

Exposure scenarios and chemicals safety assessment

A major communication issue for actors throughout the supply chain

- revised version based on questions during the Stakeholder Day -

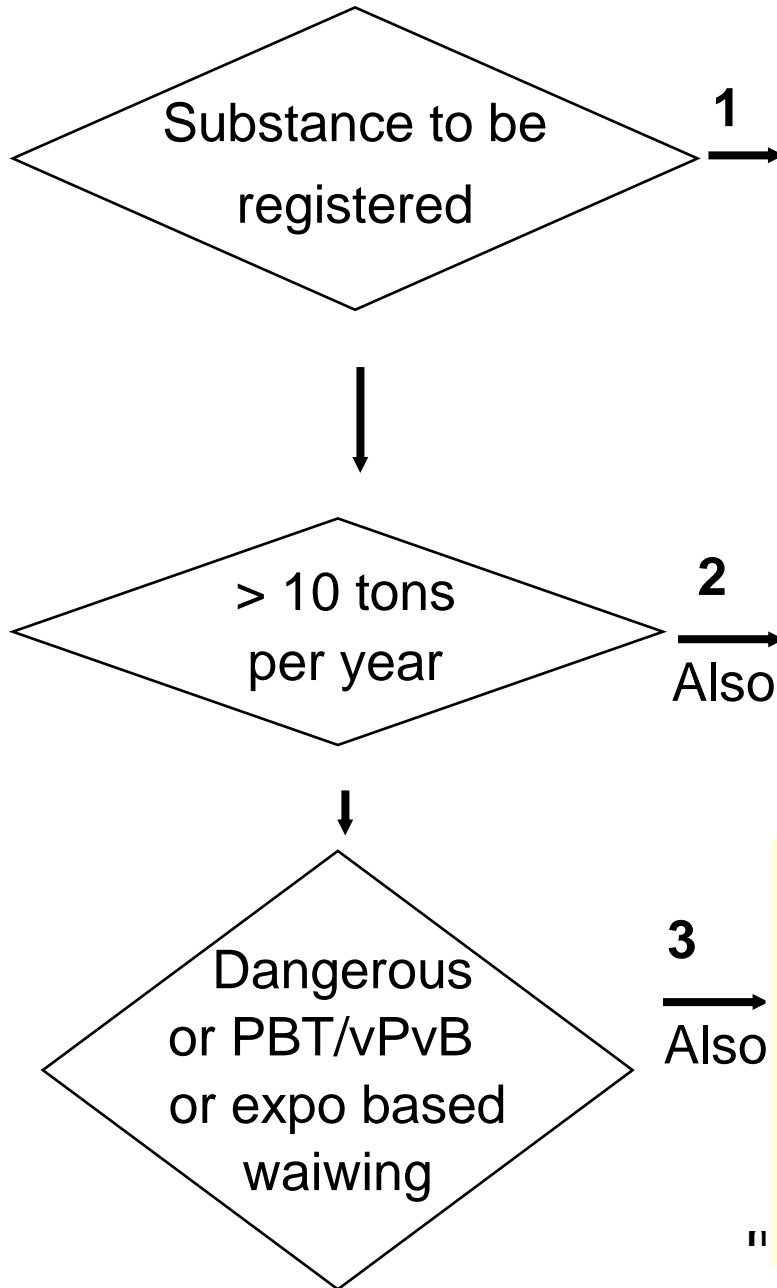
Andreas Ahrens, ECHA

ECHA's First Stakeholders' Day
10 October 2008, Helsinki

Content

- Registration and CSA Framework
- Content of exposure scenarios: How to control the conditions that determine the exposure?
- Dialogue in the supply chain and process of building exposure scenarios
- Available guidance
- Challenges

Registration



Information in Technical Dossier, i.a

- Manufacture and use of the substance
- Classification and labelling
- Guidance on safe use of the substance
- Study summaries – substance properties
- Test proposals (if relevant)
- exposure

2

Also

Chemical Safety Report

- Hazard and PBT Assessment

3

Also

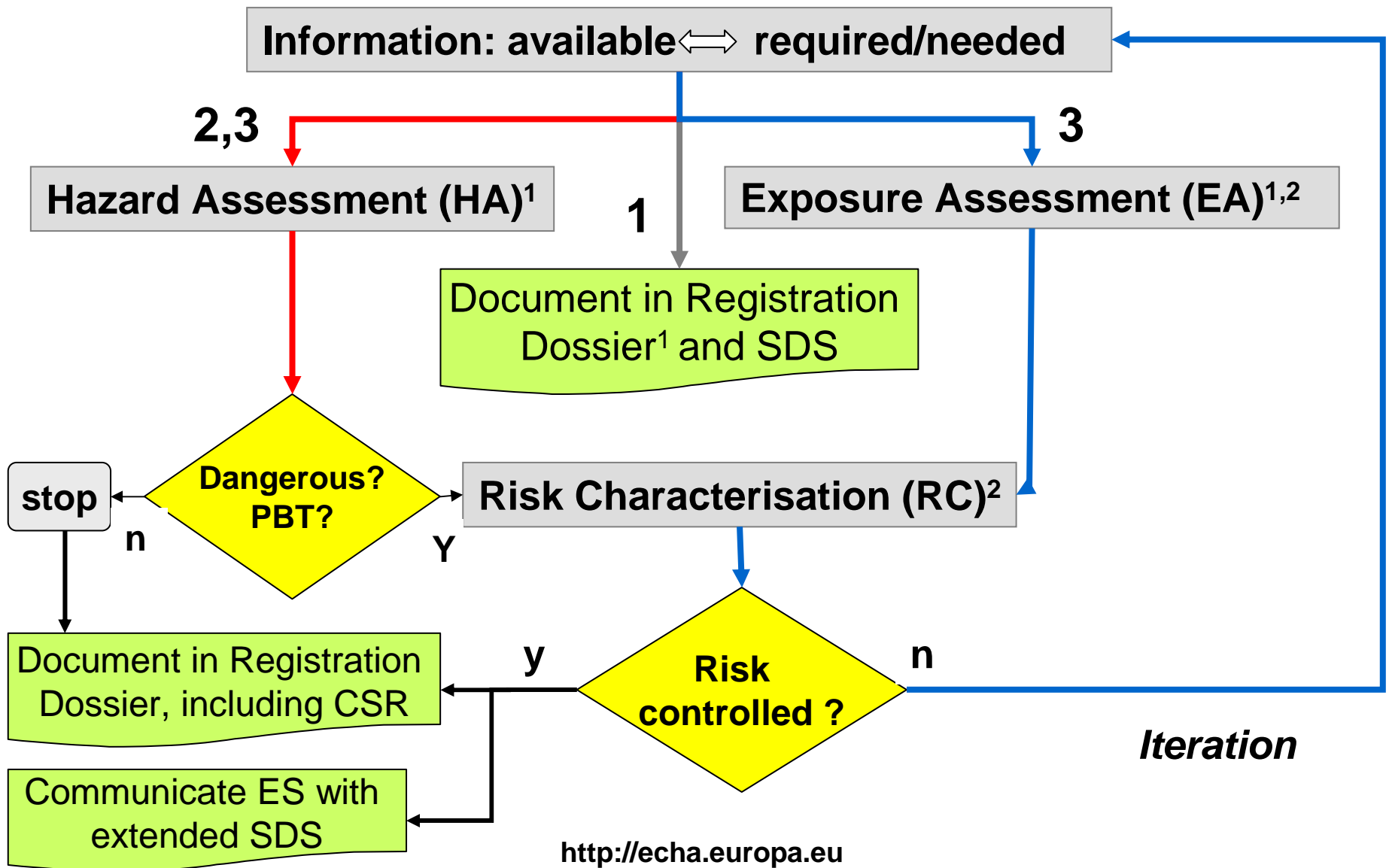
Chemical Safety Report

- Exposure Assessment
 - Exposure Scenarios
 - Exposure Estimation
- Risk Characterisation

CSA

"

CSA Framework



CSA Framework

Information: available ⇔ required/needed

- substance intrinsic properties
- manufacture, use, tonnage, exposure, risk management

Hazard Assessment (HA)

- Hazard Classification and PBT conclusion
- Dose/Concentration-Response Characterization

Exposure Assessment (EA)*

- Build Exposure Scenarios
- Estimate Exposure Level¹

¹ For PBT/vPvB: emission characterisation only

Aim of the CSA Process



- Identify the conditions ensuring control of risks arising from manufacture and use(s) of a substance.
- Prepare a set of corresponding information on operational conditions and risk management measures to be communicated to the users of the substance (for dangerous substances) = **Exposure Scenario**
- Document the assessment in a CSR for the companies' own documentation.
- Submit CSR to the authorities as part of the registration.

Content of exposure scenarios



- Description of conditions suitable to ensure control of risks related to the uses of a substance during its entire life cycle. Environment, workers and consumers to be covered. One ES can cover one or more uses.
 - Operational conditions determining the exposure (e.g. temperature during processing)
 - Practical measures suitable/needed to prevent, reduce or limit risks (e.g. wearing gloves)
- Explanation how the exposure estimate for these conditions and measures has been derived.
- Description of uses for which these conditions and measures are suitable (title and boundaries of the exposure scenarios).

Environment (examples, non-exhaustive list)

- [substance properties: e.g. degradation, volatility, solubility, partitioning]¹
- amount manufactured per year by a registrant
- amount used in a local environment (large single source)
- amount used in a region (multiple sources from wide disperse use)
- emission factor determined by process or product design
- onsite measures to reduce emissions before released into sewage system, air or waste disposal
- municipal sewage treatment; waste treatment;

Conditions determining exposure



Workers (examples, non-exhaustive list)

- [substance properties: e.g. volatility]¹
- physical state of product, e.g. particle size, viscosity
- concentration of substance in a preparation
- amount used at a workplace
- type of process carried out with the substance
- level of containment or local exhaust ventilation
- general ventilation and room volume before inhalation
- personal respiratory protection
- skin contact area and personal skin protection
- frequency and duration of exposure

¹not part of the exposure scenario itself

Conditions determining exposure

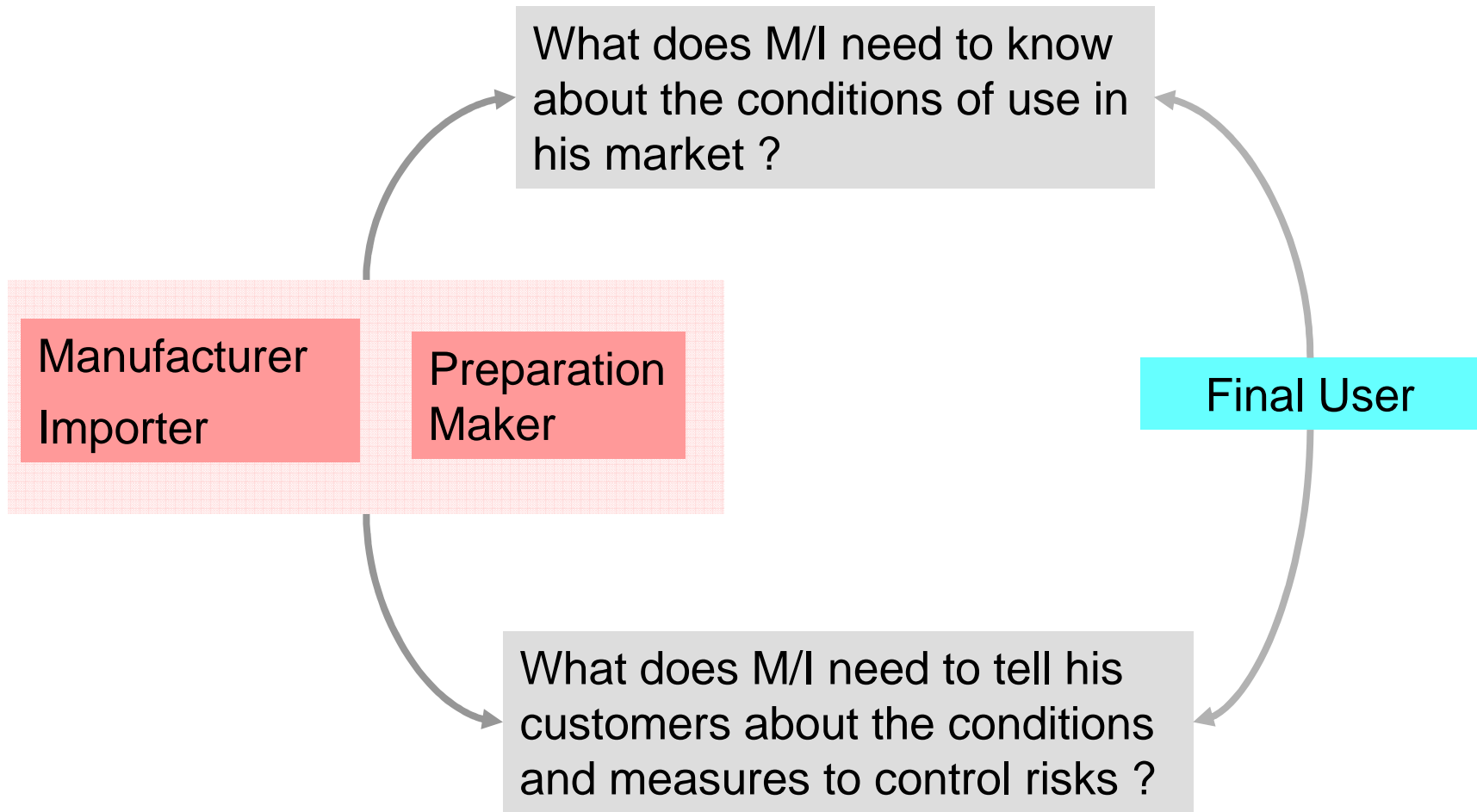


Consumers (examples, non-exhaustive list)

- [substance properties: e.g. vapour pressure, water/fat solubility]¹
- physical state of product, e.g. particle size, viscosity
- concentration of substance in a product
- amount of preparation or article used per application
- package design
- fraction of substance available for exposure
- skin contact area
- room volume before inhalation
- frequency and duration of use

¹not part of the exposure scenario itself

Communication needs



Use Descriptor System

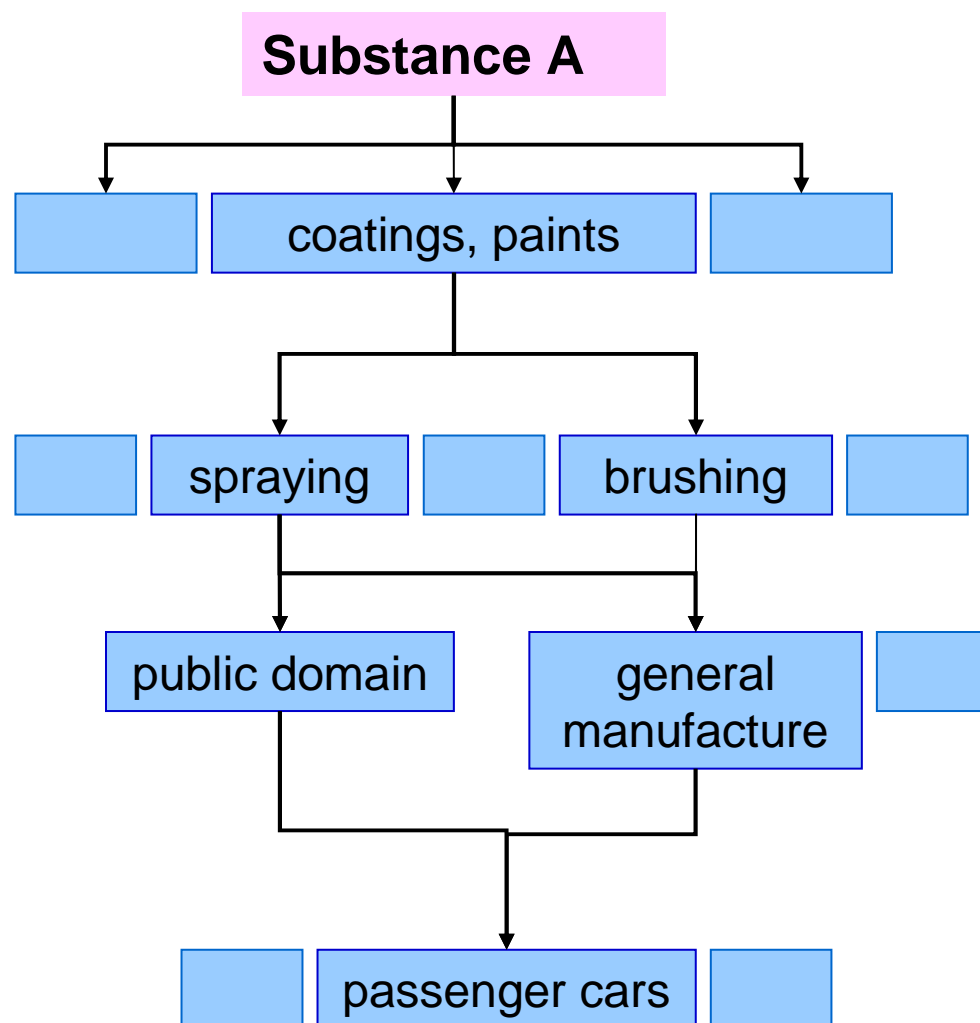
Which sectors of Chemical Industry buy it?

In which categories of chemical products is it used?

How is it used?

In which sectors is it used?

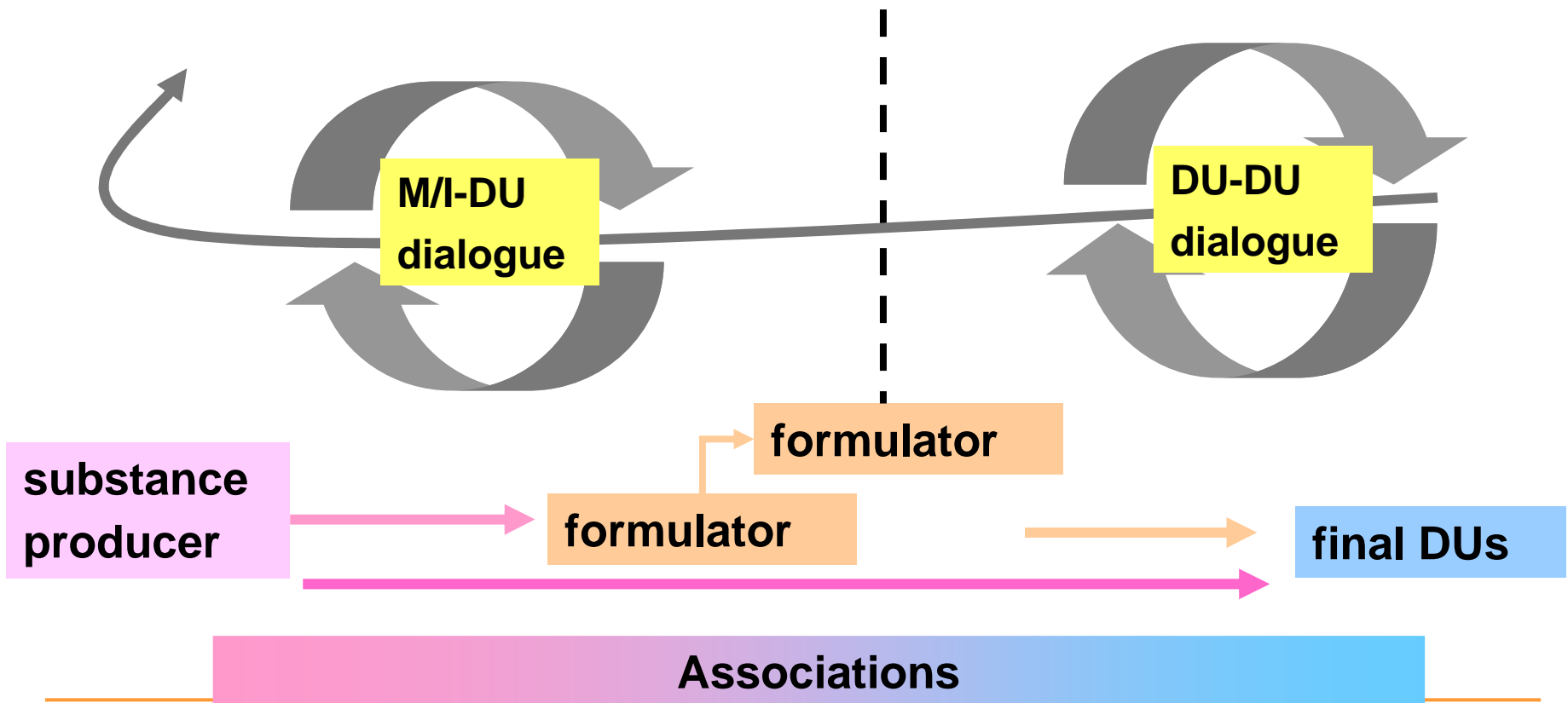
Processed into article?



Dialogue in the supply chain

- Identify uses
- Build exposure scenarios
- Conduct safety assessment

- Make uses known to M/I
- Inform on conditions of use
- Give feed back to exposure scenarios



Building Exposure Scenarios

Initial Exposure Scenarios

- Short title
- Operational conditions (OC)
- Risk management measures (RMM)



Final Exposure Scenarios

- Short title
- Operational conditions (OC)
- Risk management measures (RMM)

If risk not demonstrated to be controlled



Decisions by M/I

- Refine hazard assessment
- Refine exposure estimate
- Modify RMM or OC
- Advise against use



What is new ?



- The manufacturer or importer needs to cover the whole life cycle of the substance in his exposure scenarios
- Control of risk related to environment and consumers to be integrated into the safety data sheet information
- Use specific information in extended SDS
- The downstream users of substances as such or in preparations are obliged to
 - work within the conditions described by the suppliers or to carry out an own CSA
 - for own processing
 - for products supplied further down the chain
 - forward corresponding information to customers

**Available Guidance
on Information Requirements and
Chemicals Safety Assessment**

Published in May and July 2008

Two types of guidance

- Reference guidance
 - Technical and scientific details of hazard and exposure assessment
- Concise guidance
 - Focus on processes and dialogues
 - Guidance where to find more in depth information in the reference part, and when it is needed.

Both guidance parts document the common present understanding among experts on how to implement the REACH requirements. The Guidance does not yet reflect good practice. Such practice will emerge over time.

The guidance is however intended to be generic and does not aim to address particular sectors of industry (and the related technical jargon).

— Concise Guidance —

A: Introduction

B: Hazard Assessment

C: PBT and vPvB Assessment

D: Exposure Scenario Building

E: Risk Characterisation

F: Chemical Safety Report

G: Extension of the SDS

— In Depth Guidance —

R.2-R.7: Information Requirements

R.8-R.10: Dose- or Concentration-Response Characterisation

R.11: PBT/vPvB Assessment

R.12: Description of Uses

R.13: Conditions of Use (RMM, OC)

R.14-18: Exposure Estimation

R.19: Uncertainty Assessment

R.20: Explanation of Terms

<http://echa.europa.eu>

R7 R3,4,6 R2 R5

Information: available – required/needed

Hazard Assessment (HA)

B C R8-10 R11.1

Exposure Assessment (EA)

D R12 R13 R11.2 R14-R18

E R19

Risk Characterisation (RC)

Dangerous Or PBT?

n y

Stop

F Document in CSR

G Communicate ES via eSDS

Risk controlled?

y n

Iteration

Challenges

- Mind set: Risk management to become integral part of the assessment process
- Organising the communication up and down the supply chain well before the first registration deadline
- Linking the risk management focus under REACH to traditional exposure assessment
- Identification of exposure estimation methodology allowing high throughput without being overly conservative
- Translating exposure scenarios for substances into guidance for safe use of preparations

Thank you

for your attention