Industry contributions to RIPs – developing guidance on exposure scenarios – developing intelligent information strategies

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cefic

CEFIC & REACH

View on REACH

- **an opportunity to restore confidence in chemicals**
- **Need to have a workable REACH**
- **Major contributions to the RIPs incl RIP 3.2-2 and RIP 3.3-2**

Overview

- RIP 3.2-2 Development of a Technical Guidance Document for preparing the CSR
  - Background
  - On-going work on exemplification of ESs
  - Guidance testing
- RIP 3.3-2 Information strategies for industry
  - Objectives
  - Approach
  - Plan

Industry involvement

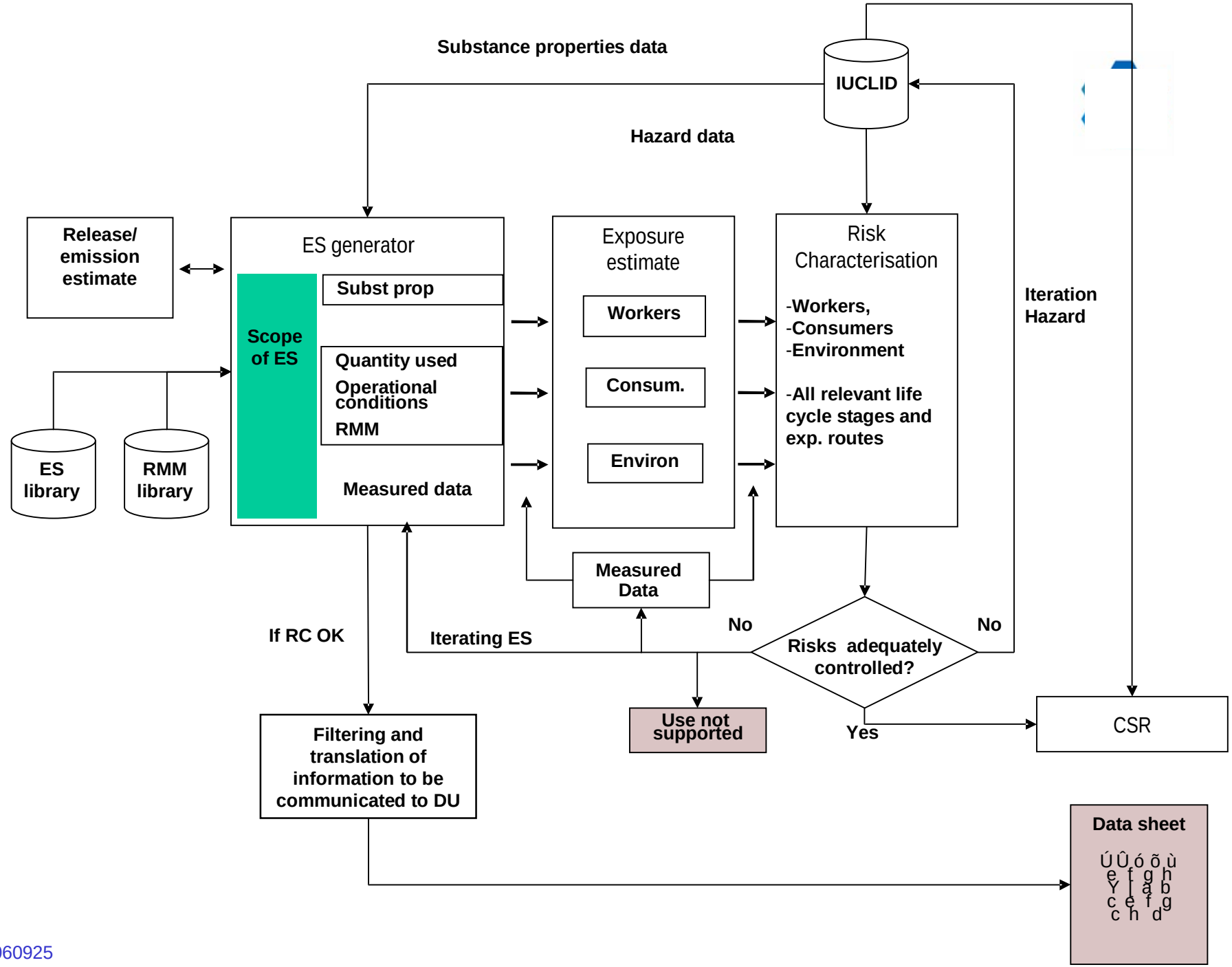
Background to RIP 3.2-2

RIP 3.2 CSA/CSR Objectives

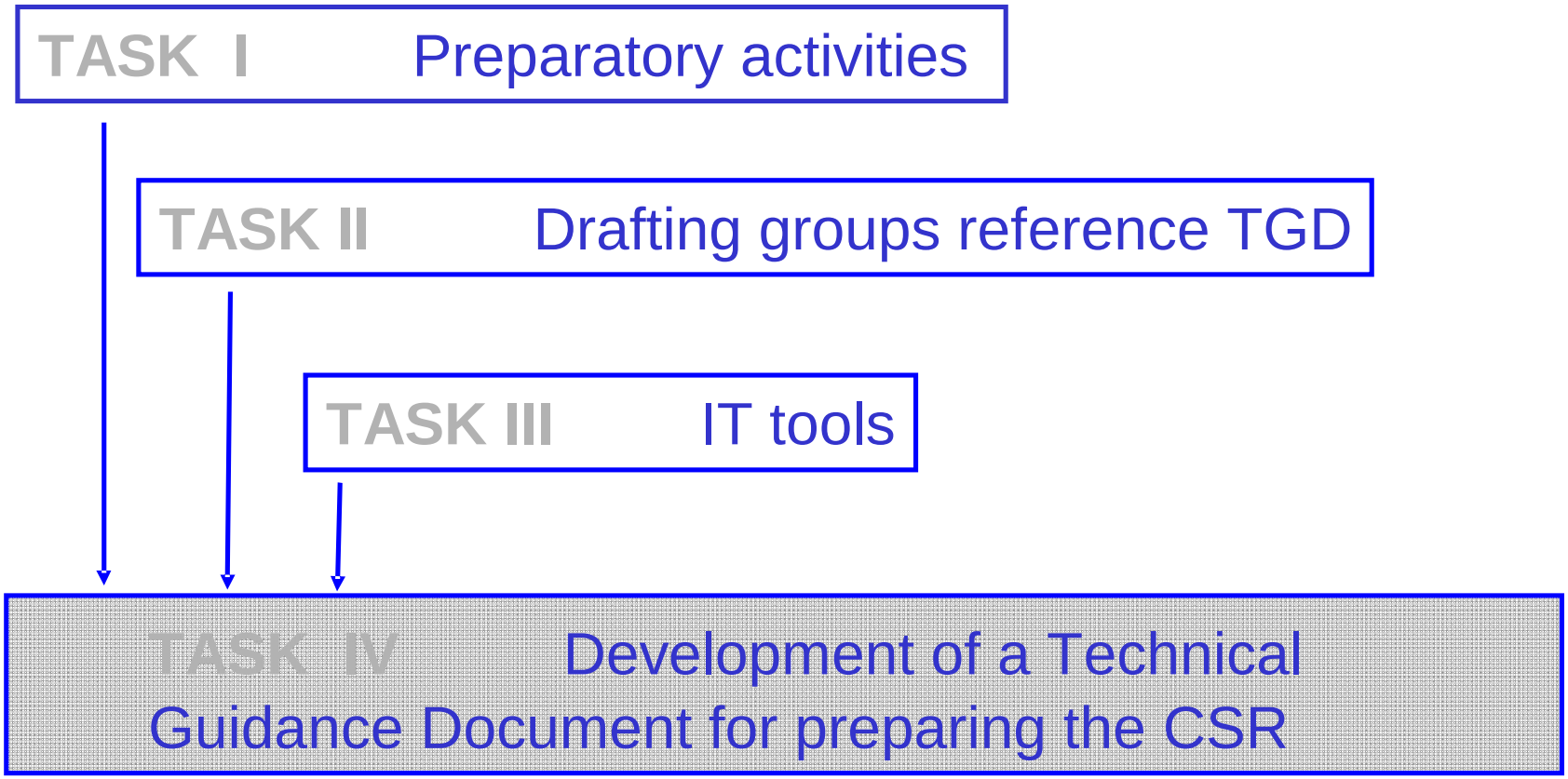
To develop Technical Guidance Documents **and supporting** IT applications for industry **on:**

§ Conducting the Chemical Safety Assessment (CSA)

§ Preparing the Chemical Safety Report (CSR)


Substance properties data
IUCLID
Hazard data
Release/ emission estimate
ES generator
Scope of ES
Subst prop
Quantity used
Operational conditions
RMM
Measured data
ES library
RMM library
Exposure estimate
Workers
Consum.
Environ
Risk Characterisation
-Workers,
-Consumers
-Environment
-All relevant life cycle stages and exp. routes
Iteration Hazard
Measured Data
If RC OK
Iterating ES
No
No
Risks adequately controlled?
Yes
Use not supported
CSR
Filtering and translation of information to be communicated to DU
Data sheet

RIP 3.2-2: Task IV - dependency



RIP 3.2-2: Overview of Task IV

§**TASK IV** Development of a Technical Guidance Document for preparing the Chemical Safety Report

RIP 3.2-2 Task IV: Objectives

- Further development of exposure scenario concept

- Two-level guidance document for developing the chemical safety assessment and documenting it in the chemical safety report

- Specification of needs / requirements for supporting tools and outline of elements for these tools

- Development of a system of short titles / identifiers

WHERE
- are Exposure Scenarios developed ?

-> Chemical Safety Assessment (CSA)

The CSA is conducted and the exposure scenarios developed by using…

…all available and generated information on the use of the chemical, and related exposures

…all available and generated information on properties and toxicity of the chemical

The Chemical Safety Assessment is documented in the Chemical Safety Report

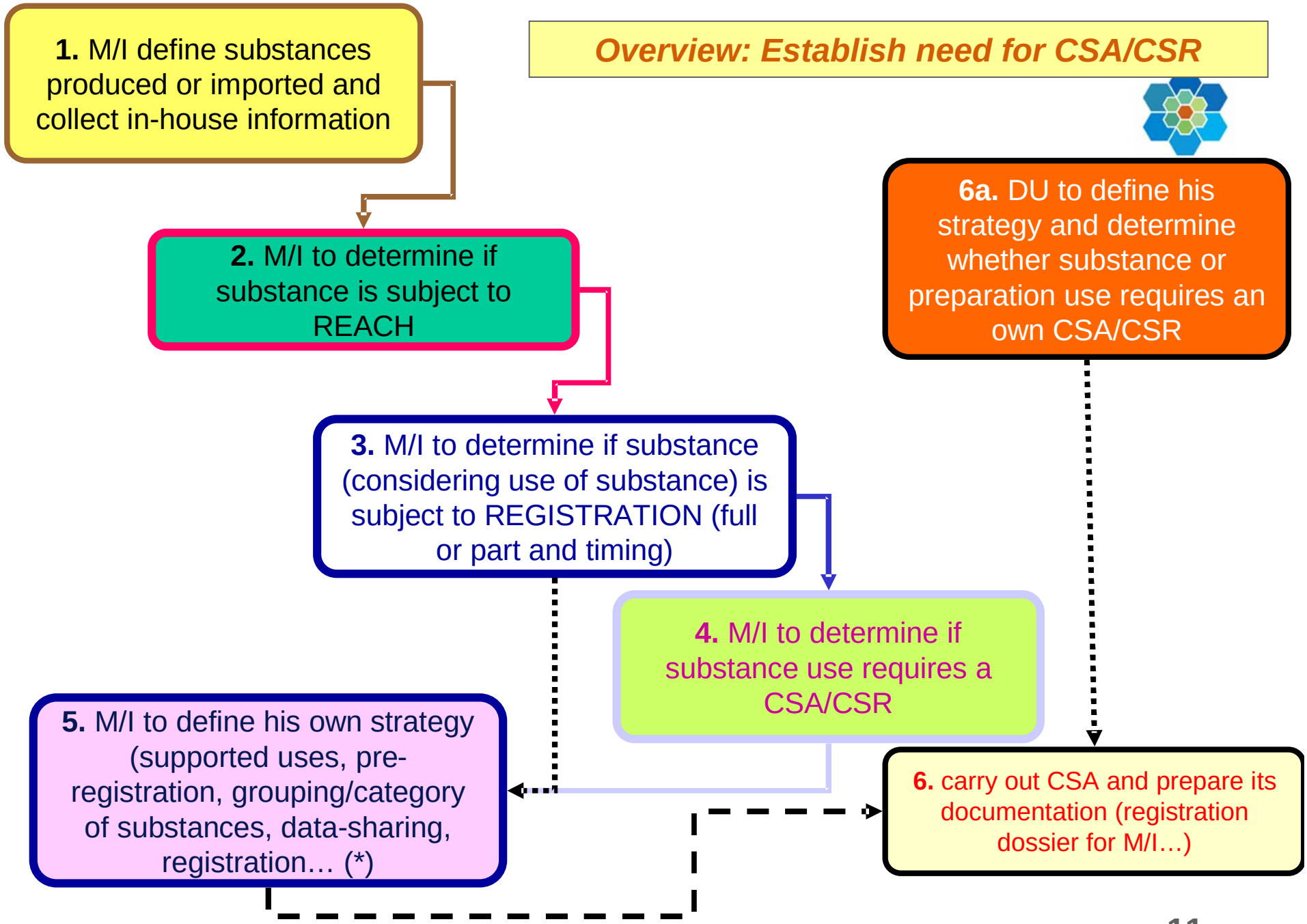
HOW
- will the user know ?

Safety Data Sheet

Exposure Scenarios will be attached to the Safety Data Sheet (SDS)

-> Extended Safety Data Sheets (e-SDS)

Overview: Establish need for CSA/CSR



(*) for phase-in substances

HOW

Identification of down stream uses up to and including the waste stage

Consumer use categories

- **What are they used for**
- **How much is used**

} **Combine these**

Consumer product use categories

Strategies to identify critical exposures

ð **Tiered approach including Risk Management Measures**

Exposure Scenarios

Issues considered:

- Use identification
- Determinants of exposure
- Questionnaires on use (identification of use conditions)
- Integrated ESs (occupational, consumer, environment)
- Existing tools and approaches
- Review of industry/use/function/etc. categories
- Future needs (library of exposure scenario's)
- Iteration

- RMM's (IPPC,COSHH)
- Efficacy of RMM' s (uncertainties)

Risk Management Measures

Major change in RA under REACH:

Risk Management Measures **are integrated part of the Chemical Safety Assessment**

The CSA is not about 'is there a risk or not?' but about ES's describing how the chemical can be used in a way that risks are adequately controlled

focus on Risk Management Measures!

Exposure Determinants

ES 'label'	e.g. IC/UC codes (3.2-2)	
Substance characteristics	Phys-chem and biological properties	from IUCLID
Operational conditions.	Quantity used	From description of use and ES library Specific for the use processes
	Duration and frequency	
	Key operational parameters	
	Preparation characteristics	
RMM	Containment	From description of use and RMM tool Can be modified
	LEV	
	On-site treatment	
	PPE	
Target characteristics	e.g. dilution	From description of use Can not be modified
	RMM outside control	
	e.g. skin area	
	Other characteristics	

Workflows for industry

§ Focus on **what the supplier has to do** fulfil the REACH requirements on CSA/CSR:

- § Information gathering (substance properties, use and exposure conditions)
- § Test plans/derogations development
- § Dossier preparation (Technical dossier, CSR, SDS)

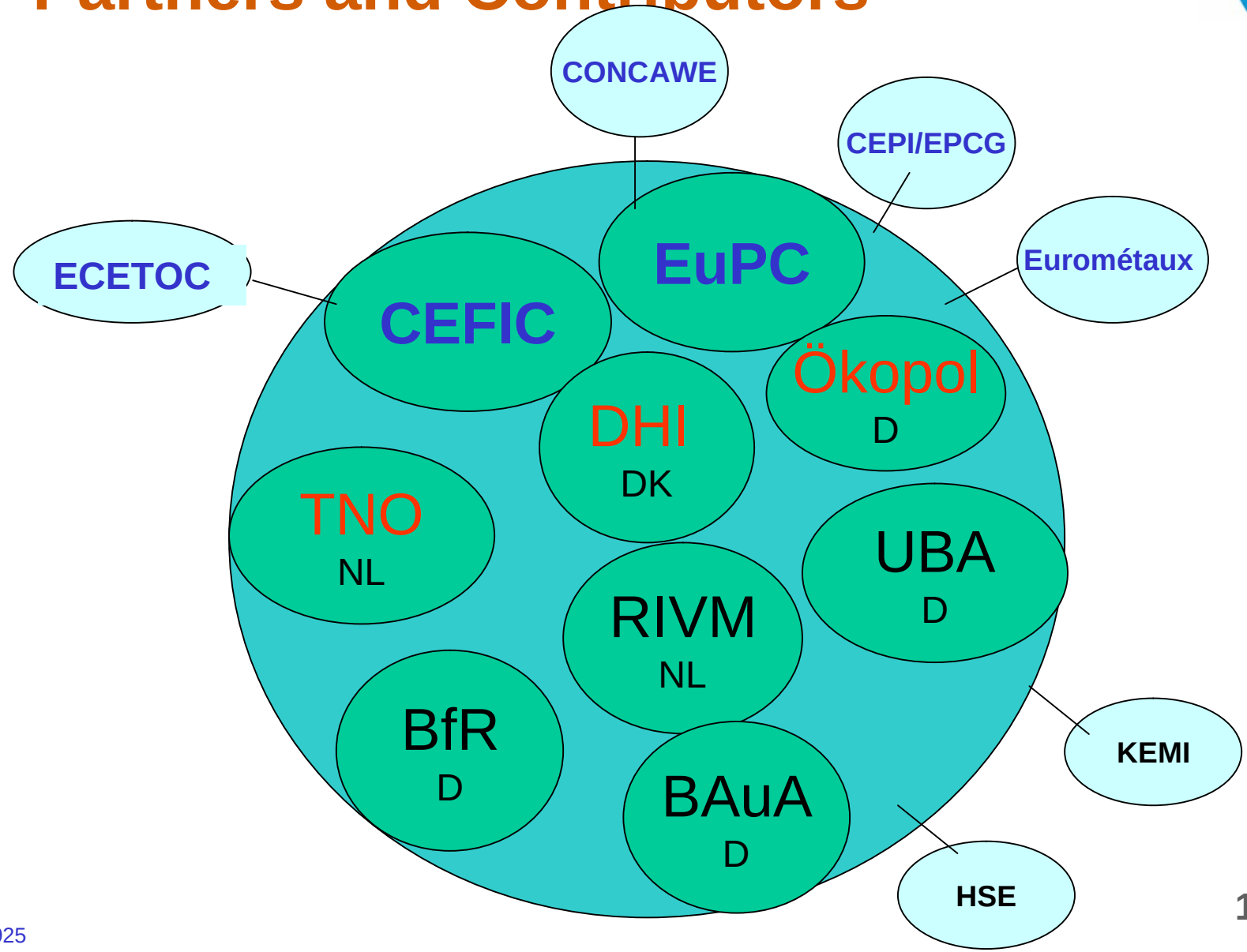
RIP 3.3-2 (to follow)

§ Information down the supply chain ð SDS

RIP 3.2-2: Task IV - Elements

- Exemplification of ES and testing certain elements of the guidance
- Refining the Exposure Scenario concept
  - Additional guidance, tools and systems
  - Emission and exposure estimation
- Testing the two level guidance

RIP 3.2-2: Task IV - Partners and Contributors



Cefic Support Groups – RMM OH & Env

Terms of Reference

Provide experience with the different risk management strategies … workplace/environment... and evaluate them for their usefulness under REACH

- **Compile a library of operational Risk Management Measures and their efficiencies for [reduction ….]**
- **Assist in developing the worker/environmental exposure scenarios for the relevant sectors participating in the exemplification**
- **Propose a hierarchy of models and tools**
- **Identify how the current exposure assessment tools should be further developed**

RIP 3.2-2 Case Studies

WHY

- **Exemplify**
- **Create empirical knowledge**
- **Testing the draft guidance**

RIP 3.2-2: Task IV Case Studies

§ **PREPARATORY ACTIVITIES** : workshops leading to the selection of 4 core case studies for Task IV (ECB-4)

- **AISE : substances in final use of a cleaning product**
- **CEPE screen printing (total life cycle)**
- **EuPC production, downstream use of master batch (different substances)**
- **FEICA 2K-Epoxy Adhesives in professional and consumer use**

RIP 3.2-2: Task IV Case Studies

ECB-4: AISE:

Scope

3 Working Groups

1. **Household Washing/Cleaning**
2. **Professional Washing/Cleaning**
3. **Air Care & Other Vaporizing Products**

Substances in final use (surfactant, fragrance component, solvent) of a cleaning product

RIP 3.2-2: Task IV Case Studies

ECB-4: AISE:

Focus

Description of uses and conditions of use

- **Matrix model for systematic description of uses & use conditions**
- **Grouping of similar exposure patterns to relevant Exposure Scenarios**
- **Number of A.I.S.E. Exposure Scenarios to be developed not yet know**

RIP 3.2-2: Task IV Case Studies

ECB-4: CEPE screen printing (total life cycle)

Scope & Focus	User categories ð Key Exposure / Emission routes
• Manufacture of solvent borne and UV curable screen printing inks	• Industrial ð workplace, environment
• Application of solvent borne and UV curable screen inks	• Industrial, Professional ð workplace, environmental
• Printed article service life	•Public ð consumer exposure, environment
• Recycling of printed articles	•Industrial ð workplace, environment

RIP 3.2-2: Task IV Case Studies

ECB-4: EuPC

Scope & Focus

EuPC production, downstream use of master batch (different substances): additives in plastic compounding and plastic conversion

- **A masterbatch based on PVC polymer or the manufacture of cable sheathing**
  - ð **all life cycle stages**
  - ð **Note: recycling during manufacture and article end of life**
- **An additive masterbatch based on HDPE polymer and used as an anti-static additive in food and other packaging.**
  - ð **consumer exposure life cycle stage**

RIP 3.2-2: Task IV Case Studies

ECB-4: FEICA

FEICA 2K-Epoxy Adhesives in professional and consumer use

Two types of preparations are used in the process:

i) epoxy-component

ii) hardener-component.

RIP 3.2-2: Other Case Studies

Why

- Assess progress of non-facilitated case studies
- Broaden experience in industry as part of the extra effort to prepare for REACH

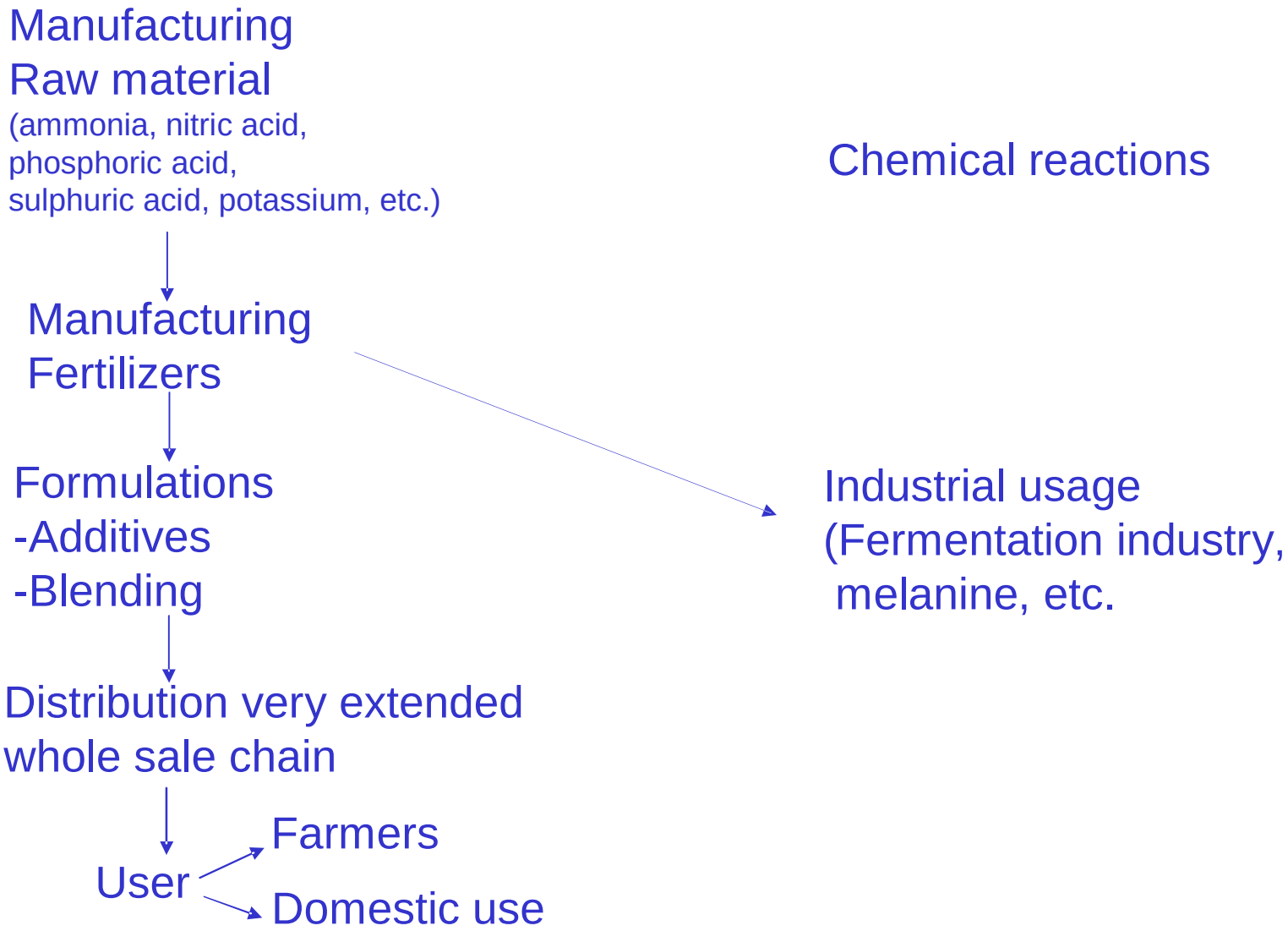
RIP 3.2-2: Other Case studies

- **Cefic-7 Other Case Studies**

  Confirmed
  Eurometaux
  CEPE (painting and coatings)
  Lucite (acrylate & methacrylate)
  Dystar (leather and textile dyes)
  CEPI / EPCG (paper industry)
  Yara (Fertilizers)
  ATIEL (lubricants)

RIP 3.2-2: Other case studies

§ Cefic-7 Other Case Studies

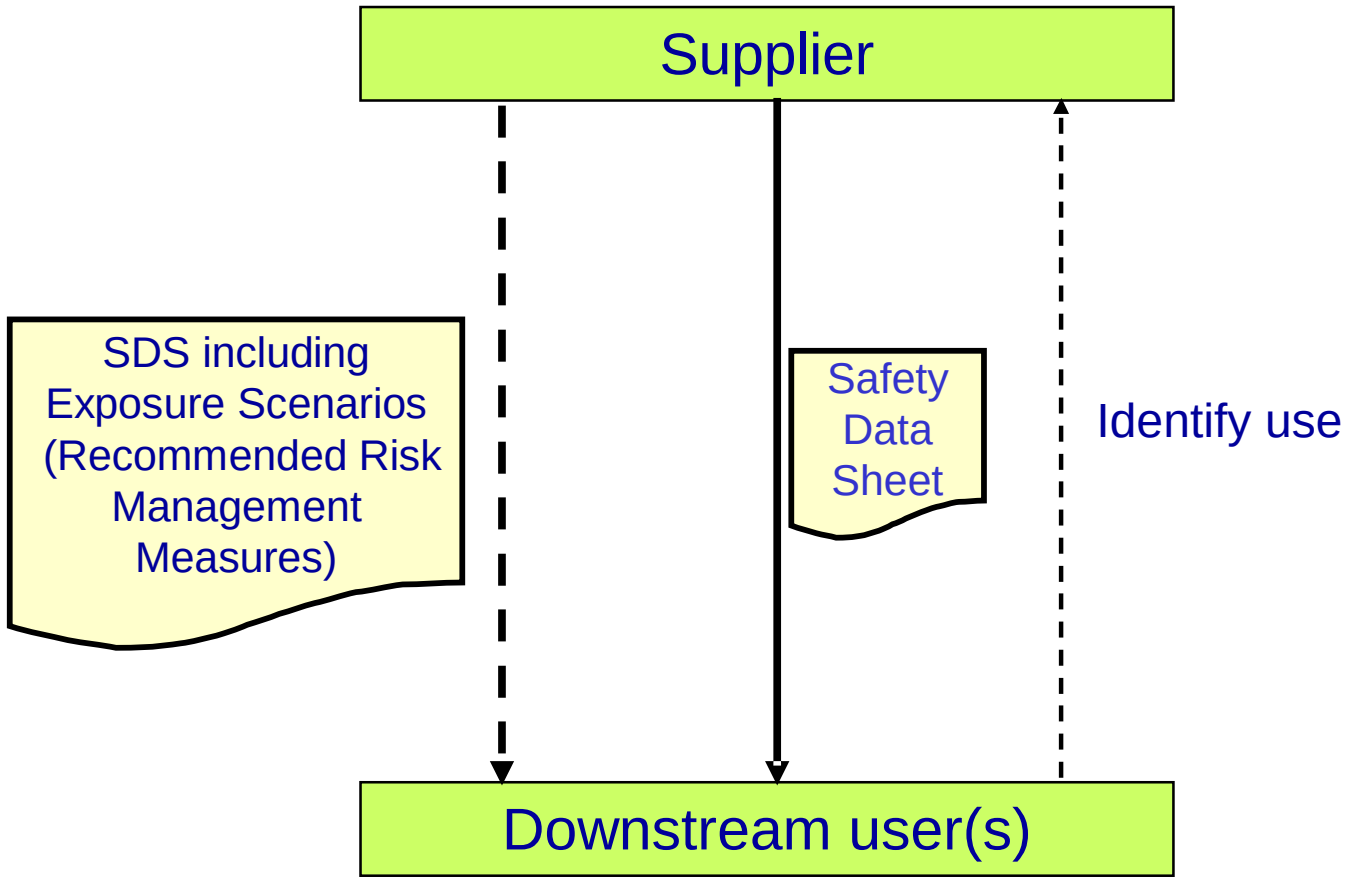


RIP 3.2-2: Case studies

Some observations

- ECB-4 core case studies
  - Bottom up approach
  - Mainly DU, followed by formulators, few manufacturers
- Cefic-7 other case studies
  - Top down approach
  - Mainly manufacturers, some formulators and distributors, few DU

Supply chain communication



Objective of RIP 3.3

Guidance for industry on

how to fulfill the information requirements **on intrinsic properties (Annex VI to XI) and**

how to use all information **and testing in an optimal way for decision-making under REACH**

- **Carry out Chemical Safety Assessment (CSA)**
  - **includes whether substance is PBT or vPvB**

- **Classification and labelling**
  - **includes assessment whether a substances is CMR**

RIP 3.3-2 Information requirements on intrinsic properties

General requirements

- **Annex VI**

Requirements depending on tonnage

- **Annexes VII to X, Annex III**

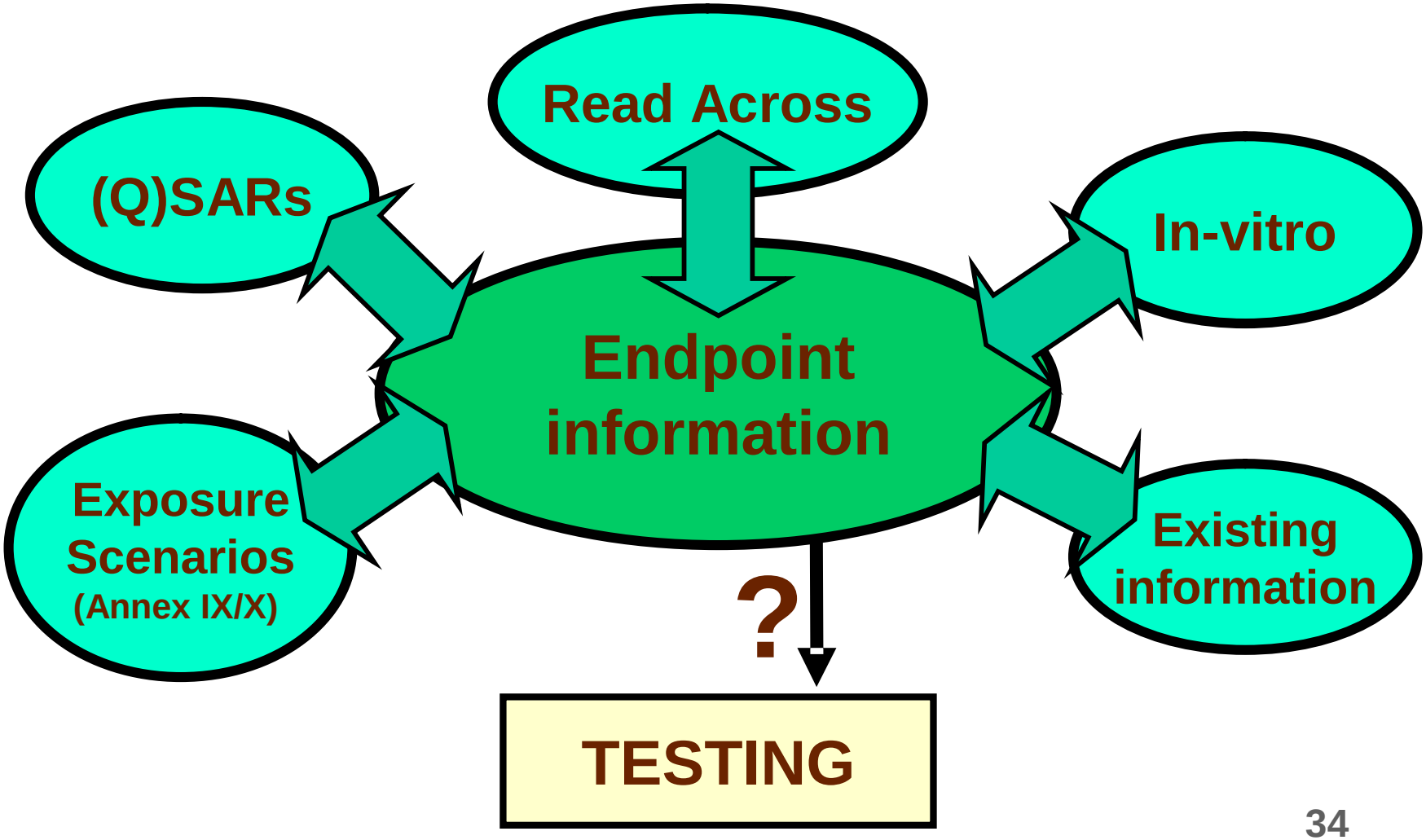
Specific adaptations for individual endpoints

- **Annexes VII to X, column 2**

General adaptations

- **Annex XI(1): Testing is not scientifically necessary**
- **Annex XI(2): Testing is technically not possible**
- **Annex XI(3): Substance-tailored exposure-driven testing**

Integrated Testing Strategies (ITS)



Process for obtaining information

- **Collect and evaluate all available information**
- **Consider information needs**
- **Identify information gaps**
- **Generate new data**

Deliverables

Guidance on strategies for generation of information on relevant inherent properties; should explain and illustrate:

- **How to find and use existing information (including human data, non GLP studies and other information obtained with non-standard test methods);**
- **How to implement the rules for adaptation as provided in the different annexes, especially for substances manufactured/imported in higher tonnages;**
- **The guidance shall provide the rationale for adaptation (waiving) from the test requirements specified in column 2 of Annexes VIII-X.**

Partners and Organisation

Cefic

- **Internal Coordination – PMG lead**

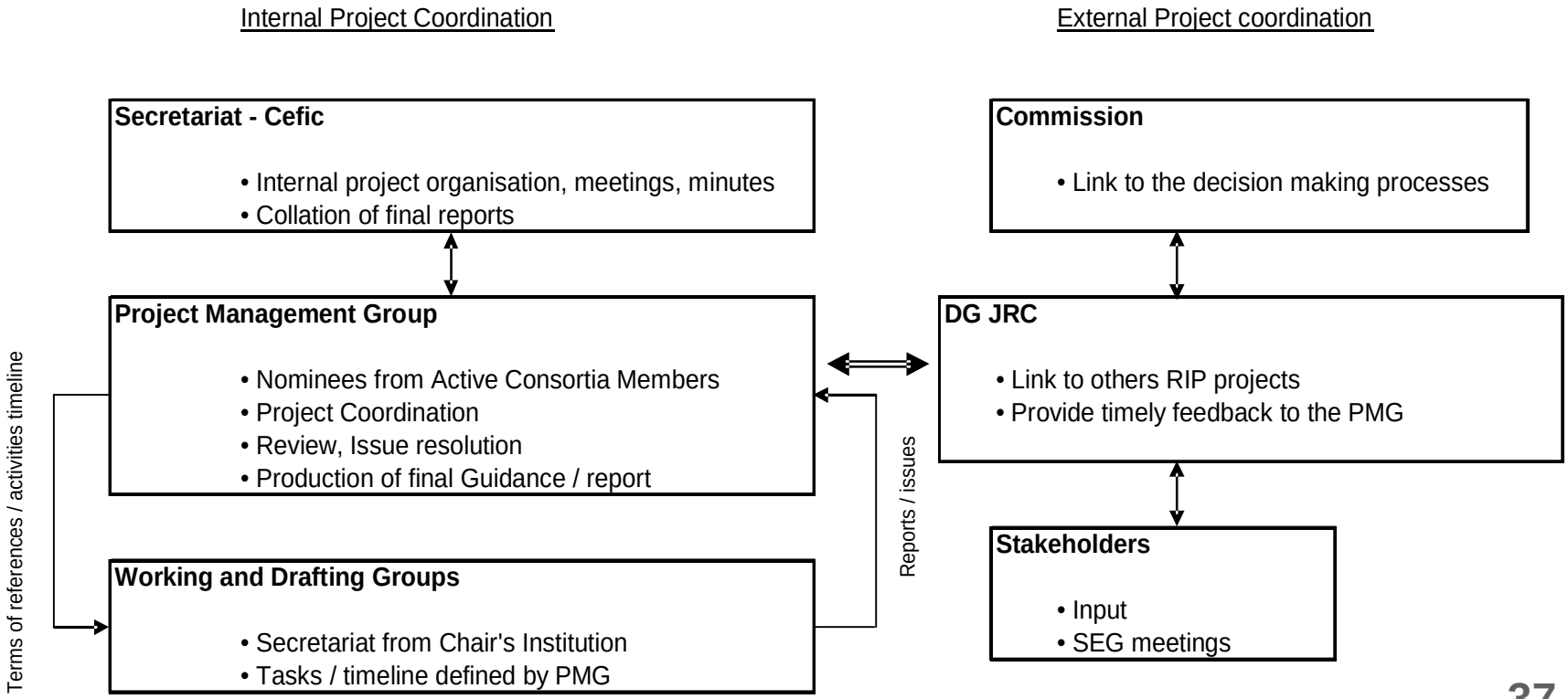
DG JRC - ECB / ECVAM

- **External Coordination – SEG lead**

DG Enterprise , DK EPA , ECETOC , INERIS, Kemi , OECD, RIVM , TNO, Environment Agency, Eurométaux , CONCAWE, (UBA)

Project Management Group

- ***Ad hoc* working groups**
- **Endpoint Working Groups**



Task 1: General structure / cross-cutting issues

- **ToRs ,Templates (Human Health and Environment) and source documents for EWGs**

  Status: issued as preparatory material for the start of work by EWGs

Task 1: General structure / cross-cutting issues

- **Harmonisation of horizontal issues**
  - **Toxicokinetics**
  - **Non-standard substances**
  - **QSARs**

- **Status**
  - ***Toxicokinetics*: initial draft issued, will be updated in the light of first draft of EWGs on generics; endpoint specific aspects in EWG reports**
  - ***Non-standard substances*: document be sent to EWGs for incorporation into main EWG reports**
  - ***QSARs*: document recently prepared; through interactions with EWGs they can concentrate on quantitative aspects for their endpoints**

Task 2: Endpoint Working Groups

PURPOSE OF REACH

- Balance between ensuring high level of Human Health and Environmental protection - limitation of EU industry administrative burdens/costs in order to maintain competitiveness and innovative capacity (Council document 7524/06 AD1)

MEANS

- Providing adequate information for C&L and for carrying out CSA

HOW

- Providing integrated testing strategies.
- Minimizing animal testing

THEREFORE

- Integrated testing strategy: move from old to new strategy; tiered approach
- Guidance which is accessible and understandable for non-expert
- Scientifically robust but practical

NOTE: this helps the formation of SIEFs

Task 2: Development of Guidance & ITS for Specific Endpoints

Deliverables:

Guidance on identifying information sources and how to ensure the reliability of the used information (generic aspects part of Task 1);

A testing strategy to help registrants provide adequate and relevant information for registration sufficient for

- C&L,
- carrying out a Chemical Safety Assessment
- assessing whether a substance is CMR, PBT or vPvB;

Guidance on when and how to use alternative information (instead of (animal) testing) including guidance on what is “adequate and reliable documentation”;

Task 2: Development of Guidance & ITS for Specific Endpoints (1)

EWG N°	Description	Leader	First Reviewer
1	**Physico-chemical properties; adsorption /desorption**	**E. Mombelli**	**M. Penman**
2	**Skin and eye Irritation/corrosion / respiratory irritation**	**V. Zuang**	**B. Hakkert**
3	**Skin and Respiratory Sensitisation**	**M. van Zijverden**	**J. Wilmer**
4	**Acute toxicity**	**S. Tissot**	**B. Hakkert**
5	**Repeat Dose Toxicity**	**G. Veenstra**	**D. Owen**
6	**Reproductive and Developmental Toxicity**	**P. Ridgway**	**M. Kayser**

Task 2: Development of Guidance & ITS for Specific Endpoints (2)

EWG N°	Description	Leader	First Reviewer
7a	**Mutagenicity**	**H. Cederberg**	**M. Penman**
7b	**Carcinogenicity**	**H. Cederberg**	**T. Hartung**
8	**Aquatic toxicity / long term toxicity to sediment organisms**	**J. Ahlers**	**B. Diderich/H. Tyle**
9	**Degradation / Biodegradation**	**J. Snape**	**I. Lundbergh**
10	**Bioconcentration accumulation / long term toxicity to birds**	**S. Dungey**	**S. Dungey/D. Sijm**
11	**Effects on terrestrial organisms**		

Task 3: Guidance on Chemical Categories / Grouping of Substances

Develop non-prescriptive guidance:

1. **explanation of key concepts: SARs, read-across and categories (including sub-categories)**
2. **how to perform qualitative and quantitative read-across**
3. **how to build a category (including special cases)**
4. **how to justify and report the "adequacy" of a read-across or category proposal ð appropriate reporting formats**

Status: 6 consensus chapters + >10 individual appendices
Submission to PMG by 2 October

Task 4 – Preparation of draft TGD

Specific objective: To combine all the input from the Working Groups into the overall Technical Guidance Document

Deliverables:

- **final draft of the Technical Guidance for RIP 3.3**

Status:

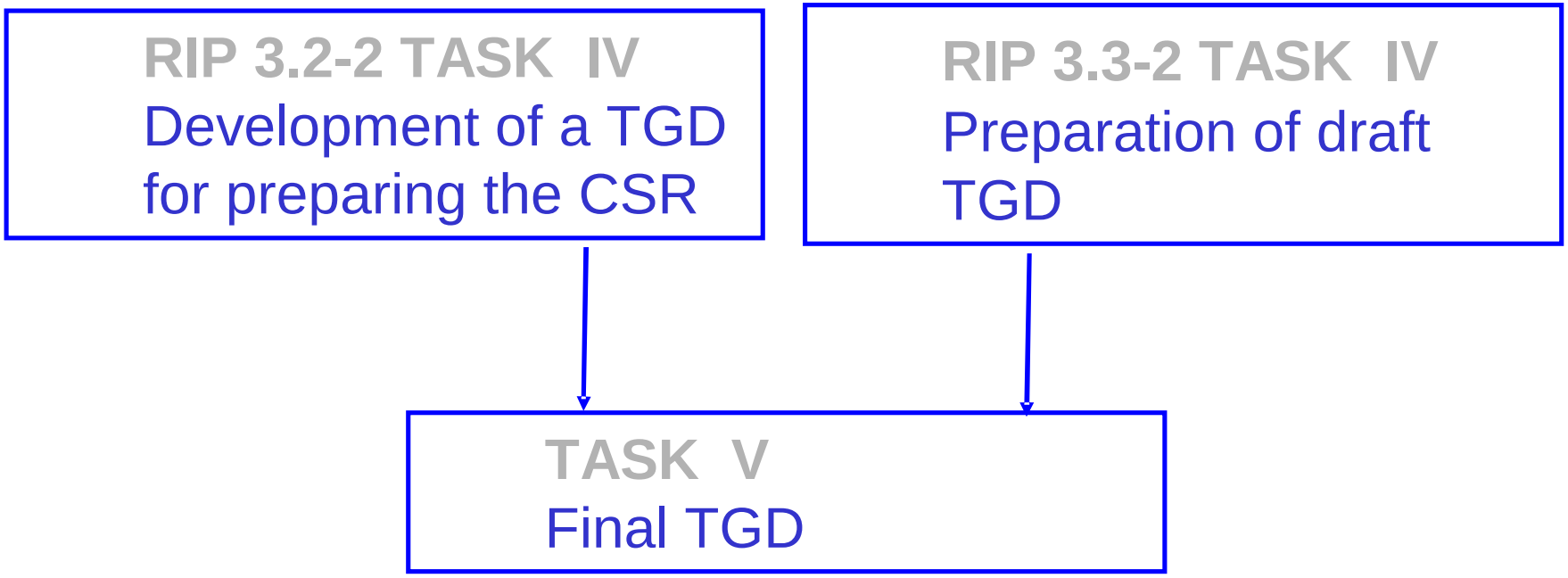
Task 1 Drafting Group is already engaged in defining the structure and generic content of the overall TGD Information Requirements, liaising with RIP 3.2 to ensure compatibility

Next steps and Timeline

REACH Implementation Project (RIP) 3.3 Phase 2
Overall timeline deliverables

	2006												2007											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
CWG meeting									27		23-24													
SEG II meeting							6-7																	
"Oct package to SEG"																								
SEG III meeting												20-21												
Collated SEG feedback to EWG													19											
SEG IV written procedure																								
Final drafts to SEG for comments														m										
Final comments from SEG to EWG															b									
Final documents to ECB for CWG																2								

RIP 3.2-2 & RIP 3.3-2 dependency



What else is Cefic doing (i)

- Engage with the various sectors and branches
- Regular Awareness Workshops
- Newsletters • Suggested actions

What else is Cefic doing (ii)
What to do now?

Manufacturer/importer

Make inventory of substances and preparations that you produce or import.

Per substance:

- **What is your role in the supply chain. (own producer, produced in EU or importer)**
- **Overview of your customers**
- **Overview of composition and tonnages**
- **Collect all substance data**
- **Start identifying uses in the supply chain**

What else is Cefic doing (iii)
What to do now?

Distributor

Inventory of substances and preparation that you distribute

- **Overview of your suppliers**
- **Overview of your customers**
- **Warn customers and suppliers on REACH and future needs**
- **Try to collect usage data**
- **Check if your supplier will pre -registrer**

What else is Cefic doing (iv) What to do now?

User

Overview of substances you work with

- List your suppliers
- § Collect exposure information
- § Identified use in pre registration?
- § Overview of your customers
- § Warn customers and suppliers on REACH and future needs

What else is Cefic doing (vi)

- Developing templates, standard letters, questionnaire
- Setting up helpdesk
- Q&A’s
- REACH presentation/training in many workshops, symposia, etc.
- ReachCentrum

How to get involved

- Case studies require input and support
  - Manufacturers
  - Importers
  - Distributor
  - Downstream User
- Become part of the guidance testing groups

Thank you for your attention