpage)

Support:

- Data Submission Manual No 20
- Video Tutorial

Communication of substances in articles down supply chain



Communication of substances in articles

A supplier of articles has the duty to

- communicate to recipients* in the supply chain if the article contains a SVHC in a concentration over 0.1 % (Article 33 (1) REACH) within six months from the date of inclusion of that substance on the Candidate list.
- provide enough information to allow safe handling if relevant

*recipients here mean industrial or professional users and distributors, not consumers

Experience so far companies are unaware of their obligation in this regard...

Substances in articles and the consumer's right for information (art. 33.2)



Substances in articles and the consumer's right for information

- Article 33(2): if SVHC in article, provide consumer 'safe use' instructions (at a minimum the identity of SVHC)
- Consumers can request information on whether article /product contains SVHC 0.1% (w/w)
- The supplier of the article has to provide this information within 45 days, free of charge

Substances in articles and the consumer's right for information

- Experience so far actors in supply chain: DU and retailers are largely unaware of their obligation in this regard
- Companies need
 - to keep up to date with what is added to Candidate List (SVHC)
 - to coordinate in supply chain
 - to educate those dealing with customers /public
- There is existing good practice available, e.g. strategies and templates for dealing with these requests

Classification Labelling and Packaging

for communication of hazards
and safe use



Labelling according to CLP

Suppliers must label a substance or mixture contained in packaging according to CLP before placing it on the market when:

- A substance is classified as hazardous.
- A mixture contains one or more substances classified as hazardous above a certain threshold

CLP Pictograms

- A hazard pictogram is an image on a label that includes a warning symbol and specific colours intended to provide information about the damage a particular substance or mixture can cause to our health or the environment.
- CLP pictograms in line with the United Nations Globally Harmonised System.
- The new pictograms are in the shape of a red diamond with a white background, will replace the old orange square symbols which applied under the previous legislation
- the old pictograms can still be on the market until 1 June 2017

Labelling

- Products containing these labels may cause harm if not handled correctly.
- Make sure chemical users understand what the labels mean and read the instructions to ensure safe use



Awareness of labelling

- Will need to build awareness with workers and general Public... about new labels & pictograms
- Some material on ECHA website: video, quiz..



Packaging for the protection of workers & the general public

- Small packaging exemptions (Article 29 CLP)
- Child-resistant fastening and tactile warnings (Annex II to CLP)
- Outer packaging (Article 33 CLP)

Recommendations/Support etc.



Some tips/ good practices

- Know what you use – chemical inventory/ incorporate REACH&CLP into your chemical management
- Get everyone on board – this is key!!
- Establish Routine & tools
- Sign up to ECHA News Alerts
 - stay informed of developments so you can minimise risks to your business.

Pay attention on viability- future-proofing your products from the impact of REACH

Need for cooperation

- ECHA is determined to support DUs with development of necessary methods, tool and formats but.....
- Optimal supply-chain communication is really a matter for industry sectors
 - Knowledge on uses
 - Knowledge on risk management
 - Knowledge on how best to communicate
- Positive examples so far: ENES, CSR Road Map Action Plan, ESCOM Standard Phrases, Use Mapping, SPERCs etc

Support on ECHA website

ECHA is determined to support companies

- Our Website
 - Improved user interface; Users can navigate website in different languages; better search functionalities;
 - Dedicated sections for e.g Downstream Users, SMEs, registrants;
- Support Material:
 - Webinars, Fact Sheets, Guidance (translations available), Illustrative examples, FAQs, Practical Guides, IT Manuals; Submission Manuals (C&L notification, submitting DU report); video tutorials; Presentations and recordings from workshops and other 'events'; Navigator tool, information Toolkit;
- Helpdesks: ECHA – HelpNet, links to National Helpdesks

Upcoming Events:

- 19 September 2013 Webinar for Downstream users: *Navigating ECHA's website for information on chemical substances*
- 22-23 October 2013 Workshop: Content essentials on use, exposure and risks in Chemical Safety Reports (CSR/ES Roadmap action 1.1)
- 21-22 November 2013 Fifth meeting of the ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES 5)
- 21 May 2014 Ninth Stakeholders' Day

Some useful links...

- Icelandic Competent Authority for REACH and CLP (&their Helpdesk): Umhverfisstofnun (Environment Agency of Iceland)
- Chesar website (for CSRs and ES for communication)
- ENES: echa.europa.eu/enes
- Chemical Watch global risk ®ulation news: <http://chemicalwatch.com/>
- UEAPME umbrella organisations for unions of SMEs in Europe: <http://www.ueapme.com>
- List of Accredited Stakeholders (including special support for industry!!) <http://echa.europa.eu/web/guest/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations>
- DG Enterprise and Industry: http://ec.europa.eu/enterprise/sectors/chemicals/index_en.htm
- Enterprise Europe Network>Iceland Fréttir: <http://www.een.is/>
- The European Agency for Safety and Health at Work (EU-OSHA): <https://osha.europa.eu/en>
- EU funded Substitution Support portal source of information on alternative substances and technologies: <http://subsport.eu>
- Guidance for Suppliers of Articles: http://www.kemi.se/Documents/Forfattningar/Reach/Guidance_for_suppliers_of_articles_EN.pdf

Conclusions



Conclusions

- REACH matters! Is relevant for your business
- Supply-chain communication and DU obligations are key to the success of REACH
- Need for cooperation on implementation methods and tools at EU and national sector level
- Avail of available support, best practices etc.

Thank you! / Þakka þér fyrir!

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