



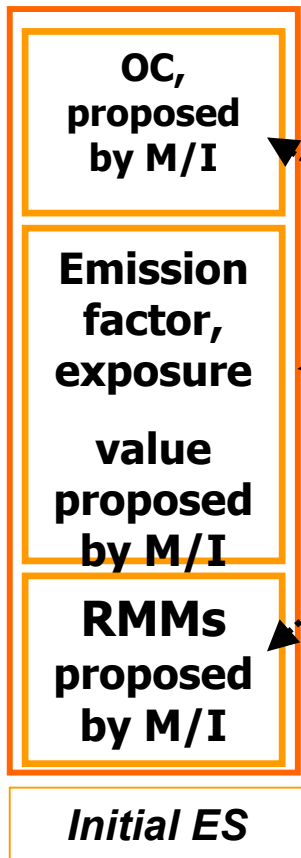
Difficult issues and problems after refinement: future risk management measures

France Capon

- Intro
- Obligations of DUs after receiving the ES
- Use of the final Exposure Scenario in the supply chain
- Updates of Exposure Scenario
- Non-compliance of DUs with SDS recommendations
- Conclusions



M/I



DU



A: default ES
implemented
by DU.

B: largely
similar RMMs
& OC

C: OC & RMMs
different, but
similar emission
factor or
exposure value

D: OC & RMM
different.
Exceedance of
values proposed
by M/I

E: OC & RMM
largely different,
ES not suitable

may
inform
M/I

inform
M/I

Refinement

Carry out
own CSA +
notification
to ECHA



M/I

Before Registration

OC, proposed by M/I

Emission factor, exposure value proposed by M/I

RMMs proposed by M/I

DU



- A:** default ES implemented by DU.
- B:** largely similar RMMs & OC
- C:** OC & RMMs different, but similar emission factor or exposure value
- D:** OC & RMM different. Exceedance of values proposed by M/I

Refinement



AGREEMENT

At Association/Consortia level

between M/I & DU:

- **Comply with conditions** described in the SDS and ES:
 - Review *Description of Use*
 - Review *Operational conditions*
 - Review *Risk Management Measures*



- ⇒ Your **use** is **covered**: no further action needed
- ⇒ Your **use differs** from the ES: more detailed compliance check
- ⇒ Your **use conditions** are **not covered** by the ES: further important actions are needed

If **discrepancies** between DU use and ES:

⇒ Contact supplier to:

⇒ identify a use: this can be done at any time after Registration

⇒ adapt ES

⇒ Change work practices

⇒ Find another supplier providing an *ad hoc* ES

⇒ Prepare CSR – to be kept in-house but ECHA should be advised

⇒ Find an alternative substance or process

No “Best solution”: decision to be taken on a case-by-case basis and following business strategy of the company



- Three important **requirements to help DUs** to achieve their obligations:

1. The **Risk Management Measures** advice should be **practically useful** for the recipient

- Recipient may be a **formulating DU**:

- Practical advice relating to the formulator's **own technical activity**
- Information relevant to formulator's choices on **product composition and design**
- Information and advice relevant to **formulator's customers** and further DUs

- Recipient may be a **end-user**:

- Practical advice relating to its **own technical activity**
- Information relevant with regard control of risk down the supply chain (**article and waste**)



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2. The **assumptions** under which supplier considered uses as safe must be **transparent**
3. Need to include advice on how the recipient of the ES can **check whether the conditions in the ES are met in practice**

Flexible communication: package of individual exposure scenarios referring to certain life cycle steps and/or certain uses (group of uses)

- When...

- **new information on the hazard** of the substance is available
- **new Uses** are identified
- **Operational Conditions** change
- **Risk Management Measures** are not anymore appropriate



At any time before, during or after Registration !

- DUs should apply, identify and recommend Risk Reduction Measures **at the latest 12 months after receiving SDS**
 - If **DUs** do not comply with their obligations they will be **liable in case of enforcement procedure**
- N.B.:** Member States are in charge of enforcement



- DUs have also important obligations
- Good communication throughout the supply chain is key all over the REACH process
- Exposure Scenarios are “leaving documents”
- There is a chain of responsibilities:
Manufacturer, Downstream Users, Distributors...

