

Communication in the Supply Chain

How to prepare for Registration

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Communication in the Supply Chain Overview

- **Definition Use**
- **Scope of Downstream User**
- **Basic Information Needs**
- **Identified Use**
- **Start of Communication in the Supply Chain**
- **Use and Exposure Communication**
- **Extended Safety Data Sheet**
- **Further Communication Obligations**
- **Check of Compliance with Supplier`s ES**
- **The Formulator**
- **Communication Upwards**

REACH – Definition “Use”

Article 3. 24

- **Processing**
- **Formulation**
- **Consumption**
- **Storage**
- **Keeping**
- **Treatment**
- **Filling into containers**
- **Transfer from one container into another**
- **Mixing**
- **Production of an article**
- **any other utilisation**

REACH – Scope of “Downstream User”

Article 3. 12

Industrial / professional users

- incl. formulators
- incl. manufacturers of articles
- incl. fillers
- incl. re-importers
- incl. importers where an only representative is established by the non-EU manufacturer

No Downstream Users are

- Consumers
- Traders and distributors
- Transporters (outside the scope of REACH)
- Any user outside the EU

Which substances do I use and how are they used?

Establishment of a substance inventory

- Substances as such
- Substances in preparations
- Substances in articles

Identification of suppliers / manufacturers

Assignment of my role for each substance

Use of the substance – own and along the supply chain

- Volumes
- Probable exposure routes
- Fate of the substance – life cycle steps

REACH – “Identified Use”

Definition Article 3.26

Means a **use of a substance** on its own or in a preparation, or a use of a preparation, that is intended by an actor **in the supply chain**, including his own use, ...

Article 37

- Any **downstream user** shall have the right **to make a use**, as a minimum the brief general description of use, **known in writing to the manufacturer, importer downstream user or distributor** ... with the aim of making this an identified use. ..., he shall **provide sufficient information** to allow ... **to prepare an exposure scenario**, or if appropriate a use and exposure category for his use in the ... chemical safety assessment

REACH – “Identified Use”

- **Distributors shall pass on such information** to the next actor or distributor up the supply chain.
- Where the **manufacturer** ... having assessed the use in accordance with Article 14, is **unable to include it for reasons of protection of human health or the environment**, he shall **provide** the Agency and the downstream user with the **reasons** for that decision
- A **downstream user** of a substance ... shall **prepare a chemical safety report** in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet **or for any use his supplier advises against.**

Identified Use

State of Discussion in RIP 3.2-2

For Technical Dossier and Exposure Scenarios

„*a brief general description of use*“ is needed

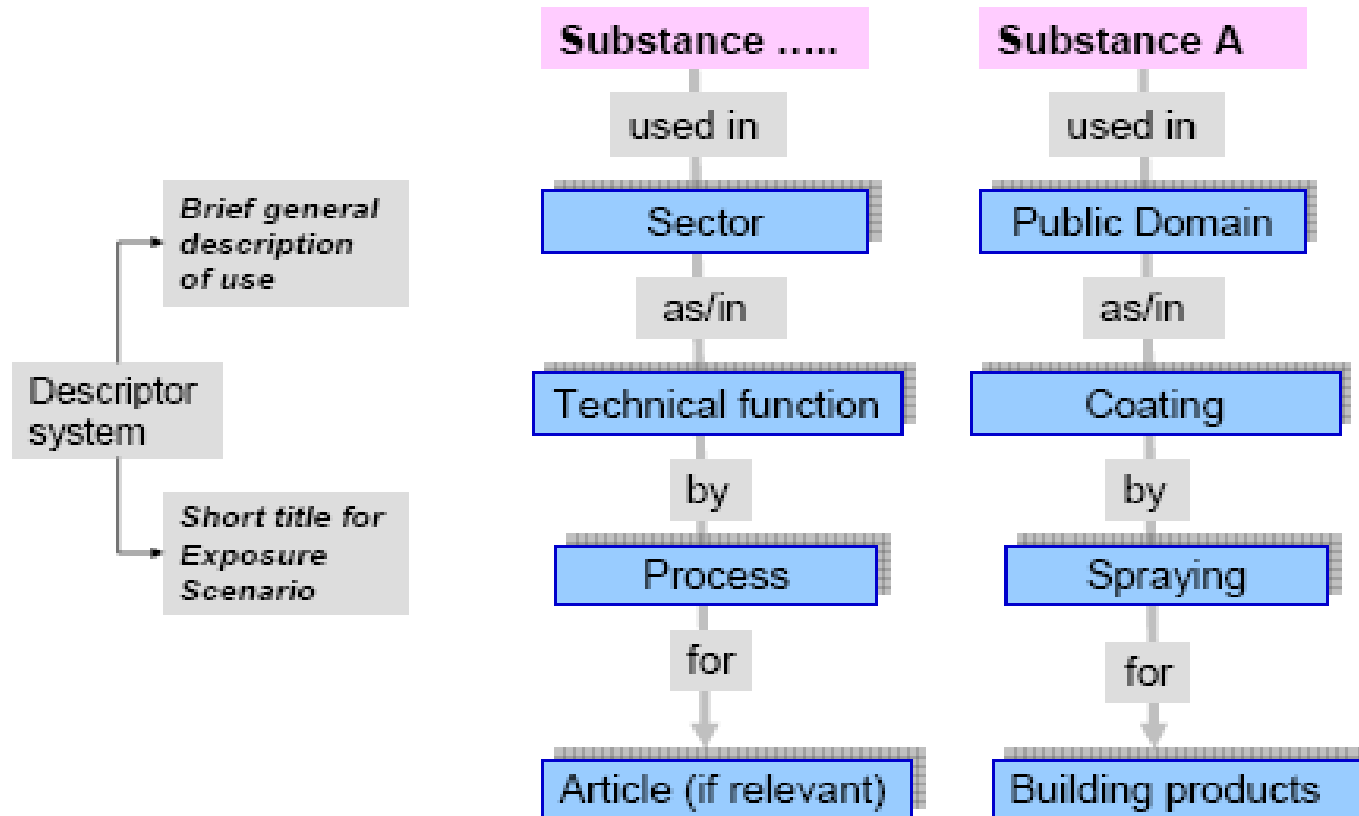
4 Levels of Descriptors:

- Service and **industry sectors**, incl. private households and public domain (NACE code)
- **Technical function** / purpose of substance or prep.
- Type of **technical process**
- **Type of article** into which it is manufactured

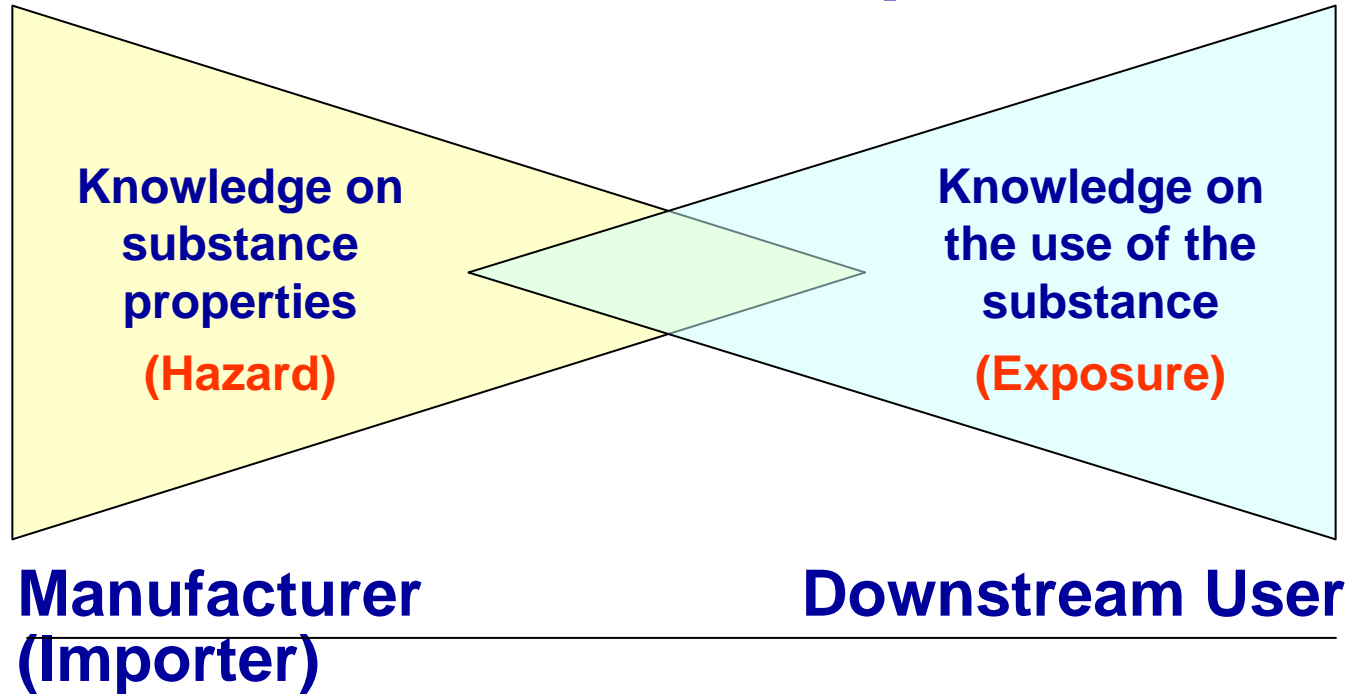
Identified Use

State of Discussion in RIP 3.2-2 – cTGD Part D1

Standard Descriptor System



New under REACH : Description of safe use



Sources for information on use and exposure:

- In-house handling and use of substances
- Customers
- Industry and branchspecific associations
- Standard Exposure Scenarios
- Existing exposure calculation models

Starting Communication in the Supply Chain

VCI / CEFIC Questionnaires

- Downstream User / Customer => Supplier
- Supplier => Downstream User / Customer
- Questions regarding (Pre-) Registration
- Questions regarding generic use / exposure

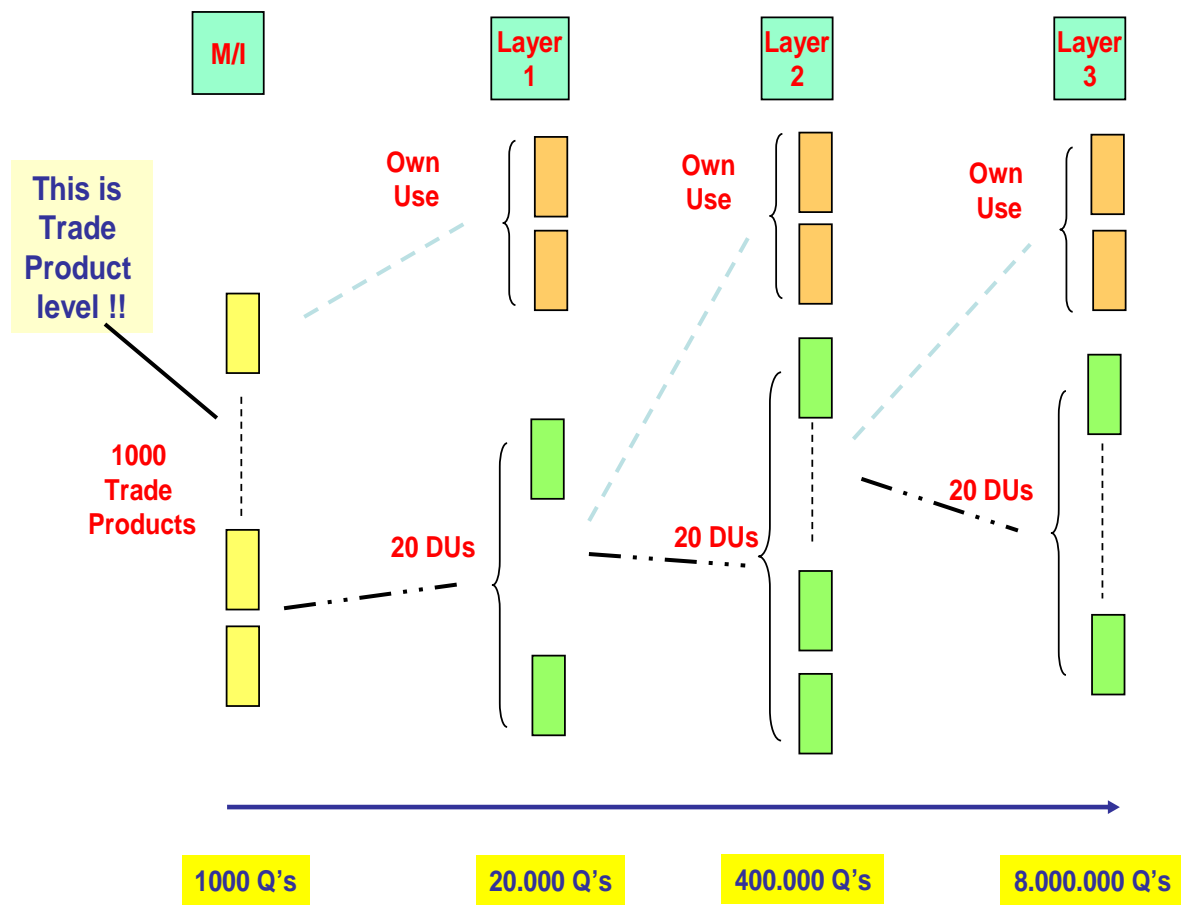
CEFIC is proposing an IT tool to support Questionnaires

Wait sending / completing Questionnaires regarding use and exposure information at least until Pre-Registration
!

(Use and exposure information is not part of the Pre-Registration)

Communication in the Supply Chain

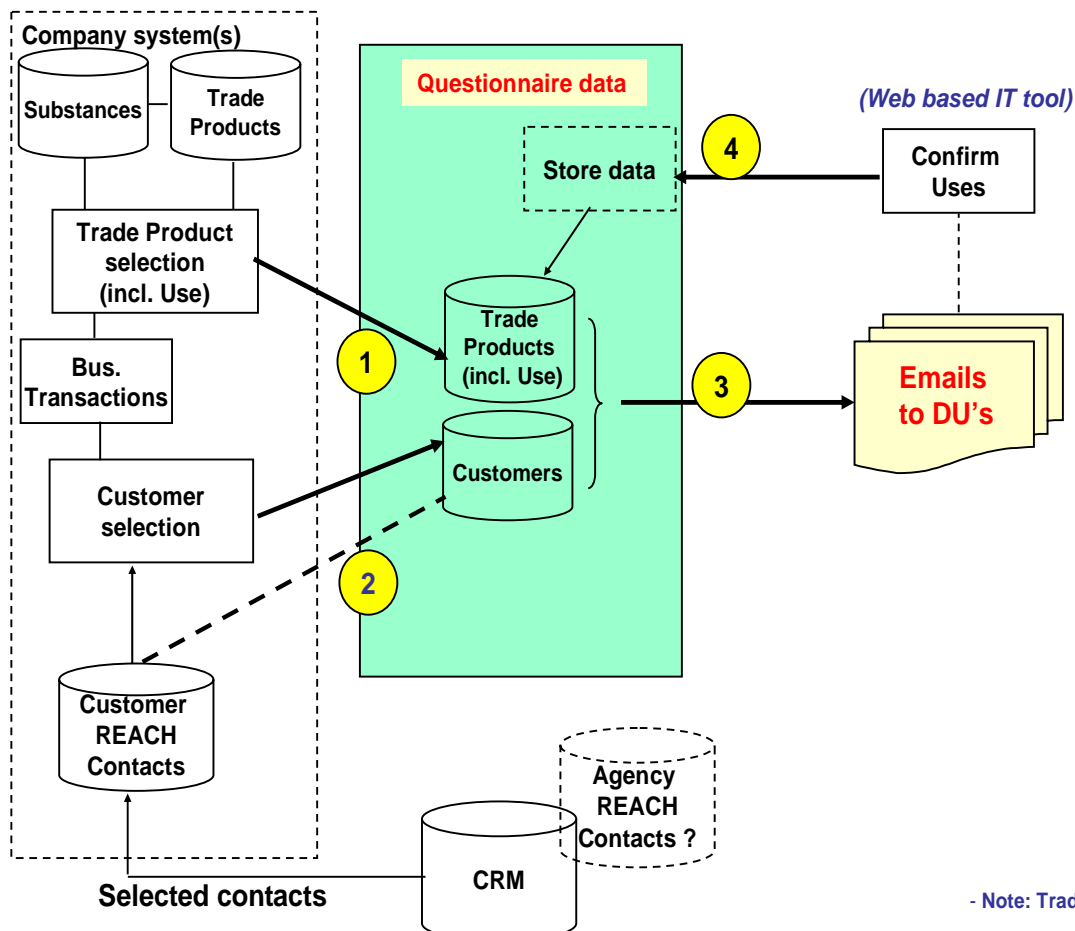
Questionnaire from Supplier to DU



CEFIC

Communication in the Supply Chain

Part III – Questions from Supplier to Downstream User: Alternative process



CEFIC

- Note: Trade Product may

Questionnaire DU => Supplier

- Productspecific
- Substance, Polymer, Preparation, Article ?

Part I

1. Can we assume that the **substances contained** in the product requiring registration, **will be pre-registered** by your company / upstream supplier?
2. Can we assume that the **substances contained** in the product requiring registration, **will be registered?**
3. If 1 or 2 are answered with "yes": mark the **crucial REACH registration deadlines**

Part II

1. Which of the **uses / exposures** listed in the Annex will you **include** in the Registration? (mark +)
2. Which of the **uses / exposures** listed in the Annex will you probably **not support** in the future? (mark -)

Questionnaire Supplier => DU

- **Productspecific**

1. Are all future **uses < 1 t/a or exempted** from Registration?
2. Is the product **used in open / closed system** or used as a **transported intermediate**?
3. Mark in the Annex the **required uses and exposures**
4. Are you in the possession of **information on type and amount of exposure** (data, experiences etc), regarding the uses and exposures listed
5. Are you in the possession of experiences, data or **information on** appropriate, sector-specific **risk management measures** (no general measures!), referring to the uses and exposures listed in the Annex (e.g. studies on suitable glove material)?

Use and Exposure Categories

Example – Manufacture of an industrial adhesive (VCI)

Work step	Exposure	Matrix element
Cleaning of vessel and stirrer	Respiration Environment	16 28
Feeding of adhesive components	Skin	7 not volatile
	Respiration	(10, volatile)
	Environment	16 28
Mixing	Respiration	16
	Environment	28
Filling in prescribed transport containers	Respiration	16
	Skin	7
	Environment	28
Storage, dispatch	--	--
Disposal of adhesive residues etc.	Environment	34
	Skin	7

	Industrial	professional	consumer
Human: Oral, Short-term	1	2	3
Human: Oral Long-term / repeated	4	5	6
Human: Dermal Short-term	7 X	8	9
Human: Dermal Long-term / repeated	10 X	11	12
Human: Inhalation Short-term	13	14	15
Human: Inhalation Long-term / repeated	16 X	17	18
Environment: Water, single instance / Short-term	19	20	21
Environment: Water, continuous	22	23	24
Environment: Air, single instance / Short-term	25	26	27
Environment: Air, continuous	28 X	29	30
Environment: Soil, single instance/ Short-term	31	32	33
Environment: Soil, continuous	34 X	35	36

“Extended Safety Data Sheet”

Major source of information for the Downstream User

The „e-SDS“ will have supplemental information

- Information on „identified use“
- Information on „uses advised against“
- Exposure Scenarios / Use and Exposure Categories describing the safe use of a substance
- Information on Authorisation and Restrictions

But,

- SDS not mandatory for all substances (Information acc. Art. 32)
- „e-SDS“ starting with Registration only – Content unsystematic
- No „e-SDS“ if no Registration required
- Permanent adaptation required – new ES / UEC, new DNEL / PNEC
- Further adaptations due to parallel implementation of GHS

Communication in the supply chain - Further new obligations

- If a Downstream user is not compliant with received ES
 - **Inform supplier** on new uses
 - Prepare own CSR (if > 1 t/a) incl. **ES for e-SDS**
 - If no CSR required (< 1 t/a or PPORD), **inform the Agency**
- A downstream user has to **inform the supplier** on new information on hazardous properties or inappropriate RMM
- Formulators to **consolidate ES / UEC** for e-SDS (**or pass on all**)
- Distributors to **pass on all information** upwards and downwards
- Downstream users to **inform the Agency** on any use of an authorised substance; submit own Authorisation if necessary
- Manufacturers of articles to **notify the Agency** if the article contains an authorised substance > 0.1 % and provide **information on safe use to customers (consumers on request)**

Check of Compliance with Supplier`s ES

RIP 3.5 Draft Technical Guidance Document new WF3-1

Is the use an „identified use“?

Is the use an „use advised against“?

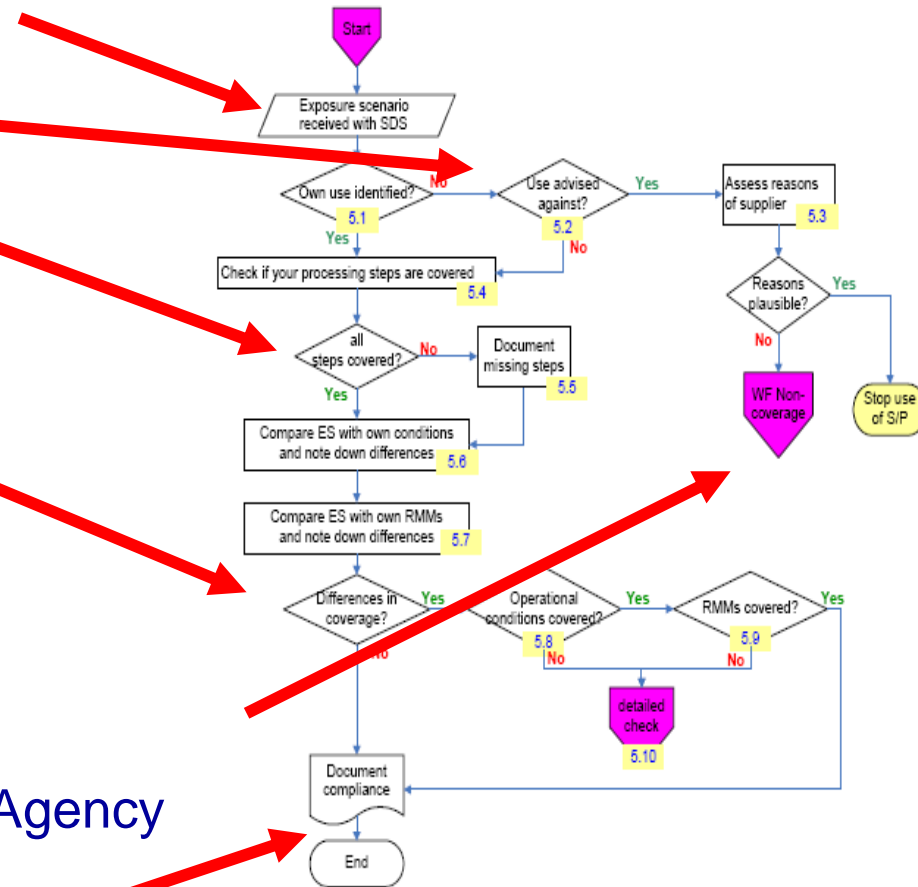
Are all Processes / Conditions of Use described?

Are RMM sufficient?

If not,

- Return to supplier
- Adaptation to CoU in ES, RMM
- Search for another supplier
- DU CSR on own use
- Notice on new exposure to the Agency

Documentation of compliance with ES



Integrative risk control indicator for Systemic Exposure via Skin– Modeling concentrations for open use of a substance (FEICA, Henkel)

Assumptions:

- Skin is exposed to the neat substance
- DNEL reflects systemic effects
- K_p is the skin permeation coefficient, estimated or measured

Integrative dermal risk control indicator S_{Safe}
 is skin surface area which can be exposed such that $MoE=1$

Allows for Scaling (generic => specific) due to changes in OC, RMM, PP

$$S_{Safe,IP} = \frac{DNEL_{systemic,IP}}{K_{P,IP}} \times \frac{BW}{t \times n} \times \frac{1}{(1 - E_{RMM})} \times \frac{1}{C}$$

Integrative risk control indicator

Substance properties

Operational conditions

RMM

Product Properties

Exposure Scenario delivered by Substance Supplier: Abbreviated Example for Isopropanol (FEICA, Henkel)

EXPOSURE		USE			
		Industrial	Professional	Consumer	
Human	<u>Oral</u>	Short	unapplicable	unapplicable	unapplicable
		Long	unapplicable	unapplicable	unapplicable
	<u>Inhalation</u> $p^0=6050\text{Pa}$, $m=740\text{g}\times\text{m}^{-2}\times\text{h}^{-1}$, Free evaporation, $V_{\text{Room}}: 100\text{m}^3$, $q: 0,5/\text{h}$, $C=1$ (100%) $A_{\text{SafeIP}} = \frac{DNEI_{\text{IP}}}{m_{\text{IP}}} \times q_{\text{Room}} \times V_{\text{Room}} \times \frac{1}{1-E_{\text{RMM}}} \times \frac{1}{C}$	Short			
		Long (8h/d)	DNEL(mg/m ³): 500, no RMM, $A_{\text{Safe}}:0.03\text{m}^2$	DNEL(mg/m ³): 500, no RMM, $A_{\text{Safe}}: 0.03\text{m}^2$	DNEL(mg/m ³): 250, no RMM, $A_{\text{Safe}}:0.016\text{m}^2$
	<u>Dermal</u> Log K_{OW} : 0.05, MW: 60 g/mol, skin penetration $K_{\text{P}}=0,1$ cm/h, $C=1$ (100%) $S_{\text{SafeIP}} = \frac{DNEI_{\text{systemIP}}}{K_{\text{P,IP}}} \times \frac{BW}{t \times n} \times \frac{1}{(1-E_{\text{RMM}})} \times \frac{1}{C}$	Short	Goggles, gloves (see Chapter 8)		
		Long (3*10 min/d)	DNEL: 400mg/kg/d $S_{\text{Safe}}:20000\text{cm}^2$		

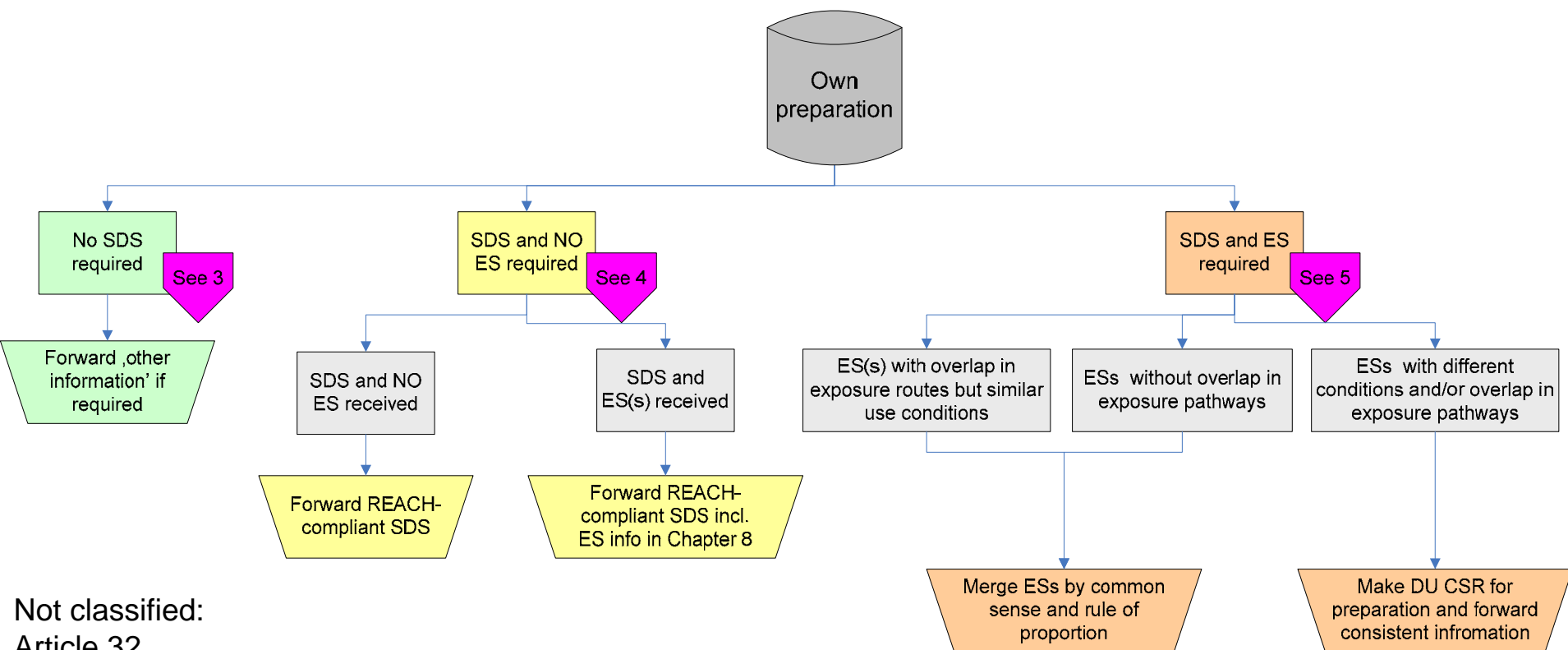
Communication by e-SDS

Latest discussions

	industrial	profession al	consu mer
Human, dermal, long term	<ol style="list-style-type: none"> 1. Limit values (DNEL, OEL, PNEC etc.) 2. Additional Information on Toxicity and Ecotoxicity (e.g.: degreasing) 3. Tool used for Exposure Assessment (Measurement, Tegewa-Tool, EUSES, ECETOC, qualitative, ...) possibly LINK to website (tools) 4. Conditions of Use for Exposure Estimation (Default-Values, set of parameters used; duration, frequency, etc.) 5. Suitable RMM (additional information on special exposure situations, e.g. spraying, etc.) 6. Threshold (lower limit) not requiring any RMM 7. Statement on Uses advised against 8. Relevant physical parameter, e.g. pressure, temperature, etc 		

The Formulator -

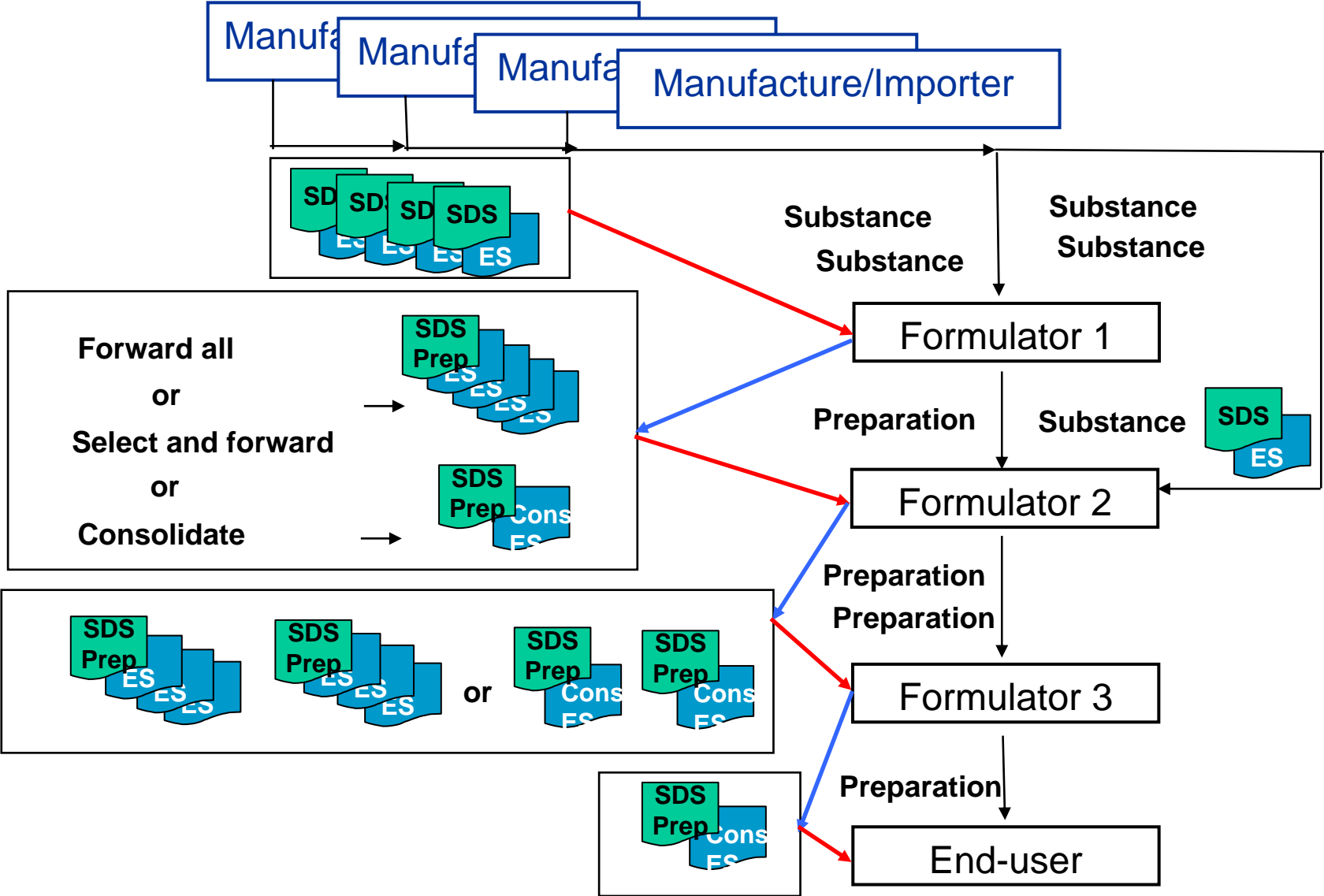
When to prepare SDS and ES ... (RIP 3.5)



Not classified:
Article 32

To consumers
Article 31.4

The Formulator - ...and how (RIP 3.5)



The Formulator - Critical Component Approach (FEICA, RIP 3.5)

$$A_{Safe,IP} = \frac{DNEI_{IP}}{m_{IP}} \times q_{Room} \times V_{Room} \times \frac{1}{1 - E_{RMM}} \times \frac{1}{C}$$

Substance	Concentration of substance in preparation (C _{Substance}) (%)	A _{Safe} (m ²)	(A _{Safe} /C _{Substance}) x 100
1	24.3	40	1.6 x 10 ²
2	10.8	40	3.7 x 10 ²
3	7.7	0.0028	0.037
4	2.0	0.025	1.2

The critical component triggers CoU, RMM and finally the preparation's ES

Communication of new Information upwards

RIP 3.5 Draft Technical Guidance Document new WF2-1

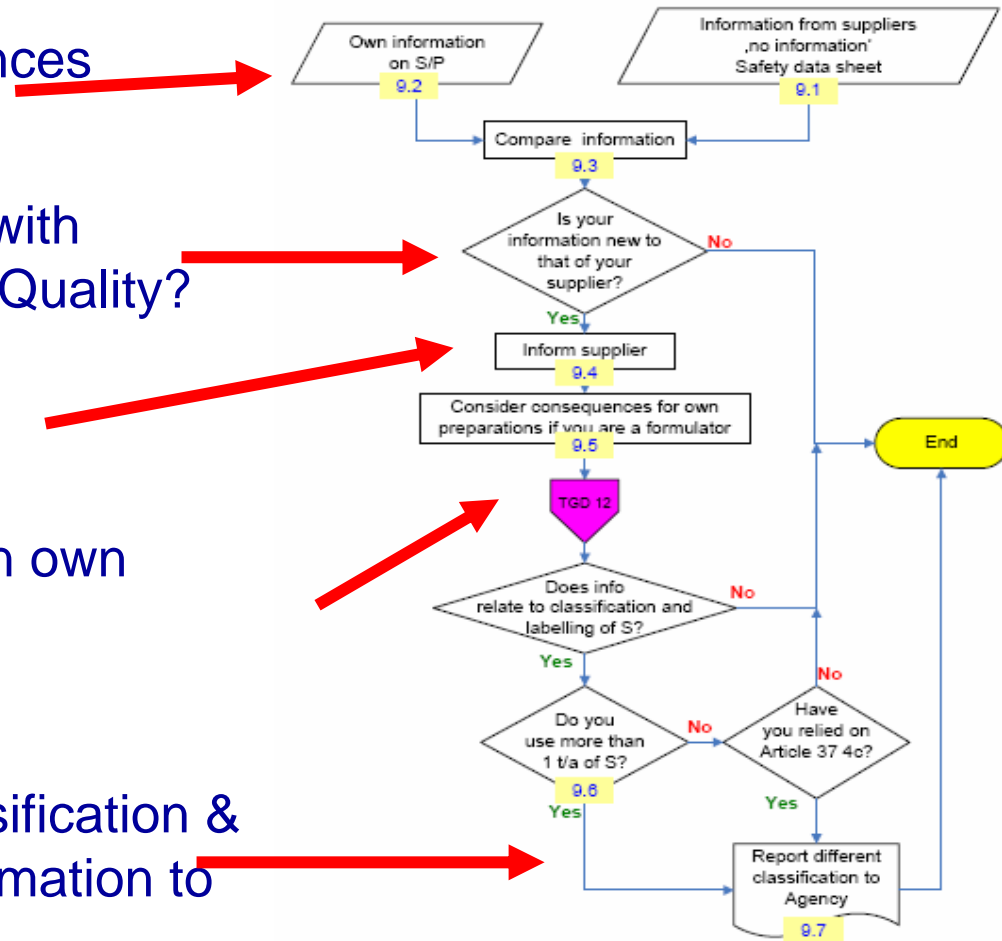
Own new information on substances and preparations available?

Comparison of own information with information of the supplier. New Quality?

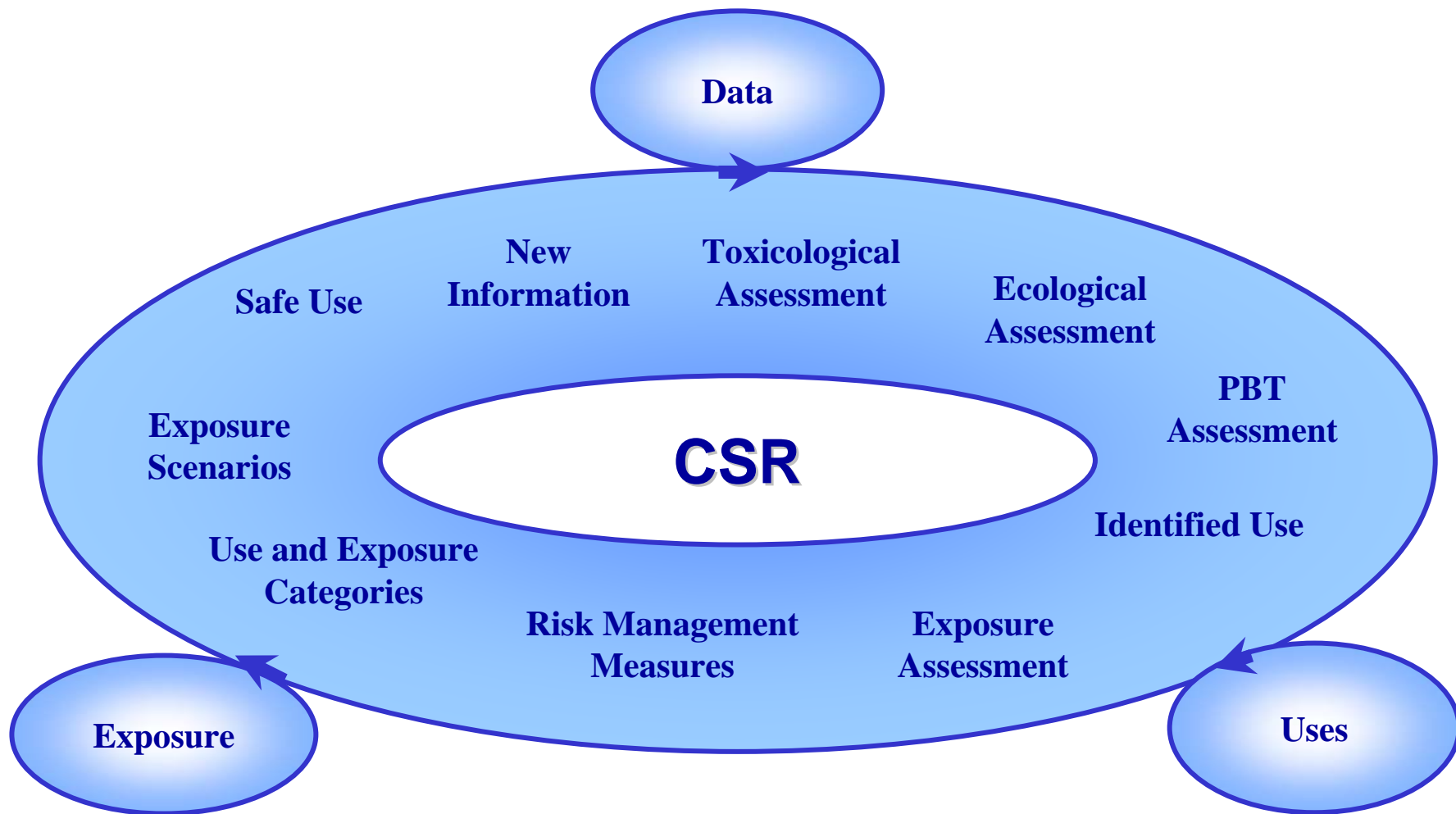
Information of the supplier on new information

Assessment of consequences on own substances` SDS and when formulating preparations

If consequences regarding Classification & Labelling occur, submit this information to the Agency (only > 1 t/a)



Chemical Safety Report and Communication



**Thank you for your
attention !**

Do you have questions?