Experiences with CSR and (e)SDS, impact on SMEs, how to deal in practice with the REACH and OSH regimes, future needs and who may be acting on these

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Agenda

- Experiences with CSR and extended SDS: main challenges

- REACH & OSH:
  - introduction
  - how to deal in practice: some thoughts

- Further needs and conclusions

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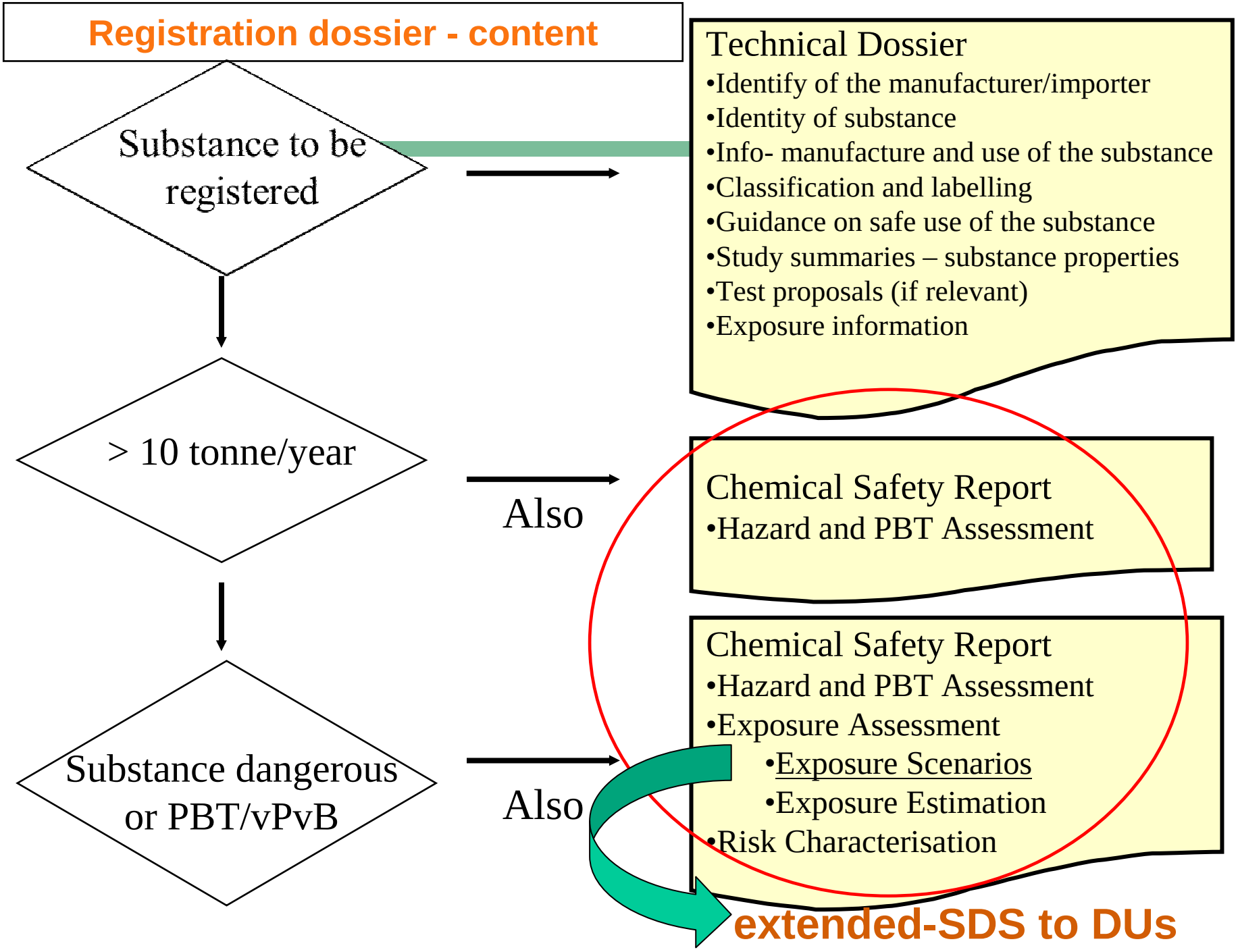
Links between REACH and other legislation

Registration dossier - content



Main challenges for M/I

- Developing a **realistic CSA/CSR**

- Obtain **information from the supply chain** on OCs & RMMs in place

- **Handle use information** from the supply chain

- Keeping **consistency among registrants:** joint/individual CSR

- **Extracting relevant information from CSR** to create the ES that will be attached to the SDS to form the ext-SDS

- **ES Format and content appropriate** for each level of the supply chain

Main challenges for DUs

- **Understand the content** of the ext-SDS
- **Diverging format** (too few standard phrases) and content (from different suppliers)
- **Many ES**: difficult to find those relevant to your uses
- Unclear which **ES parameters** (OC/RMM) are 'binding' *vs* those that are informative
- **Management of deadlines** for ES compliance: 12 months to implement per substance/per supplier upon receipt of the extended SDS incl. registration number and ES
- **Compliance when use is not covered** (decision-making among different options)
- Potential **confusion between numerical values** on SDS: DNEL and OEL

→ ***Resources/expertise required***

Impact on SMEs

Previous challenges likely to be more acute for SMEs

- Outsourcing expertise
- Changes in management systems and procedures
- Shifting resources
- Potentially inhibitive costs
- Negative impact on the SME's portfolio (particularly if they do not market many products)
- Increasing administrative burden (document all actions e.g review of ES or communication with supplier; notify DU CSR to ECHA..)

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REACH & OSH: introduction

- Chemical legislation has clearly evolved: from initiatives on plant level to protect workers, to local communities and the environment and protection of consumers against exposure from chemicals in products.
- REACH is now in place and has delivered results for the first group of phase-in substances: one of the old discussions is coming up again: *What is the relationship between REACH and chemical worker legislation and how to comply with both?*
- Cefic has always been in favour of smarter regulation and is willing to avoid overlaps/duplication between legislations.

REACH & OSH: introduction cont.

- Companies need to comply with both REACH (EU regulation) and, as employers, with the national legislation on Occupational Safety & Health to ensure safe use.

  → BUT, OSH is not completely uniform across the EU arising from differences in transposition of Directives into national law.

- Both legislations require implementation of Risk Management Measures where there is a risk to human health. Moreover, under the Chemical worker legislation, occupational exposure limits for controlling exposure by inhalation are also defined.

→ Is there a duplication?

→ How to comply with both in practice?

DNEL vs OEL: different values!

IOEL (OEL)	DNEL (inhalation workers)
Used in the workplace to check whether the actual exposure to a chemical by inhalation is below the defined (safe) limit.	Used by supplier in the CSA process to define appropriate RMMs and OCs to control the risk to human health, as given in the ES.
Developed by EU authorities through a process involving all relevant stakeholders and using extensive scientific output and expert judgement (SCOEL).	Supplier and substance specific. Developed in the context of REACH Registration process.
Hierarchy of control principle applies.	RMM recommended by the supplier.
Analytical measurements possible through monitoring data (mandatory in some Member States). EU Standard EN 689 defines requirements for measurement and comparison with limit values.	Not intended to be compared with on-site measurements.
Mandatory in every Member State after transposition of EU-IOEL into national law.	Part of the registration dossier and mentioned in the SDS

Complying with both legislations

- The main body of the SDS remains the central piece of information that needs to be taken into account
- When receiving an extended SDS, in all cases:
  - The use must be verified being covered by ES*
  - the consistency between the main body and the annexes has to be checked
- REACH requires the recipient to implement the given RMMs/OCs in the ES for the specified use within 12 months upon receipt of the extended SDS incl. registration number and ES.

* For more information on how to perform this verification, please consult: http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

Complying with both legislations (cont.)

- After the previous assessment, current conditions and controls need to be checked against those given for the use in the ES. Are they appropriate?

  - If not, there will be a series of OCs & RMMs to be implemented

- When looking at controlling risks to inhalation exposure in the workplace, the company will face either of two situations:

  - No IOEL/OEL is available for the substance

  - There is an IOEL/OEL available

Complying with both legislations (cont.)

No IOEL/OEL is available for this substance

•OCs/RMMs in the ES must be implemented **or** companies can opt for one of the different options foreseen in REACH (e.g. contact supplier, scaling)

Cefic proposes:

•If the company has available adequate data showing that risk is controlled, this is equivalent to a DU CSA following art. 37(4), and a notification to ECHA is necessary

Complying with both legislations (cont.)

There is an IOEL/OEL available

Cefic proposes:

•If compliance with the OEL is demonstrated, the existing OCs/RMMs related to inhalation exposure control are sufficient (no upgrade to the OCs/RMMs described in the ES).

→Reason: Company complies with a regulatory limit, so this should not be considered as a DU CSA and therefore, no notification to ECHA is needed.

•DUs should contact the supplier according to REACH article 34. Registrants may then decide to refine the chemical safety assessment and/or revise the DNEL. This may trigger updates of registration dossiers in the future

Further needs

- Dialogue in the supply chain in case of inappropriate measures

- The substance Evaluation process may be a good vehicle to identify potential need for an OEL revision. Authorities should consider the opportunity to revise the OELs for substances having significant inconsistencies between the RMMs coming out of the registrant's chemical safety assessment (using the DNEL) and the existing OELs. SCOEL can then follow up on the outcome of the Substance evaluation process.

- A potential revision of DNELs may be considered for these substances. This may trigger updates of registration dossiers in the future.

Conclusions

- ES are a novel concept for all parties: learning continues
- More and more ES coming in the supply chain (2013 registration deadline will generate another wave of information/ES to ensure safe use of chemicals)
- Special attention needs to be given to SMEs
- Practical guidance is needed both for companies and authorities: ES, DNELs vs OELs, (also PNECs) etc.
- Initiatives like today's workshop are very welcome: further dialogue is needed!

Many thanks for your attention!

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