Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Dr. Eva Lechtenberg-Auffarth
Hazardous Substances Management

Mixtures under REACH and in OSH management

3rd ENES Meeting Bruxelles 20. November 2012

In a perfect REACH world : unsafe uses of substances will be eliminated from the market

- REACH regulates the „placing on the market“ of substances
- Registrants
  - shall take responsibility for the safety of their substances
  - advise against (uses of) substances, that they assess as not safe
  - registrants have to assess the whole life cycle
  - registration makes sure, that they do
  - CSA/CSR is the means to assess safety of a substance and whether specific conditions are reqiuered

In a real REACH world: Registrants predefine the Supply Chain

Registrants create ES to be applied in the supply chain

Registrants

- **have vague information on conditions of use during the life-cycle**
  - **normally rely on generic information and models**
  - **assess, how a substance could IN PRINCIPLE be handled safely**

how can such ES be applied in the supply chain?

In a real REACH world: Registrants assess substances in a generic way

Registrants

- can only assess the pure substance or the substance in a supposedly „neutral“ mixture
- can only communicate (generic) conditions on safe use of a substance including (generic) RMM
- cannot assess „real“ mixtures
  - no information on other ingredients
  - no detailed information about typical and critical ways of use

In a real REACH world: Outcome of the CSA

Formulators have more information

Formulators design mixtures „on purpose“ and know

- (at least) about the technical performance of their mixture
- about parameters resulting from technical requirements
- typical and critical ways of application
- do not know about specific on - site conditions
- have to „apply“ ES that they receive
- have to consolidate and/or pass on information on ALL substances in mixtures (including those without ES)

Formulators are experienced with SDS

Formulators give substance information

- SDS section 2: classification of mixture, statements on risks and safety and other risks
- SDS section 3: ingredients, classification of ingredients
- SDS sections 9, 10, 11: relevant data

Formulators provide information on safe use

- SDS section 7: information on handling and use
- SDS section 8: specific control parameters and PSA and sector specific advice and control banding approaches

Formulators provide information beyond the REACH- ES

- SDS section 4,5,6: First aid, fire, accidental release
- SDS section 13,14: Disposal, transport

Formulators are the crucial REACH-interface

Formulators

- must consolidate ES and RRMs for several substanc
  - created by different models
  - based on different (unknown) background of information
  - including different level of detail and parameters
- also take into account substances without ES
- will compile REACH compliant SDS

by new and formalised approaches or

by intuitive approaches like in the past

Formulators will have formal problems with consolidating OC and RRMs for complex mixtures

	Intended for mixture	ES for Subst. A	ES for Subst. B	ES for Subst. C
Concentration of substance	A: 50% B: 20 % C: 10%	100%	<25	<20%
Time of use	< 4 h	<8h	<4h	<8h
Frequency				
amount				
temperature				
Additional LEV	no	no	no	yes
resp. protection	no	no	no	no
Gloves	perhaps	yes	yes	yes
Special Training				
Inclusion into matrix				
Indoor/outdoor				
dispersive/industrial				
RCR				

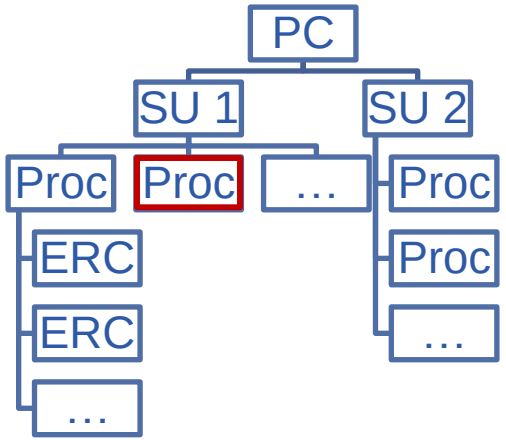
23.11.2012

Parameters are difficult to trace – also for authorities

Beitragendes Expositionsszenario	
Abgedeckte Verwendungsdeskriptoren	PROC8b: Transfer des Stoffes oder der Zubereitung (Beschickung/Entleerung) aus/in Gefäße/große Behälter in speziell für nur ein Produkt vorgesehenen Anlagen Verwendungsbereich: industriell
Verwendungsbedingungen	
Substanzkonzentration	n-Propylalkohol Gehalt: >= 0 % - <= 100 %
Physikalische Beschaffenheit	flüssig
Dampfdruck der Substanz während der Verwendung	28,2 hPa
Dauer und Häufigkeit der Anwendung	480 min 5 Tage pro Woche
Innenanwendung/Außenanwendung	Innenanwendung
	Durchführung der Aktivitäten unter Umgebungstemperatur wird angenommen.
Risikominimierungsmaßnahmen	
Bereitstellung einer Absaugung, an Stellen, an denen Emission vorhanden ist.	Effektivität: 97 %
Verwendung eines angemessenen Augenschutzes.	
Die Risikominimierungsmaßnahmen basieren auf eienr qualitativen Risikocharakterisierung.	
Expositionsabschätzung und Bezugnahme zur Quelle	
Bewertungsmethode	ECETOC TRA v2.0, Arbeiter
	Arbeiter - inhalativ, Langzeit - systemisch
Expositionsabschätzung	3,7562 mg/m³
Risikocharakterisierungsverhältnis (RCR)	0,0140
	Der Kurzzeit Expositionswert entspricht dem Langzeit Expositionswert.
Bewertungsmethode	ECETOC TRA v2.0, Arbeiter
	Arbeiter - dermal, Langzeit - systemisch
Expositionsabschätzung	6,8570 mg/kg KG/Tag
Risikocharakterisierungsverhältnis (RCR)	0,0504
Leitlinien für nachgeschaltete Anwender	
Zur Durchführung eines Abgleichs siehe: http://www.ecetoc.org/tra	

SDB

from 11/2010



baua:

Added value of ES for substances for formulators who compile SDS for mixtures

Advantage

- „Black sheep“ (like consumer uses of critical substances) are sorted out
- Formulator receives an overview on critical conditions and possible RMM

Drawback

- lot of bureaucratical effort
- R- and S-Phrases from classification also lead to similar RRM
- RRM from C&L might conflict with ES consolidation
- Control- banding approaches or branch solutions would be more easy to use and to understand

„End- users“ in the Supply Chain

End-users shall receive substances, mixtures or articles th meet the requirements of REACH

- **Consumers**
  - **use them intuitively or refer to labels and instructions for use**
  - **are not member of the supply chain**
- **Professional End-users**
  - **receive SDS with the mixture (where required)**
  - **have to apply additional precautions under OSH, environmental and product specific regulations**
  - **are member of the supply chain for on-site use of substances**

SDS for mixtures for end-users

Authorities controlling REACH compliance

- can check on formulator level whether EC for ingredients have been applied correctly
- will face the same problems like formulators

Professional end-users

- should receive „normal“ SDS for mixtures
- have to follow OSH regulation etc. (occupational risk assessment etc.)
- shall USE – NOT FOLLOW BLINDLY the SDS information

Role of ES and SDS for professional users

Professional users have especially to apply OSH – Regulation:

- take information from SDS
- combine with on-site information
- make risk assessment - OSH-authorities check risk assessment

Version: January 2010

Announcement on Hazardous Substances	Using REACH-information for health and safety at work	Announcement 409

Question 4.3:
Is it permitted to implement protection measures that deviate from the risk management measures described in the eSDS?

YES: This is possible both in the context of the Hazardous Substances Ordinance and in thecontext of REACH.

The effectiveness of such measures has to be checked and documented in connection with the risk assessment.

When protection measures for the use of a substance on its own or in a mixture deviate from the risk management measures described in the exposure scenario, obligations may arise under REACH.

However, the mere deviation from the exposure scenario in itself does not automatically entail an obligation under REACH to prepare a separate chemical safety report (see also Question 2.3).

Summary

- REACH regulates the „placing on the market“
- REACH regulates substances (over the whole life cycle)
- Registrants assess, how a substance can IN PRINCIPLE handled safely
- REACH applies without prejudice of OSH and environmental legislation
- ES for substances lose their power on their way through the supply chain
- On-site management of chemicals requires specific and comprehensive RISK ASSESSMENT and priority of specific regulation

Thank you for your attention !

Dr. Eva Lechtenberg-Auffarth
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Friedrich-Henkel-Weg 1-25
44149 Dortmund

Tel. 0231/9071-2590
Fax 0231/9071-26110
lechtenberg.eva@baua.bund.de

www.baua.de

Backup