

Extended Safety Data Sheets

REACH
Ready



Dealing with Exposure Scenarios



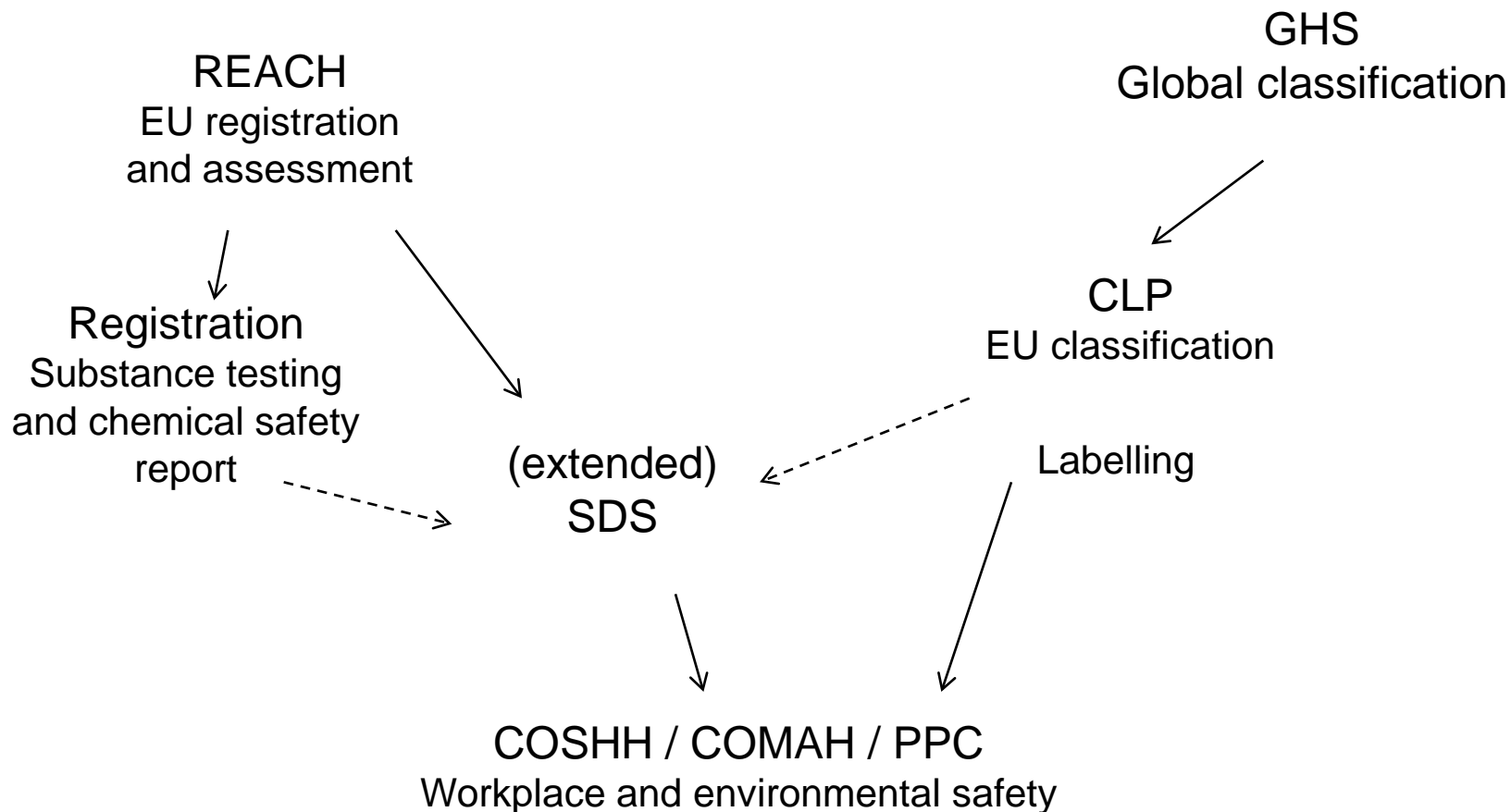
Mark Selby
REACHReady

Why we are having to do this...

- Ensure all chemicals are identified and adequately assessed to enable communication of hazards and to enable the determination of suitable risk management measures
- Ensure that suppliers of chemical products adequately communicate in a way that relates to the use of the product
- Only actively market if uses considered to have acceptable level of risk if users follow risk management advice

... Hopefully something we have been doing for years

Linking legislation



Duties of recipients of chemicals



- Consider all information provided by the supplier
 - Act on this to help protect your workers and the environment
 - Act on this to protect anyone in the vicinity of the activity (other lab workers, general public etc)
- To have confidence in the supplier's information
 - Assess quality and certainty factors of received SDS
- If passing onto third parties, responsibility is assumed
 - Need to understand incoming data / exposure scenarios
 - Supply includes samples to other sites
- Inform supplier of adverse effects

SDS must be provided for:

- Hazardous substance
- Dangerous preparation
- Substance for which there is a EU-recognised exposure limit
- No lower limit of sample size

This has effectively not changed with REACH

Described in REACH

- Exposure Scenarios needed from time when hazardous components are registered
- Obligatory for registrants to pass information down supply line
- Obligatory for recipients to pass information down supply line while hazardous components are contributing to hazard (eg > 1%)

The concepts are laudable. Detail is lacking

- Required for hazardous substances
 - Where CSR has been generated (10 tonnes per annum total)
 - Needed for uses over 1 tonne per annum
 - In practice, DUs may demand ES for all substances
- Must be relevant to real life
 - Scale of use in laboratories ?
- Individual for each supplier
 - Possible to base on generic ES prepared by industry groups or SIEF that has no real understanding of final use
- Needs to be stand-alone and readable

Many ES have failed to meet these concepts

- Determine use descriptors used for REACH
- Follow use descriptor guidance
 - (Part D or Chapter R.12 of REACH technical guidance)
- Simple coding system for description of process and use
 - Sector of Use – SU
 - Product Category – PC
 - Process Category – PROC
 - Article code – AC
 - Environmental release category – ERC

PROC 15 covers laboratory use

Quality of incoming information



- Even when registered for REACH, there is no guarantee that the information being received is correct
- Confidence in supplier information?
- REACH registration and CSR prepared collectively
- Difficult substances where data may be difficult to interpret
- Data from large firms not necessarily better

Industrial / professional / consumer?

- Modelling methods
- Standard defaults
- Site specific data?
- Scale of use?

Consider real use scenarios and remember that many of those writing ES have never been to the sites of use

It is very likely that you know more about this than a consultant

- Predicted Environmental Concentrations
- Disposal of waste water from factories
- Airborne loss (LEV?)
- Environmental exposure from use
- Loss from domestic / non-industrial sources

Exposure Scenario must consider life cycle of substance(s) until diluted to level where not hazardous

Persistent substances of concern even when diluted

- Defaults in guidance and models
- Assume certain percentage discharge (ERC / SPERC)
 - Assume 100% loss to environment for professional use
- Assume specific reduction in worker exposure with gloves and coveralls
 - Models suggest 90 or 95%
- Assume efficiency of certain engineering controls
 - Models suggest 90% for LEV
- These defaults will save time and allow comparison between products on multiple sites

Laboratory use is covered by PROC 15

- Assumed to be professional users
- Assumed to have access to risk management
 - Ventilation control, protective clothing
- Assumed to have limited environmental control
 - Bottles of waste or down drain
- Assumed no onward supply to general public

Note that it the need for an ES is based on 1 tonne supply,
so many suppliers will not include PROC 15

Risk characterisation ratio (RCR)



- Outcome of exposure scenario should be to confirm that if risk management measures (RMM) followed, exposure is estimated to be less than effect levels
- $RCR = \text{Exposure to workers or consumers vs DNEL}^*$
- $RCR = \text{Exposure to environment vs PNEC}$

If RMM cannot result in exposure to be below DNEL or PNEC, then use is unsuitable

*DNEL = Derived No Effect Level

Scaling?

Although not accepted by all as a mechanism for users to validate the risk management measures for their use, the term 'scaling' describes changing parameters to fit personal specific uses

- Tonnage
- Daily use
- Duration of exposure
- Concentration in mixtures
- Size of waste water treatment
- Size of point of discharge to surface water

Do not be baffled by jargon and size

- Science for CSR / ES is good
- Methods have been in place for over 20 years.
- Models are big spread-sheets using defaults
 - Pencil and paper with pocket calculator just as good
 - None are perfect
- Most CSR authors know less than factory safety and environmental managers about real life
- Most of the CSR is not worth reading
 - Advice from EA years ago was if over 20 pages, it is too long!

Good luck!



The purpose of the ES and the extension of the SDS is based on good principles of risk communication

Unfortunately, early examples have not necessarily lived up to the theory

Being optimistic, it will get better

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www.reachready.co.uk
enquiries@reachready.co.uk