# Cefic processes for ES development

PRISME2 workshop

24 June 2009,

***Šoporňa, Slovakia***

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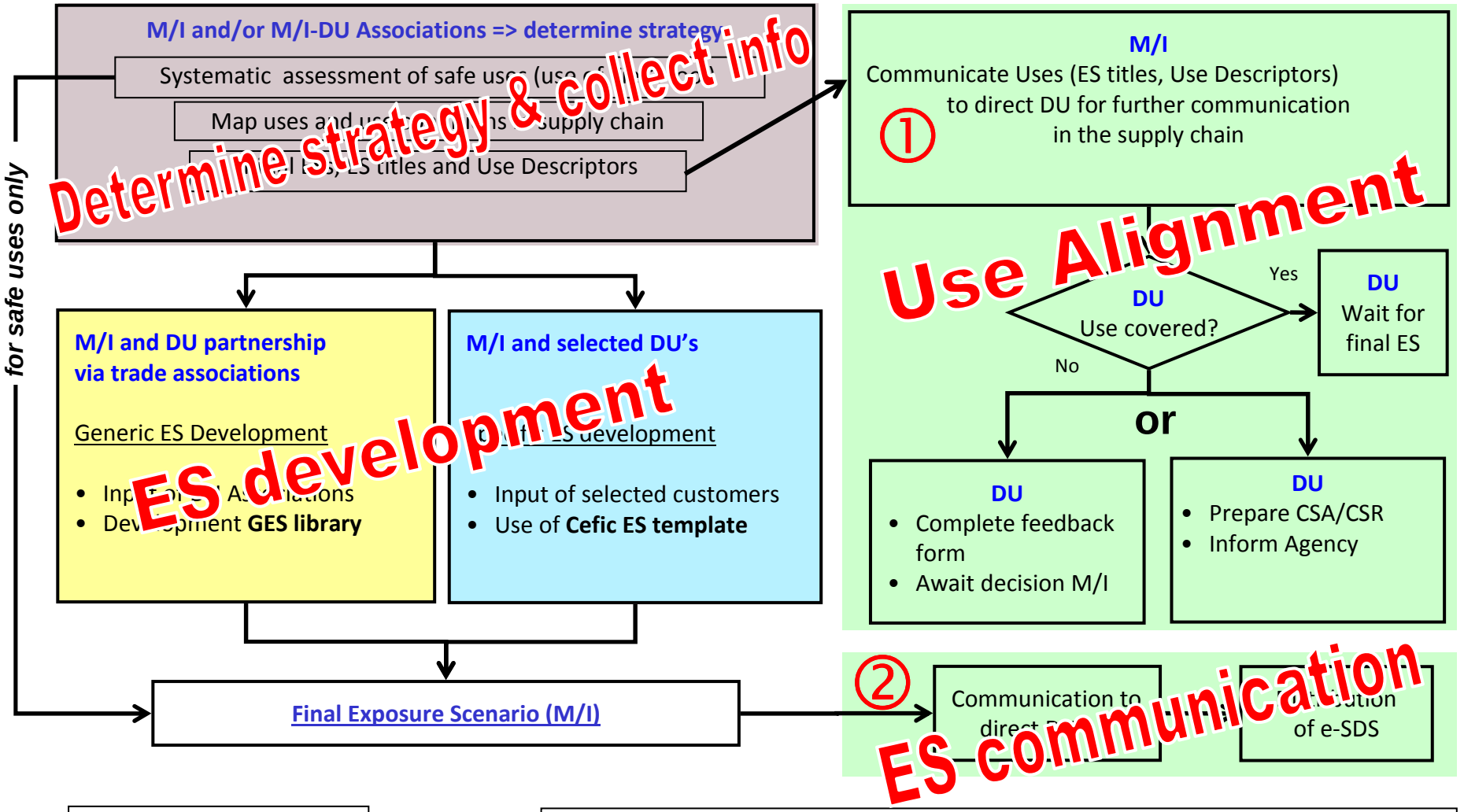
# Agenda

- Cefic flow diagram for ES development and supply chain communication
- ES Development
  - Generic Exposure Scenarios
  - Specific Exposure Scenarios

# ES Development & Communication model

Downstream Users of Chemicals Co-ordination group




Legend
M/I = Manufacturer / Importer
DU = Downstream User

***For specific products and applications the appropriate (next) steps in the above diagram need to be determined based on expert judgement: not always all steps are needed and/or the order can be adapted.***

# Content of Exposure Scenarios

Description of conditions suitable to ensure control of risks related to the uses of a substance during the entire life cycle. Environment, workers and consumers to be covered. One ES can cover one or more use:

- Operational conditions (OC) determining the exposure (e.g. duration of task)
- Practical risk management measures (RMM) suitable / needed to prevent, reduce or limit risks (e.g. exhaust ventilation)

Explanation how the exposure estimates related to these conditions and RMM have been derived

Title of exposure scenario indicating for which uses it can be applied

Boundaries within which the exposure scenario is applicable.

# What is an Exposure Scenario ?

A description of safe use by describing

- Conditions of use
- Risk management measures
- “Algorithm” to be used by DU for validating safe use

ES covers all activities and processes within the value chain

- Production: chemical synthesis of the substance and use as intermediate
- Formulation: mixing and blending into a preparation
- Industrial, professional use
- Consumer exposure and private use
- Service life
- Waste Life stage

# When are Exposure Scenarios needed?

**Exposure Scenarios and CSAs need to be included in the CSR if**

- The substance is classified as dangerous ***or***
- The substance is a PBT or vPvB ***and***
- Produced or imported in excess of 10 t/a
- In a preparation in a concentration above limits indicated in article 14

**DU can choose to do his own CSA/CSR** unless

- No SDS needs to be provided
- The supplier is not required to develop a CSA
- The tonnage limit is < 1 t/a
- The downstream uses should also be taken into account
- Exposure scenarios need to be developed for all identified uses

# Exposure scenario development

**Exposure scenarios need to be developed for:**

- **Manufacturing process**
- **Identified uses**
- **Life cycle stages from manufacturing to identified uses till waste stages.**

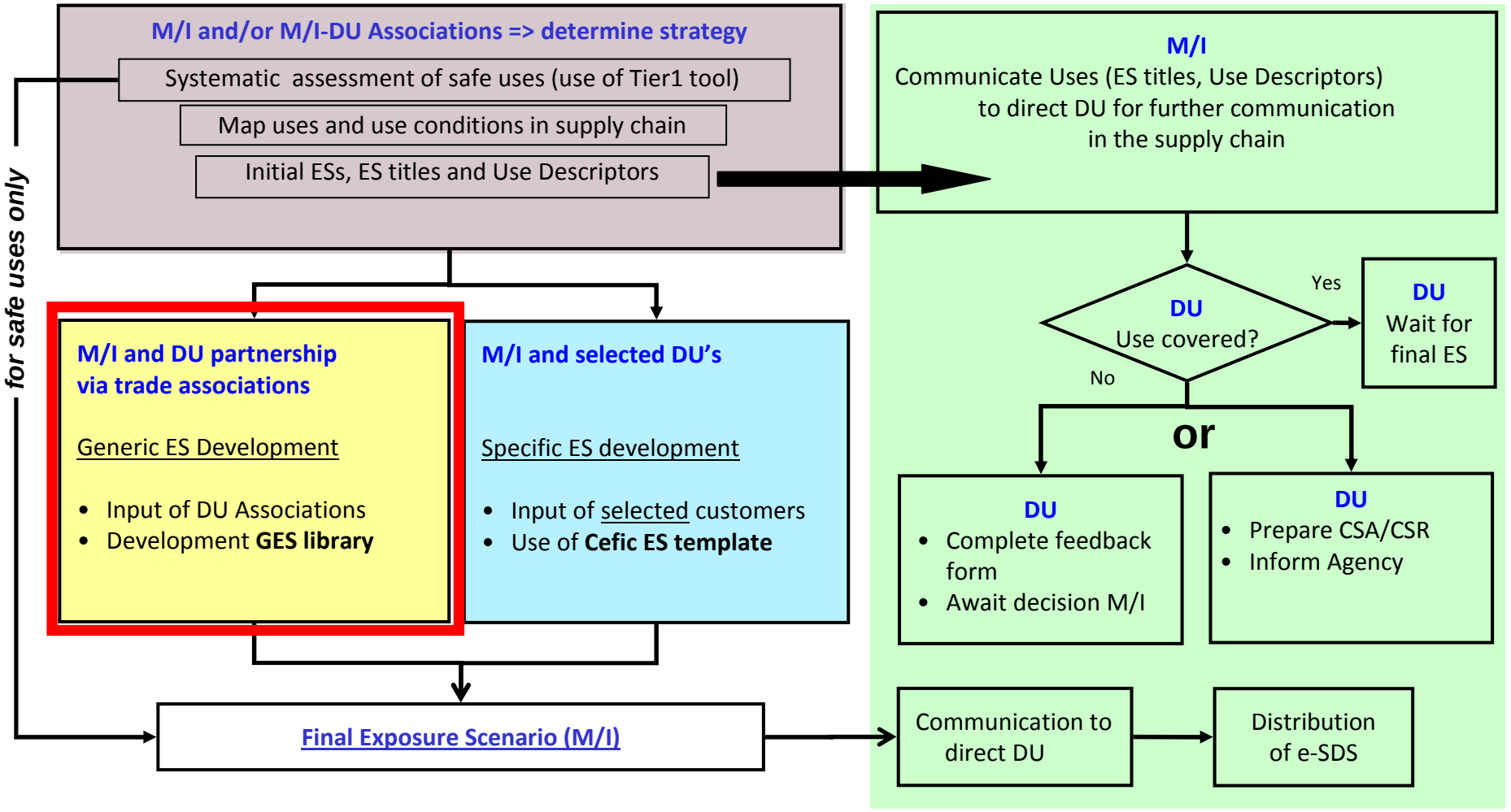
# Cefic workflow
# on ES development and communication

**Development of Exposure Scenarios, using two processes:**

- **Generic Exposure Scenario process**

- **Specific Exposure Scenario process**

# ES Development & Communication model

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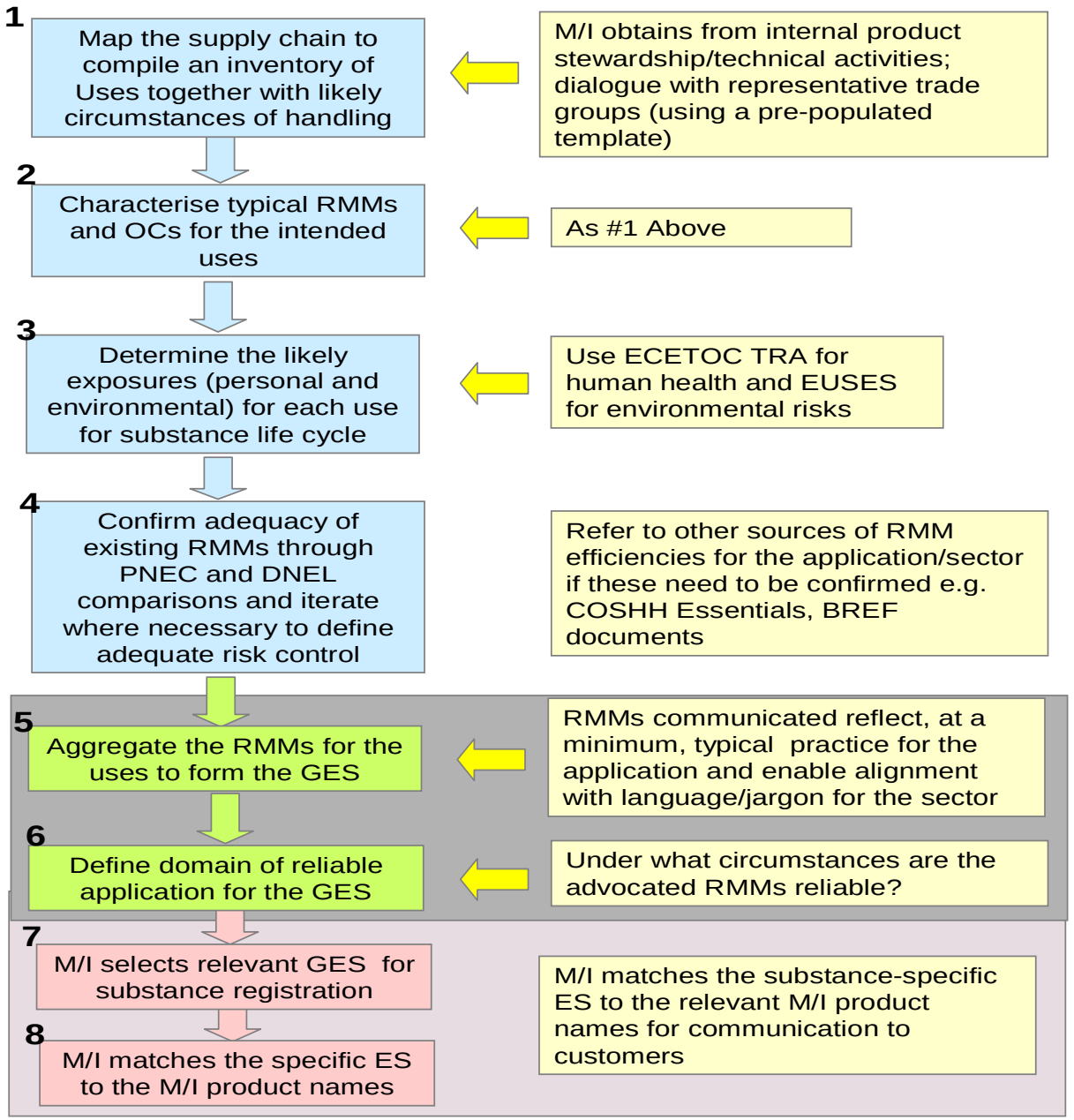
# Generic Exposure Scenarios (GES)

- GESs describe ESs for (groups of) substances for an area of operation within industry and are developed by M/Is in partnership with DU Associations (surrogate for individual DU)
- The (composite) GES is aggregated from the ESs for individual tasks/activities and incorporated into a library of GESs for access by relevant stakeholders
    - describes Risk Management Measures & Operational Conditions relevant for safe use of a group of substances with a similar risk profile
- M/I selects relevant GES to support their substance registration
    - GES and supporting documentation is refined as necessary to form the substance-specific ES for demonstration of safe use and inclusion within their CSR
    - ES is transferred to the e-SDS for communication to customers

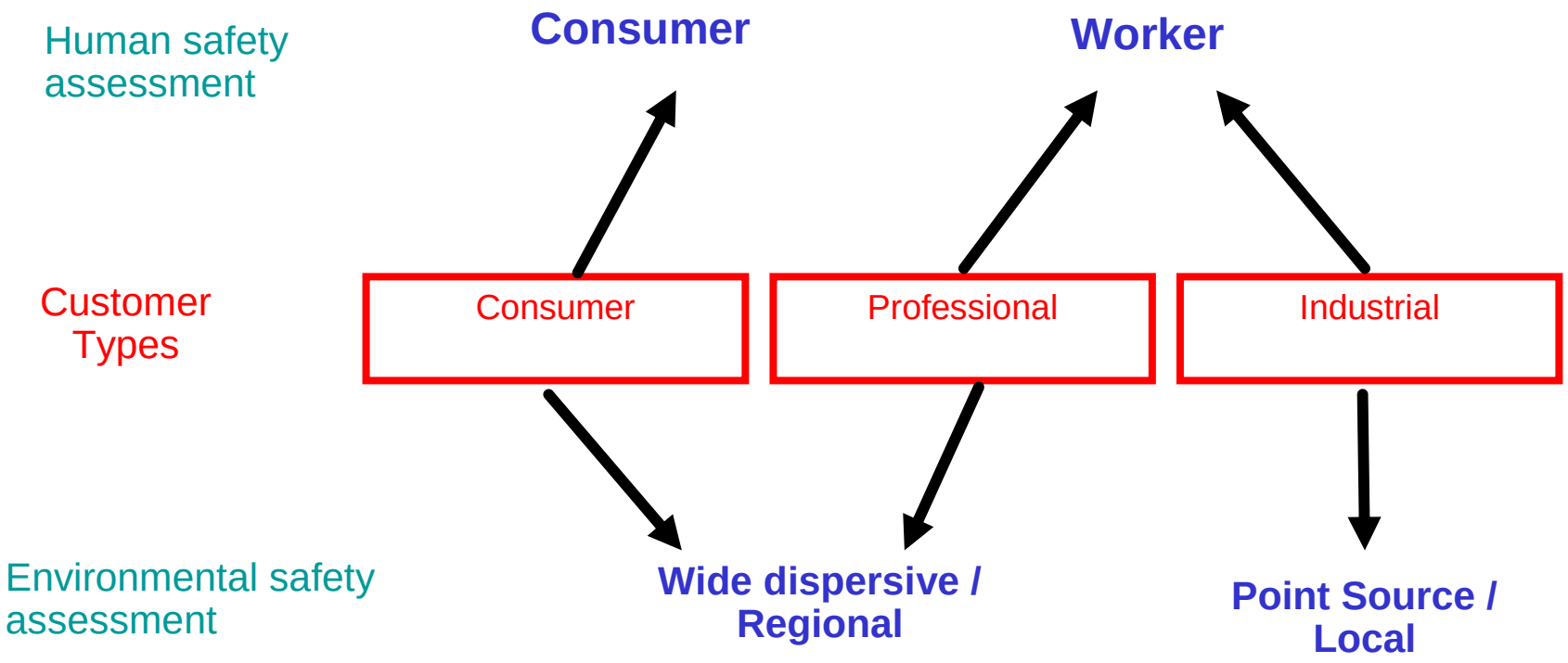
# Key Characteristics of GESs

- Focus on common areas of use of a (group of) substance (that can be characterised by groups of PROCs, ERCs and/or PCs)
- Determine simple titles (and descriptions) that describe the areas of use and that are understandable across DUs within and across supply chains
- Involve the collaboration of M/I (and/or formulator) associations and DU associations
- Represent a mapping of all (or key parts of) the supply chain for a substance (or groups of substances)
- Follow a process that aligns with the requirements of the TGD and delivers documentation sufficient to meet these for a CSR and/or eSDS (subject to confirmation on the part of the registrant)
- Communicate all relevant OCs and RMMs for the identified scenarios
- Describe the ES according to a library of standard phrases

# How is GES developed?



# Customer Types and Exposure: Assessment Approaches




4 assessment approaches appear to be required

## 1. Mapping the Supply Chain

**Seeks to characterise the nature of known uses of the substance/group of substances across the supply chain**

- **Identification of relevant Use Descriptors**
- **Description of typically encountered Risk Management Measures**
- **Description of associated Operating Conditions**
- **Characterisation of commonly used sector terminology**
- **Identification of commonly communicated Product Stewardship and related information (optional)**

**Takes place *after* an initial identification of the nature of uses known to the M/I e.g.**

- **Formulation & packing of solvent-based mixtures (industrial)**
- **Use of coatings (industrial, professional and consumer)**

# 1. Mapping the Supply Chain

**Table 1: Mapping Uses in the Supply Chain**

| Sector/User Group | Contributing Scenarios | Typical Mapped Operating Conditions | Typical Mapped RMMs | Process Category / TRA equivalent |
|---|---|---|---|---|
| **Process Solvent & Extraction Agents** | | | | |
| Industrial (SU3) | General process exposures / enclosed cleaning systems | Continuous; daily; 15 mins - 1 hour | Enclosed process; External location; closed/semi-closed sampling point | PROC2 / TRA2 Closed continuous process (with sampling) |
| Industrial (SU3) | General process exposures and sample collection | Batch; daily during production; 15 mins - 1 hour | Enclosed process; External location; closed/semi-closed sampling point | PROC3 / TRA3 Closed batch process (with sampling) |
| Industrial (SU3) | Draining equipment | Weekly; 15min - 1 hour; ambient temp | External location; Drain and flush, Permit to Work procedures, PPE | PROC8 / TRA7 Discharging to/from vessels |
| Industrial (SU3) | Quality control | Daily; <15 mins; ambient temp | Fume cupboard, PPE | PROC15 / TRA13 Laboratory analysis |
| **Cleaning agents** | | | | |
| Industrial (SU3) | Enclosed cleaning systems | Batch process; daily; 1 - 4 hours; ambient temp | Closed system | PROC1 / TRA1 Closed process (no sampling) |
| Industrial (SU3) | Filling / preparation of equipment from drums | Daily; 15 mins - 1 hour; ambient temp | Pumped transfer from drum to application equipment | PROC8 / TRA7 Discharging to/from vessels |
| Industrial (SU3) | Spraying | Daily; >4 hours; ambient temp | Enclosed plant under ventilation. Collection and containment of waste. | PROC7 / TRA6 Spray application with LEV |

M/I describes life cycle and identifies relevant OCs, RMMs and PROCs. Consumer uses (PCs) described in separate sheet.

## 2. DU Review and Feedback

DU sector/trade organisation(s) review initial M/I mapping activity and identify where revisions required e.g. increased scope; inappropriate RMM descriptions; absent PROC codes; etc.

Experience suggests that the feedback process is best undertaken as a face to face discussion

Feedback is tracked and recorded using a suitable template (Solvents example in excel)

## 3a. Justifying the Content of the ES

**Mapping seeks to characterise the likely exposures and to describe the nature of advised RMMs for defined risks**

- **Carry out exposure estimates for relevant exposure routes for defined OC/RMM combinations (using suitable Tier 1 models)**
- **Make an assessment of the potential risks based on informed assumptions of the likely DNEL/PNEC ranges for the substances of interest**
- **Identify the basis by which the identified REACH OCs and RMMs will be described (using standard phrases)**
- **Identify areas where the communication of Product Stewardship information may also be advisable**
- **Carry out the CSA if a DNEL or PNEC is available**

# 3b. Justifying the Content of the ES

| Table 1: Mapping Uses in th | | Table 2: Characterising the Risks - example Tier 1 sc | | | | DNEL >100 ppm | |
|---|---|---|---|---|---|---|---|
| Sector/User Group | Process Category / TRA equivalent | Tier 1 assumptions and adjustments where required | | Predicted Exposure - ECETOC TRA estimate | | RMMs for communication - Consolidate into GES or e-SDS (Black text REACH advised; Blue text recommended) | RMM Codes for communication (Black text REACH advised; Blue text recommended) |
| | | OCs (red text Tier 1 adjustments) | RMMs (red text additional Tier 1 adjustments) | Moderate Volatility (ppm) | Significant Dermal exposure? | | |
| **Cleaning agents** | | | | | | | |
| Industrial (SU3) | PROC1 / TRA1 Closed process (no | >4 hours, ambient temp. | Closed process. No exposure. | 0.01 | No | Skin and eye protection | PPE16 |
| Industrial (SU3) | PROC8 / TRA7 Discharging to/from vessels | > 4 hours daily; ambient temp. | No LEV | 50 | Yes | Pumped transfer from drum to application equipment. Gloves | E49, PPE15 |
| Industrial (SU3) | PROC7 / TRA6 Spray application with LEV | > 4 hours daily; ambient temp. | With LEV | 50 | Yes | Enclosed plant under ventilation. Collection and containment of waste. Gloves | E47, ENVT3, PPE15 |
| Industrial (SU3) | PROC13 / TRA11 Treatment by dipping/pouring | > 4 hours daily; ambient temp. | With LEV | 50 | Yes | Enclosed plant under ventilation. Collection and containment of waste. Gloves | E47, ENVT3, PPE15 |
| Industrial (SU3) | PROC10 / TRA9 Roller application | > 4 hours daily; ambient temp. | No LEV | 20 | Yes | Collection and containment of waste. Gloves | ENVT3, PPE15 |
| | | | | | | | |
| Professional (SU22) | PROC8 / TRA7 Discharging to/from small | > 4 hours daily; ambient temp. | No LEV | 50 | Yes | Gloves | PPE15 |
| Professional (SU22) | PROC11 / TRA6 Spraying without | > 4 hours daily; ambient temp. | No LEV | 500 | Yes | LEV and/or RPE. Gloves. Eye Protection | E53, PPE16 |
| Professional (SU22) | PROC13 / TRA11 Treatment by dipping/pouring | > 4 hours daily; ambient temp. | No LEV | 100 | Yes | Gloves | PPE15 |

## 4a. Constructing the GES

- The GES describes the combined RMMs and OCs relevant for the safe use (H & E) of a substance or group of similar substances for an area of operation in industry
- The GES is developed around the nature of the identified uses (industrial, professional and consumer) and accounts for the OCs/RMMs considered appropriate for human health and/or the environment
- The GES is constructed by integrating the conclusions from the mapping templates

# Generic Exposure Scenario

## (Professional Use of Coatings)

Risk manage-ment measures

**Human health**

-***Pouring from small containers*** **: undertake in a well-ventilated area. Wear suitable gloves (type EN374, code FJ) if skin contact likely.**

**-*Spraying* : carry out in a vented spray booth. If no dedicated facility available, then use a respirator conforming to EN140 (with Type A filter) or better standard and undertake in a well-ventilated area segregated away from other work activities.**

**-*Manual applications* e.g. brushing, rolling, spreading : undert… well-ventilated workplace. Use long handled brushes and roller… Wear gloves (type EN374, code FJ) if prolonged contact wi…**

**-*Equipment clean-down* : Wear gloves (type EN374, code F… contact expected. Transfer wash-downs in sealed containe… recycle solvent or send for disposal or recycle.**

**GES communicates the consolidated RMMs and OCs for the relevant PROCs in an area of application**

**GES format provides the opportunity for the communication of sector product stewardship advice**

**RMMs and OCs relevant for a task (PROC) clearly distinguished and described in manner relevant for DU**

## 4b. Describing the Applicability Domain

The applicability domain describes the boundary conditions (“risk band”) within which the GES information is reliable

- The GES contents are not valid outside these

The applicability domain is a concept that is only relevant for the GES *prior to* verification against a DNEL/PNEC for a specific substance

- i.e. it provides an indication of the types of substances and their conditions of use to which the GES may apply

After verification, the GES becomes a substance-specific Exposure Scenario for use in supporting a substance Registration and in customer communication via an e-SDS

# Domain of Application for the GES

| **Scenario title : X XXX** | | |
|---|---|---|
| Validity Domain | Typically Characterised By | Typical Substances/ Mixtures Not Covered |
| **Human Health** | | |
| DNEL : 10 - 200 ppm (8 hour) | Simple aliphatic solvents (except those containing n-hexane); simple alcohols and esters | R43, R42 |
| Moderate volatility | Liquids with a vapour pressure of < 300 hPa and used in processes operated at ambient temperature | Liquids having V.P > 300 hPa and processes operated at > 50oC |
| Moderate dustiness | Granules, pellets, sand like materials | Dusty solids e.g flour like materials |
| Applicable for solvent content up to 50% | N/a | Preparations having solvent content >50% |

# Benefits of Generic Exposure Scenarios?

**Developed in partnership between M/Is and DU representatives**

- **Relevance of the information for DUs. Technology, systems, language**

**Starting position is verification of the utility of 'existing practice'**

- **no surprises; business as usual**

**Aim for consistency in communication within and across supply chains**

- **Together with simplicity and understandability**

**Level of detail aligned with DU needs**

- **Simplified ES 'highlights' in the eSDS supported by availability of detailed ES information as part of Chemical Safety Assessment**

**Minimising unnecessary supply chain communications**

- **Starting assumption is what is communicated is relevant and useful**
- **GES format designed to be useful without need for further DU re-work**

**Provide basis for development of GES libraries**

- **forms a resource for the development of further ESs**

## Example of GES titles for Solvents

*From the perspective of how REACH ESs need to be communicated*

- **Manufacture of solvents (industrial)**
- **Bulk loading and repacking of solvents (industrial)**
- **Formulation & packing of solvent-based mixtures (industrial)**
- **Coatings (industrial, professional and consumer)**
- **Cleaning agents (industrial, professional and consumer)**
- **Drilling muds (industrial)**
- **Metal working fluids / rolling oils (industrial and professional uses)**
- **Propellants (professional and consumer)**
- **Blowing agents (industrial)**
- **Release agents & binders (industrial and professional)**
- **Agrochemicals (professional and consumers)**
- **Road construction (professional)**
- **Other consumer uses**

* List is illustrative and is to be fully developed and agreed within ESVOC

# Cefic workflow on ES development and communication

**Development of Exposure Scenarios, using two processes:**

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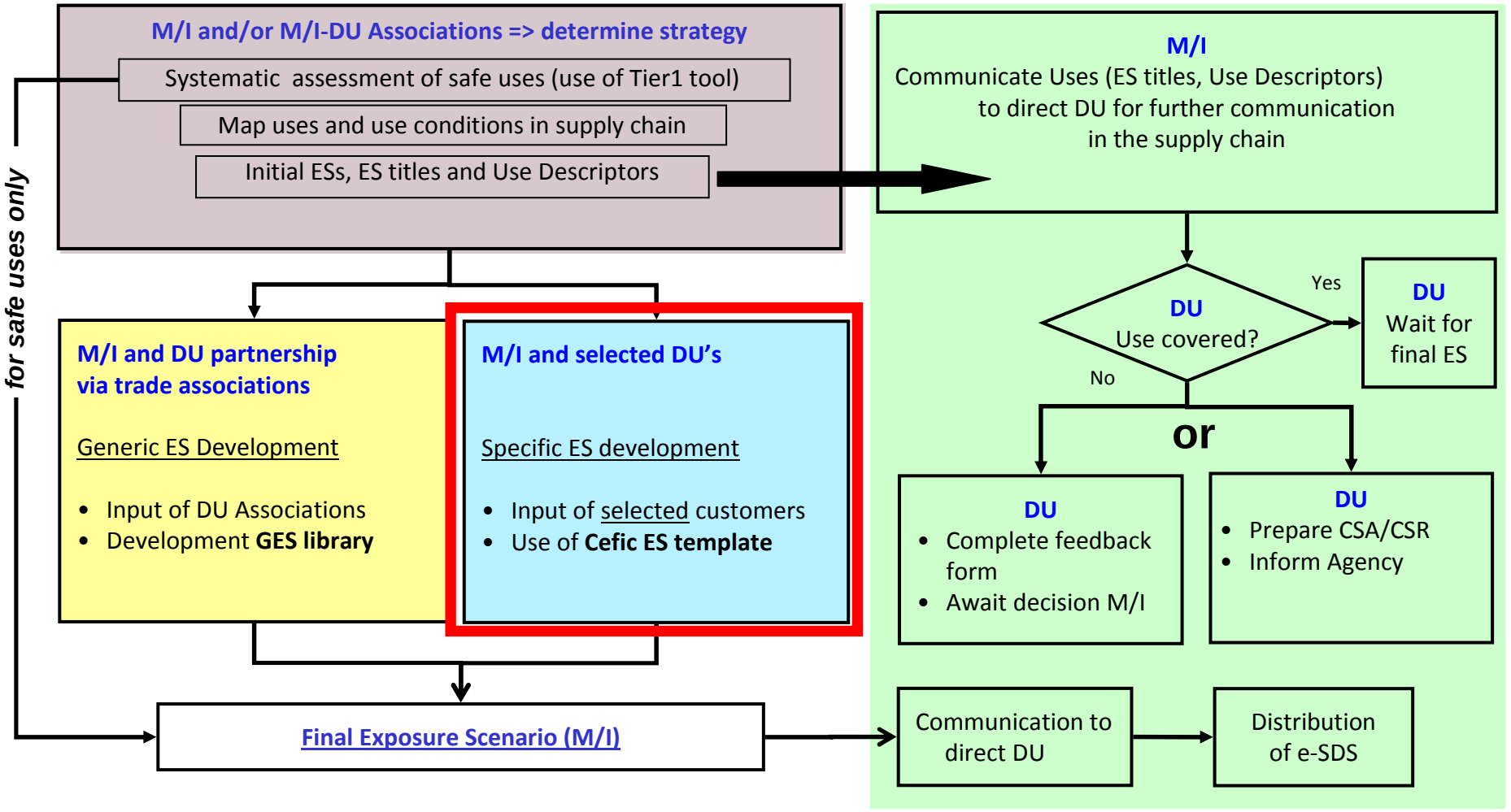
# ES Development & Communication model

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# What are Specific Exposure Scenarios?

- Specific Exposure Scenarios (SES) describe Exposure Scenarios (ES) for individual substances in both specific and general uses
- SESs are developed by the M/I in dialogue with DU selected representative customers
- SESs can cover one task or a set of tasks related to an application
- The SES process is particularly useful to develop ESs for substances in relatively short supply chains or supply chains lacking well structured sector organizations

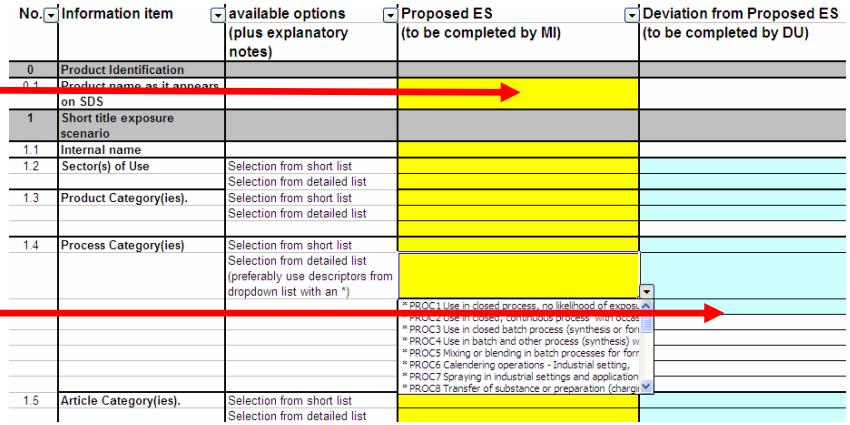
# Cefic ES template dialogue

**Draft template. Please consult Cefic website for final version**

Microsoft Excel Worksheet

# CEFIC dialogue template for SES building

- **Enables M/I to develop initial ESs, using a harmonised industry format**
- **Enables DU to give feedback on uses and use conditions to M/I in a standardized way**

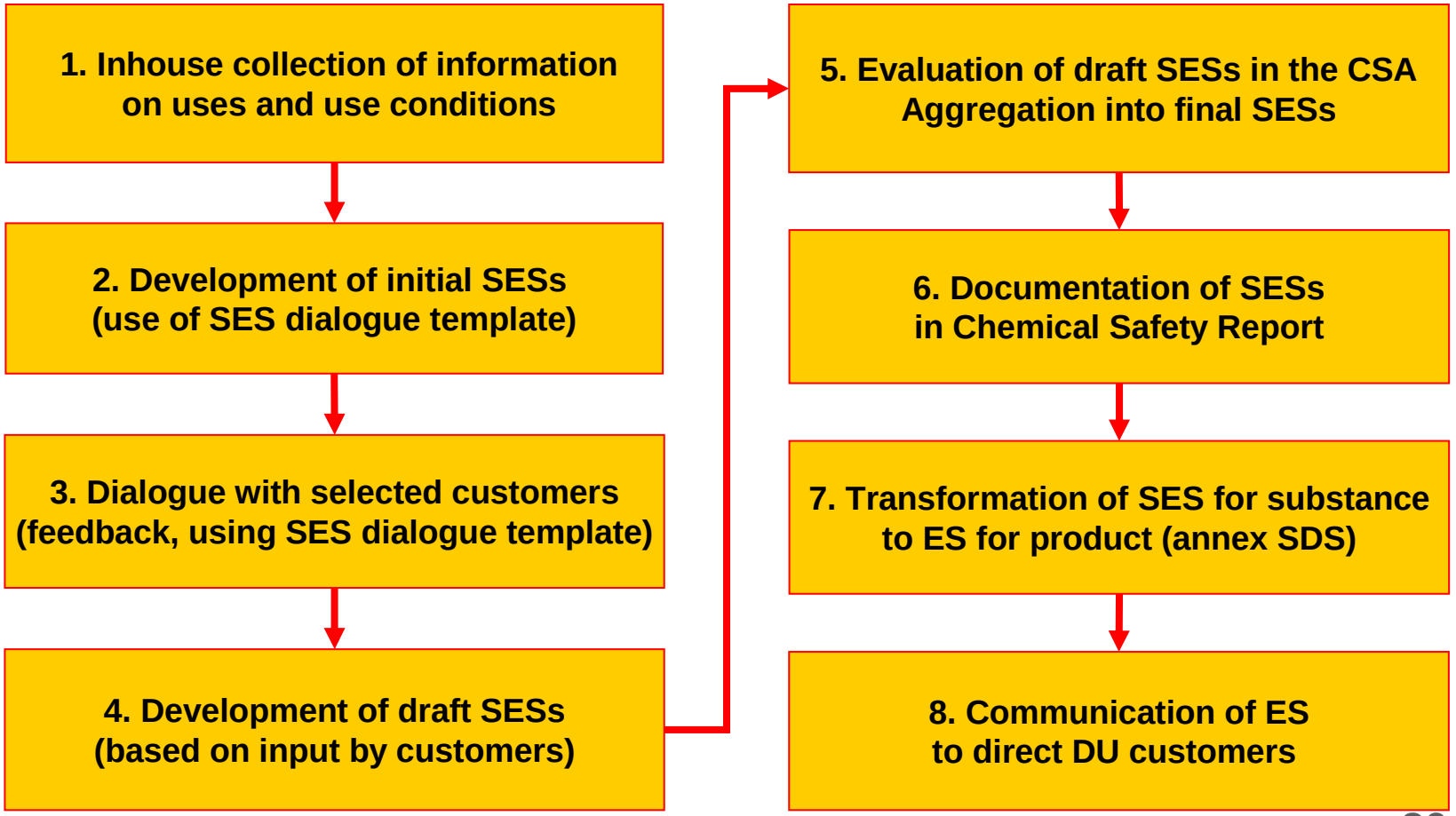


| No. | Information item | available options (plus explanatory notes) | Proposed ES (to be completed by MI) | Deviation from Proposed ES (to be completed by DU) |
|---|---|---|---|---|
| 0 | Product Identification | | | |
| 0.1 | Product name as it appears on SDS | | | |
| 1 | Short title exposure scenario | | | |
| 1.1 | Internal name | | | |
| 1.2 | Sector(s) of Use | Selection from short list<br>Selection from detailed list | | |
| 1.3 | Product Category(ies). | Selection from short list<br>Selection from detailed list | | |
| 1.4 | Process Category(ies) | Selection from short list<br>Selection from detailed list (preferably use descriptors from dropdown list with an *) | * PROC1 Use in closed process, no likelihood of exposu<br>* PROC2 Use in closed, continuous process with occas<br>* PROC3 Use in closed batch process (synthesis or for<br>* PROC4 Use in batch and other process (synthesis) w<br>* PROC5 Mixing or blending in batch processes for form<br>* PROC6 Calendering operations - Industrial setting,<br>* PROC7 Spraying in industrial settings and application<br>* PROC8 Transfer of substance or preparation (charg | |
| 1.5 | Article Category(ies). | Selection from short list<br>Selection from detailed list | | |

- **Enables DU to enter new ES, if he finds his use not covered (art. 37-2)**
- **Structured according to ES format in Technical Guidance Document**
- **Each section contains the basic information for description of the ES and exposure assessment using the ECETOC TRA tool**
- **Template will be modified to support final version of the ECETOC TRA tool**

# How are SESs developed?

## SES process: stepwise approach, initiated by M/I in dialogue with DU



# How are SESs developed?

**1. Inhouse collection of information on uses and use conditions** → **2. Development of initial SESs (use of SES dialogue template)** ⇢

- use of mapping form recommended:
  - description of tasks
  - user type (ind/prof/cons)
  - process details
  - use descriptors
  - exposure duration
  - typical RMMs used (e.g. LEV, RPE, PPE)
- utilize available sector use mappings performed by sector organizations

- based on collected information
- use of Cefic dialogue template for SES building for products

# How are SESs developed?

**3. Dialogue with selected customers (feedback, using SES dialogue template)**

**4. Development of draft SESs (based on input by customers)**

- selection of representative customers
- conference call:
  - explain purpose of dialogue and intended results
  - confirmation of correct selection
  - explanation of dialogue template
  - agreement on activities and timing
- type of dialogue (face-to-face, email, phone; separate/group) depending on opportunities and needs

- based on sufficient input by selected customers
- modification of initial SESs for product
- creation of draft SESs for substance

# How are SESs developed?

**5. Evaluation of draft SESs in the CSA Aggregation into final SESs**

**6. Documentation of SESs in Chemical Safety Report**

- Tier 1 exposure assessment for each draft SES, using ECETOC TRA tool
- comparison with applicable DNELs and PNECs
- where safe use is not demonstrated: proceed to Tier 2 assessment (models, exposure data)
- after demonstration of safe use: aggregation of SESs into final (composite) SESs for SESs with equivalent RMMs

- final SESs in combination with the results of the risk assessment are included in the CSR

# How are SESs developed?

**7. Transformation of SES for substance to ES for product (annex SDS)**

**8. Communication of ES to direct DU customers**

- combination and evaluation of the SESs of the substances
- compilation of the ES for the product
- use of the ES format in the TGD (annex to the SDS) for structuring the ES of the product
- adaptation of language (using information in RMM libraries) to more industry jargon to increase readibility and facilitate comprehension by DUs

- communication of ESs to direct DU customers using web-based communication tools
- after registering the substance (submission of CSR as part of the registration dossier): distribute the ES as annex to the SDS at first delivery of a product to a DU customer

# Final remarks

- **Dialogue template for SES building is aimed at two way communication in an effective and efficient way; it is NOT a questionnaire!**
- **SES and GES development processes are complementary; both processes on their own or in combination offer the flexibility needed to develop ESs that suit M/I needs and the needs of DU customers**
- **Cefic strongly supports and recommends the use of both ES development methods and accompanying tools to achieve optimal information exchange on uses in the supply chain**

# Selecting the Approach

| Generic ES approach | Specific ES approach |
|---|---|
| **Main Focus** | **Main Focus** |
| M/I and DU Partnership via Trade Associations | M/I and Key customer iteration |
| Common Uses, e.g. commodity chemicals | Specialised Uses, e.g. fine chemicals |
| Dispersive application | Limited supply chain |
| Assumes some knowledge of substance handling by M/I | May have limited knowledge of substance handling in the supply chain by M/I |
| Groups of substances with similar applications | Single substance with specific or general applications |

# Available tools

- **Newsletter: guidance on Use and ES development and Supply Chain Communication**
  http://cefic.org/files/Downloads/Guidance_Use_and_ES_dvlpt_and_SCCm.doc
- **VCI Practical guide CSR eSDS**