

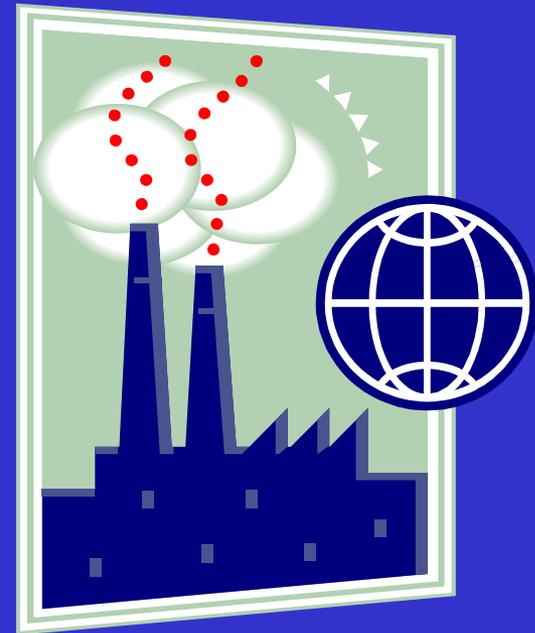
REACH and its implications for workers and worker training

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**Sean Mahar, PhD, CIH, CSP, PE
Euro Safety and Health**

REACH

- REACH
Registration,
Evaluation and
Authorisation of
Chemicals



REACH

- In October 2003, the European Commission adopted a proposal for a new EU regulatory framework for chemicals – REACH
- The REACH regulation entered into force June 1, 2007.

EU Legislation

- Directives
 - Binding, but methodology up to member state and time given to incorporate
- Regulations
 - Directly applicable law

27 EU Members

Austria

Belgium

Bulgaria

Cyprus

**Czech
Republic**

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Ireland

Italy

Latvia

Lithuania

Luxembourg

Malta

Netherlands

Poland

Portugal

Romania

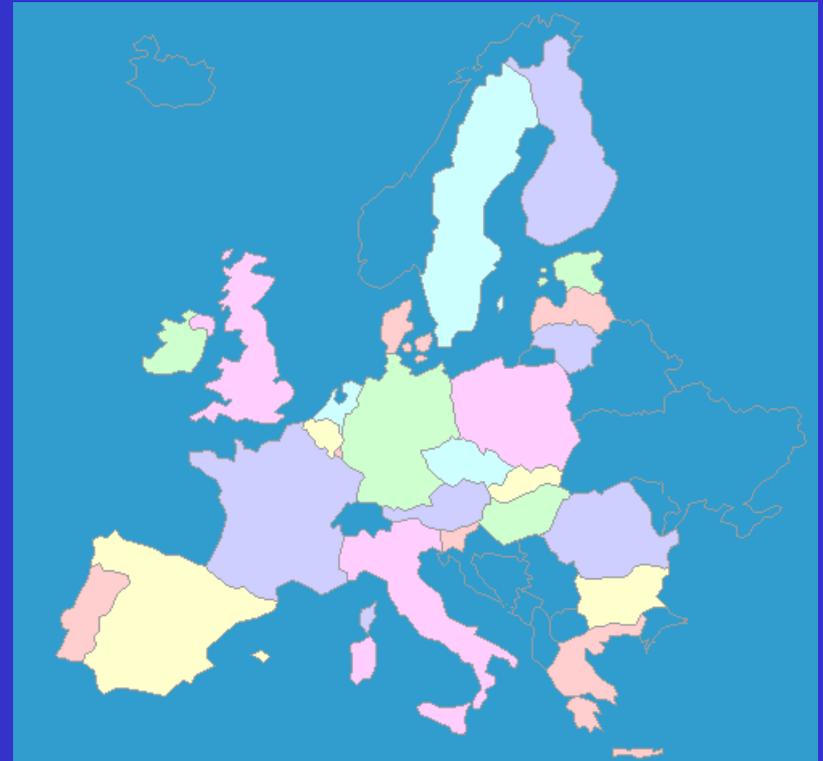
Slovakia

Slovenia

Spain

Sweden

**United
Kingdom**



REACH deadlines

- 1 June 2007: REACH entry into force
- 1 Dec. 2008: pre-registration ends
- 1 Dec. 2010: registration $> 1,000$ t/y, or
CMR 1 or 2 > 1 t/y, or
R50-53 (PBT/vPvB) > 100 t/y
- 1 June 2013: registration > 100 t/y
- 1 June 2018: registration > 1 t/y year

REACH change

- Shifts the burden of proof of safety to manufacturer/importer

No data = No market



REACH Objectives

- Protection of human health and the environment
- Maintenance and enhancement of the competitiveness of the EU chemical industry
- Prevention of fragmentation of the internal market

REACH Objectives

- Increased transparency
- Integration with international efforts
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO

Registration

- Registration of basic information
 - all existing and new substances exceeding a production volume of 1 tonne
 - submitted by companies and entered in a central database

Evaluation

- Evaluation of the registered information for all substances exceeding a production volume of 100 tonnes
 - includes development of substance tailored testing programs
 - focus on the effects of long-term exposure

Authorisation

- Authorisation of substances which are carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bio-accumulative and toxic (PBTs), very persistent, very bio-accumulative (vPvBs) and Endocrine disrupting substances on a case by case basis

Restriction

- Restriction in the use of chemicals to manage risks that have not been adequately addressed by another part of the REACH system

REACH Implications

Manufacturers/Importers

- Registration for all substances >1 tonne
- Chemical Safety Report (CSR) for all substances >10 tonne
- In the absence of available information, tests may have to be conducted
- Data sharing (in particular for vertebrate tests)
- Substance Information Exchange Fora (SIEFs)

REACH Implications

Downstream Users (Customers)

- Apply the risk management measures identified in the SDS Exposure Scenario
- Make their uses known to manufacturers/importers
- or carry out their own CSA
 - (confidentiality reasons)
- Contribute to SIEFs

Substance Information Exchange Forum (SIEF)

Mandatory forum created during pre-registration to assist the sharing and data collection of REACH compliance information and studies with other registrants of the same substance.

SIEF Members

- Potential Registrants
- Third Party Representatives
- Data Holders
- Others

Registration Dossier

Contents:

- a **technical dossier**, for substances in quantities of 1 tonne or more per year, and, in addition,
- a **chemical safety report**, for substances in quantities of 10 tonnes or more per year.

Technical Dossier

Contains information on the properties and classification of a substance as well as on uses and guidance on safe use.

The information required varies with the tonnage in which the substance is manufactured or imported.

The higher the tonnage the more information on the intrinsic properties of the chemical is required.

The Chemical Safety Report

The main goal of the chemical safety report (CSR) is to document the chemical safety assessment (CSA), including its conclusions and results.

- Required for all substances >10 tonnes

Chemical Safety Assessments

The goal is to identify and describe the conditions under which the risks are controlled.

Risks are regarded as controlled when the estimated exposure levels do not exceed the derived/predicted no effect levels (DNEL or PNEC).

Chemical Safety Assessment (CSA)

1. Human Health Hazard Assessment
2. Human Health Hazard Assessment of Physicochemical Properties
3. Environmental Hazard Assessment
4. PBT and vPvB Assessment
5. Exposure Assessment
6. Risk Characterization

DNEL

Derived no effect level

“the level of exposure above which humans should not be exposed”



PNEC

Predicted no effect concentration

“the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur”



PNEC



Spheres

- aquatic (including sediment)
- terrestrial
- atmospheric
- food-chain accumulation
- microbiological activity of sewage treatment systems

Chemical Safety Assessment (CSA)

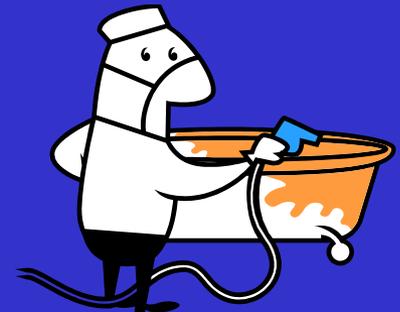
Exposure Assessment

- Generation of exposure scenario(s) or the generation of relevant use and exposure categories

Chemical Safety Assessment (CSA)

Exposure Estimation

- emission estimation
- assessment of chemical fate and pathways
- estimation of exposure levels.



Occupational Exposure Assessments

Three elements

1. emission estimation
2. assessment of chemical fate and pathways;
3. estimation of exposure levels.

Occupational Exposure Assessments

Hierarchy for estimation of exposure levels:

1. measured data, including the quantification of key exposure determinants
2. appropriate analogous/surrogate data, including the quantification of key exposure determinants
3. modeled estimates

Occupational Exposure Assessments

European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment (ECETOC TRA) Tool

Stoffenmanager

Easy-to-use workplace control scheme for hazardous substances (EMKG/ BauA-COSHH)

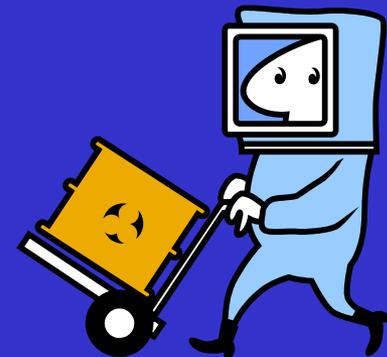
Chemical Safety Assessment (CSA)

Risk Characterization

- human exposure comparison with DNEL
- environmental exposure comparison with PNEC
- assessment of the likelihood and severity of an event from physicochemical properties

Exposure Scenarios (ES)

- a set of information describing the conditions under which the risks associated with the identified use(s) of a substance can be controlled.



Exposure Scenarios (ES)

Two facets

- Operational conditions
- Risk management measures (RMM)

Exposure Scenarios (ES)

Operational conditions

- processes involved
- activities of workers and consumers and environment
- duration and frequency of exposure



Exposure Scenarios (ES)

Risk management measures (RMM)

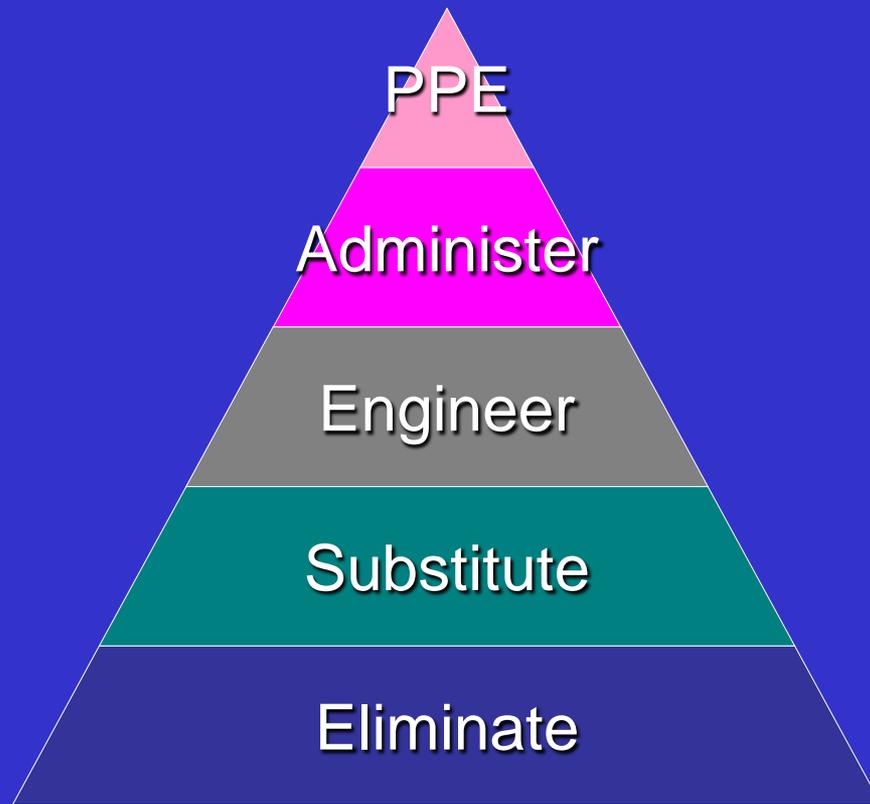
- to reduce or avoid direct and indirect exposure of humans and the environment during use and disposal

Risk Management Measures (RMM)

Purpose

- To mitigate hazards identified for occupational users, consumers and to the environment following a hierarchy of control.
- Risks should be eliminated or reduced to a minimum by **substitution**
- If not substitution isn't possible then by protection and prevention

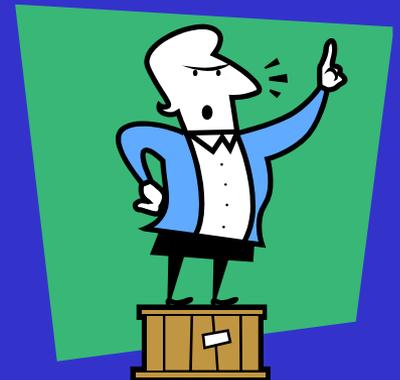
Hierarchy of Control



Extended Safety Data Sheet (SDS)

Where ESs developed as a result of conducting a CSA, they must be annexed to the SDS and passed down the supply chain.

Supplier informs his customer about the RMM recommended for safe uses of the substance.



Questions?