

REACH implementation issues

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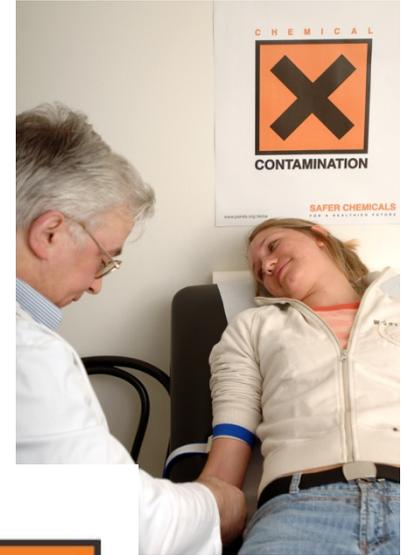
Outline

- REACH guidance – what's that?
- Overview REACH Implementation Projects (RIPs)
- Chemical safety assessment – a key concept
- REACH – framework and process
- Conclusions





A toxic Europe?
No thank you!



DETOX

C A M P A I G N



For a strong REACH





Some general remarks on REACH

- addresses manufacture and use of industrial chemicals
- integrates parts of existing EU laws
- aims to better protect human health and environment and enhance innovation
- has implications for business outside Europe

- REACH is a compromise/has been compromised
- REACH is work “in progress”: clear legal framework but flexibility for evolving knowledge





REACH Implementation Projects

- writing REACH guidance – for industry and authorities (since 2004)
- Lead: European Commission
- Stakeholder groups: Member States, industry, trade unions and NGOs
- At REACH Commission Working Group/Competent authorities meeting: endorse/send back for update
- Not legally binding but become soft law

- Info on Agency website: http://echa.europa.eu/reach_en.html





Overview completed RIPs

Guidance documents finalised (or nearly) on:

- *registration*
- *data sharing*
- *fulfilling the requirements for articles*
- *Identification and Naming of Substances in REACH*
- *evaluation*
- *preparation of dossiers for hazardous substances for further action*





Overview running RIPs

Guidance documents still being finalised on

- *preparing the Chemical Safety Assessment (CSA)*
- *information requirements*
- *Downstream User requirements*
- *preparing an Authorisation Application*
- *Carrying out a Socio-Economic Analysis*
- *Identification of substances in authorisation and guidance on priority setting for evaluation*
- *Link to Classification and Labelling under GHS*



NAVIGATOR

What are my obligations under REACH?

Obtain a list of your obligations by answering questions about the chemicals you handle !

[Enter the Navigator](#)



DOCUMENTS

- [Technical Guidance Documents](#)
- [REACH Legislation \(legal text\)](#)
- [Formats](#)
- [Other Documents](#)



What can you find on this website?

This website assists industry and authorities to understand their obligations under REACH and provides guidance on how to fulfil them. It contains 5 main elements:

- **About REACH**
gives an overview of the processes foreseen by REACH, its scope and the main obligations of the actors involved in REACH
- **Navigator**
is an IT-tool to help industry determine its obligations under REACH
- **Guidance documents**
provides the Guidance Documents on REACH processes and methods, to be used by industry and authorities.
- **Formats**
contains the key templates that industry and authorities can use in the context of REACH (e.g. format for Chemical Safety Report, format for Substance Evaluation Report, formats for Annex XV dossiers)
- **Legislation**
contains different legislative texts related to EU chemicals policy, in particular the **REACH Regulation** in all official languages of the EU

Some parts of this website are still under construction, especially "Guidance Documents", and will be regularly updated with new documents as soon as they become available.

Parts of this website are accessible in all languages of the European Community. For the parts which are not translated, the default language used is English.

If you need an overview of REACH, we recommend that you start with "[about REACH](#)".



RIP 3.2.2

Example for guidance for companies:

Performing Chemical safety assessment (CSA) and documentation in chemical safety report (CSR)





Chemical safety assessment (CSA)

Chemicals > 10 tpy, burden of proof on companies

Annex 1: CSA for manufacture and all identified uses for all stages of lifecycle :

- a) Human health hazard assessment (DNEL)
- b) Physicochemical assessment (C&L)
- c) Environmental assessment (PNEC)
- d) PBT and vPvB assessment

- e) If classified as dangerous or PBT/vPvB: exposure assessment needed for all uses
- f) Risk characterisation (measures for adequate control)





Information in supply chain crucial

Downstream:

Chemical manufacturer recommends risk management measures and relevant exposure scenarios in safety data sheets (including operational conditions and risk management measures)

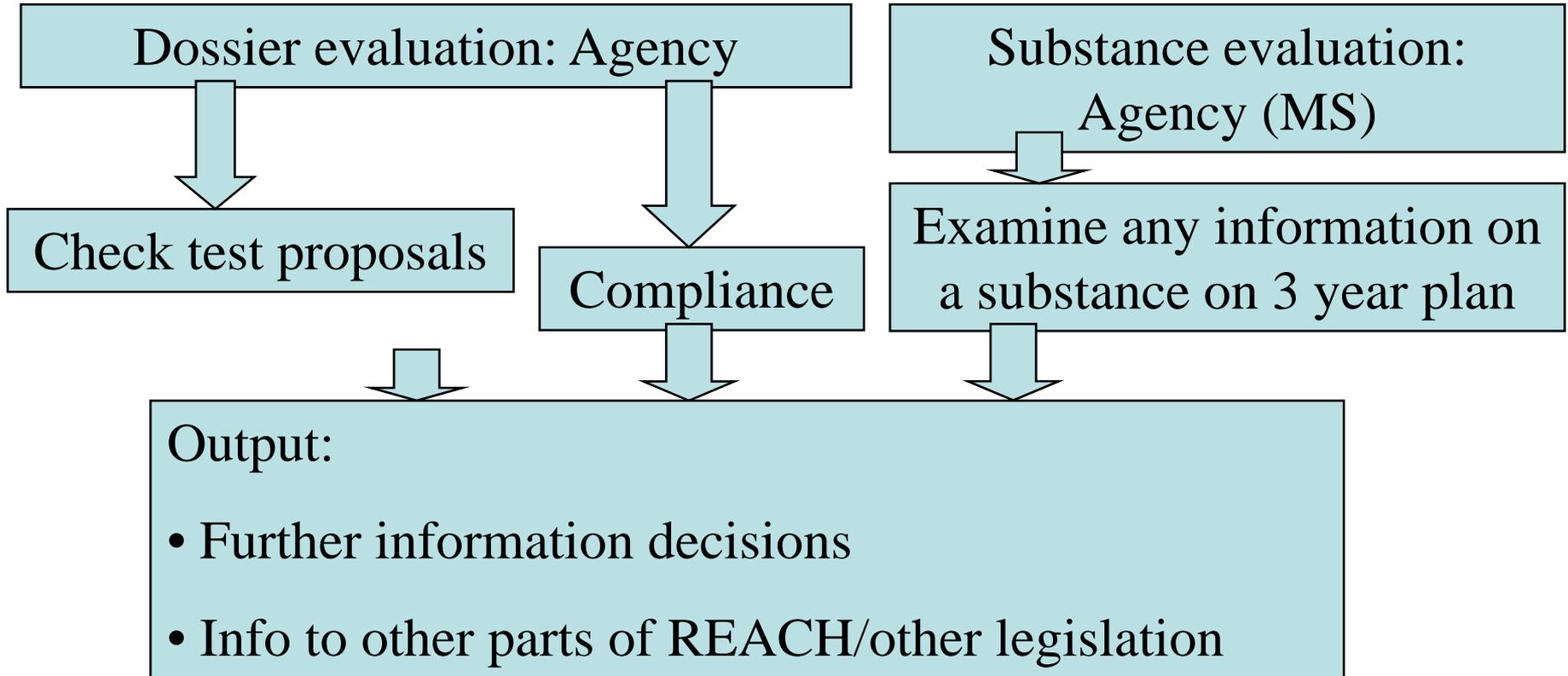
Upstream:

Chemical users communicate their uses and new hazard information (can also decide to keep use confidential and make own CSA)





Oversight by Agency and Member States





RIP 3.2.2 develops detailed guidance for e.g...

- What are the concrete steps of hazard assessment?
- How should exposure scenarios be developed?
- What use descriptors should be used?
- What provides adequate justification for waiving and how does it need to be documented?

some issues left open in the political debate continue to be controversial in the RIPs





RIP 3.7

Preparation of an application for Authorisation

Guidance documents on all tasks:

- **process description**
- **application content including joint + multiple applications**
- **analysis of alternatives**
- **substitution plan**
- **3rd party information on alternatives**





RIP 4.3/4.5

Guidance document on Inclusion of Substances into authorisation and on priority setting for evaluation

Priority setting methodology for

- Testing proposal evaluation,
- Compliance check of registrations, and
- Prioritisation for inclusion in Annex XIV





WWF and RIP participation

Technical input and Watch dog function

e.g. in RIP 3.2.2:

...for PBT and non -threshold chemicals REACH does not foresee a risk assessment approach, aim is exposure reduction and replacement

...consumer exposure (including indirect exposure) needs to be adressed properly

...waiving is an exception, not the rule and requires solid documentation





Future REACH reviews (selection)

- June 2008: revision of list of exemptions and methodologies for thresholds for C and M substances
- Dec 2008: Specify waiving criteria and review PBT criteria
- 2012: general scope and info obligations for <10tpy chemicals
- 2013: review if substitution route should apply to EDCs
- 2014: review to extend CSA to CMR chemicals < 10 tpy





How does REACH address evolving knowledge?

- Aim of REACH: promotion of alternative methods for assessment of hazards of substances
- Update of test annexes (regular review of Test Methods Regulation)
- great flexibility on QSAR, grouping and read across
- Industry has to update dossiers when new info available
- For authorisations: substances of “equivalent concern” on a case by case basis
- Many possibilities for input by “3rd parties”





Conclusions

- REACH is setting the path towards safe chemicals management
- Still loopholes and uncertainties but many good concepts to get moving
- Manufacturers have to prove safe use, not only give hazard data
- supply chain info crucial: information available in SDS
- Companies importing into Europe have to abide by the REACH rules





What's next in California?

