Experiences from Registration Dossiers

- Andrew Phillips
- ECHA, Evaluation Directorate

- Workshop--interface REACH and OSH
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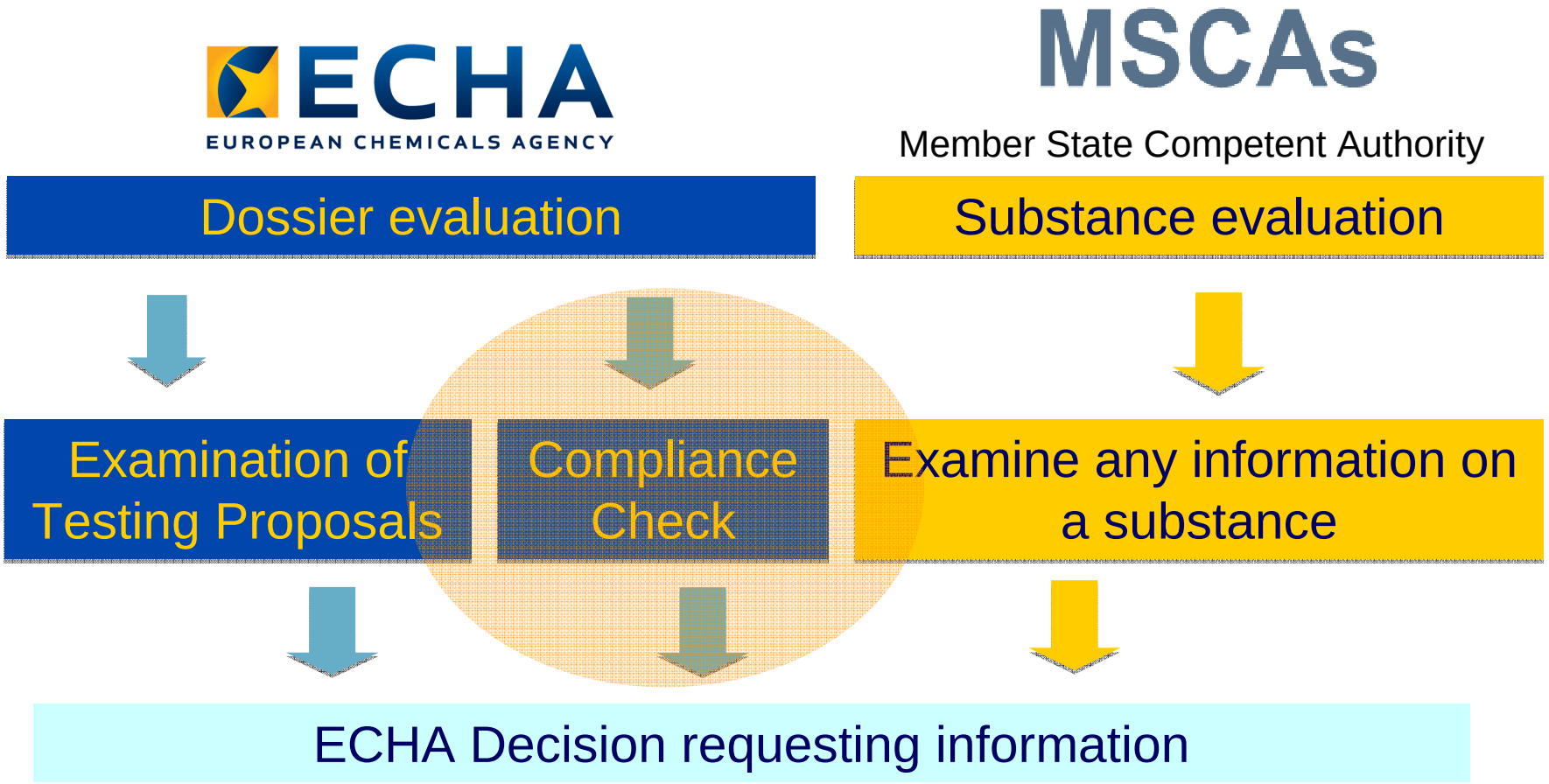
Outline

- Evaluation of phase–in dossiers
- Risk management measures
- Intermediates and strictly controlled conditions

Evaluation


ECHA
EUROPEAN CHEMICALS AGENCY
MSCAs
Member State Competent Authority
Dossier evaluation
Substance evaluation
Examination of Testing Proposals
Compliance Check
Examine any information on a substance
ECHA Decision requesting information

Experiences from phase-in dossiers

- Quality and completeness
- Missing elements
- Assessing exposure
- Addressing risk management measures

Quality and completeness

- Quality in what sense?
  - Science
  - Presentation
  - Vague description of uses don’t help – important detail missing
    - Too many unlikely uses included
    - Too few uses for a well known substance which is widely used
    - Description of processes jobs and tasks – needs to be illustrative enough
  - Developing proportionate risk management options
  - Lack of understanding on OHS issues in some dossiers
    - Key is availability of competent OHS expertise during dossier development

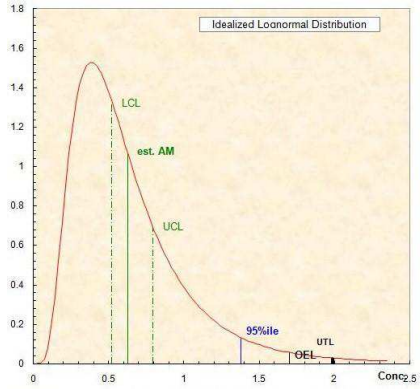
Missing elements (sometimes)

- Uses not supported – tracking what is in the dossier to downstream uses – role of joint registrants
- Recognition of all available information sources
- Routes of exposure not fully developed
- Generally no information on dermal absorption

Assessing exposure –why?

- For addressing testing needs – route, waiving
- To establish acceptability of exposure scenarios through comparison with endpoints – quantitative
- To determine risk management measures in the workplace
- To assist qualitative risk assessment – a useful metric

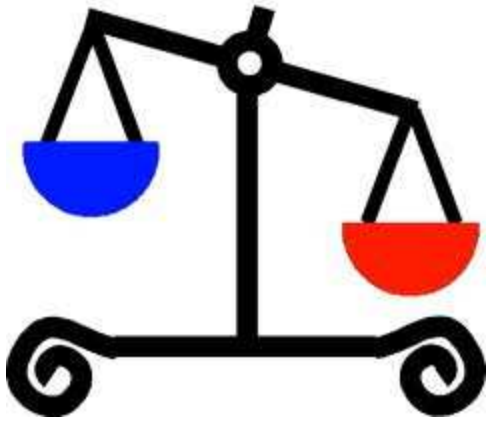
Assessing exposure



- The role of Process Categories (PROCs)
- Understanding routes of exposure
- Understanding exposure distributions
- Modelling v real data
- Understanding downstream users – insufficient knowledge
- From theory to practice - from PROCs to real life
- Hidden dangers – dealing with uncertainty

Understanding risk characterisation

- Clear on the hazard? – Let's assume so
- What about the exposure
  - Distributions
  - Real data not often seen
  - Reliance on models
  - Inappropriate use of models
  - Misunderstanding of routes of exposure
  - Issues with application of risk management measures
    - What can be achieved – the ideal
    - What may be achieved – the informed user
    - What is achieved in practice – when things start to go wrong



A question of balance?

The role of classification

- Classification allows judgement on what to be concerned about and level of concern
- Very important for non-threshold effects
- Knowledge of implications of over-exposure
- Knowing what you are protecting against
- Consequences for route of exposure and …
- Support selection of appropriate risk management measures

The role of classification

- Has been used for control banding approaches
- Making control banding relevant and protective?
- Important in qualitative risk assessment

Addressing risk management measures

Addressing risk management measures

PROC 7

Industrial spraying?

Addressing risk management measures

PROC 8

Transfer of chemicals from/to vessels

Addressing risk management measures

- Generic v specific (LEV – what does that mean)
- Impact of local conditions – REACH dossiers and SDSs are not a workplace risk assessment - but they guide required action
- Uncertainties over application of PROCs
  - what do they cover
  - what don't they cover.
  - Interpretation in the context of local conditions

Addressing risk management measures

- Substances are not used in isolation – can lead to conflicting RMM needs

Q. Why is a substance controlled to a specific level?

A. For a range of reasons

- **Known toxicity**
- **Local effects**
- **Odour**
- **Properties other than toxicological**
- **Keep the place clean**
- **Protect the product**
- **Generic controls for a range of substances handled on site**

Risk management measures in context

- Aspirational levels of control
- Real levels of control
- Generic controls for a wide range of substances
- Expectation in the workplace
- What is found in practice

RMMs need to be realistic

Risk management measures in context

- REACH Registrants have to anticipate downstream users are sufficiently compliant with OHS legislation.
- Addressing appropriate limits of exposure
- How far can manufacturers go to ensure safe use?

Intermediates

REACH defines an intermediate as a *substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance* (Article 3(15)).

The lifecycle of an isolated intermediate begins with its manufacture (in practical terms, with its removal from the manufacturing process). This lifecycle ends with the use of the substance in the synthesis process for the manufacture of another substance.

Intermediates

- Use under strictly controlled conditions
  - Rigorously contained
  - Minimise emissions
  - Properly trained
  - Special procedures during cleaning and maintenance
  - Control technologies for accidental release
  - Documented procedures

If not, a standard registration is required

Intermediates and downstream users

- For transported isolated intermediates requirement to have knowledge or assurance that downstream users synthesise another substance and strictly controlled conditions apply

- "Article 36" letter sent to seek confirmation of status through provision of information

- Follow-up investigation to seek further confirmation through National Enforcement Authorities – pilot currently running.

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Thank You.