



Improving safe use in the supply chain

Safer Chemicals – ECHA Conference

22 May 2019

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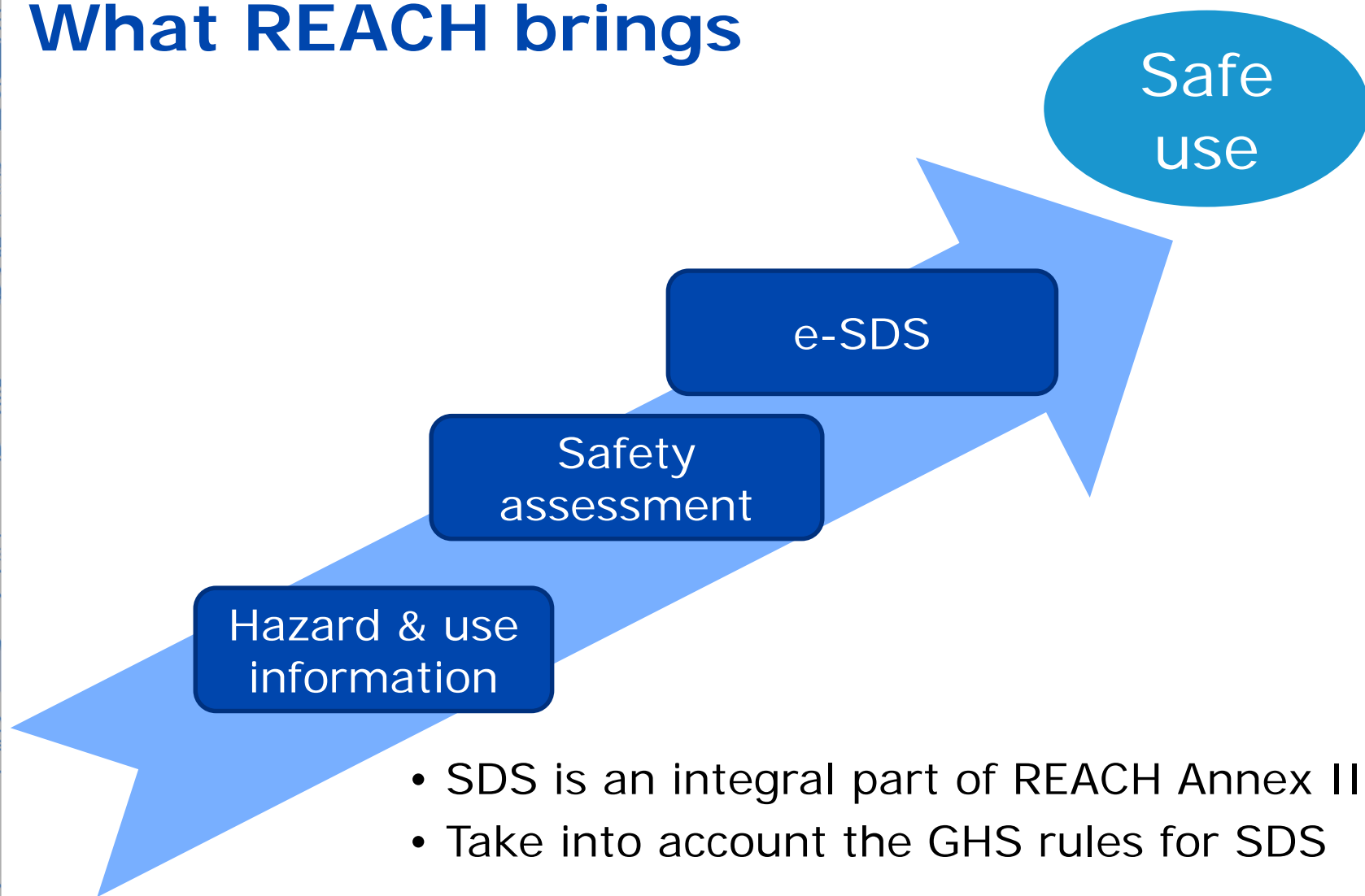
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Content

- REACH chemicals safety assessment
- Supply chain mechanisms
- Current tools and methods
- Obstacles identified
- REACH review action 3

What REACH brings



- SDS is an integral part of REACH Annex II
- Take into account the GHS rules for SDS

Chemical safety assessment needs information on substance properties and conditions of use

Manufacturer



Knows the properties of the substance

- Information generation
- Classification
- DNELs and PNECs

Downstream user

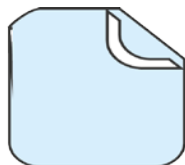


Knows how the substance is used

- Foreseen products and processes
- Concentrations and amounts
- Operational conditions
- Risk management measures
- Technical language of users

- **Exchange of information** (via supply chain or other means)
- Allocation of **assessment responsibility**
- **Capacity** to carry out the assessment

REACH introduced extended SDS



Safety Data Sheet



Exposure Scenarios

Substance-specific

- Properties and classification
- Regulatory information (e.g. registration number)
- Overview of registered uses

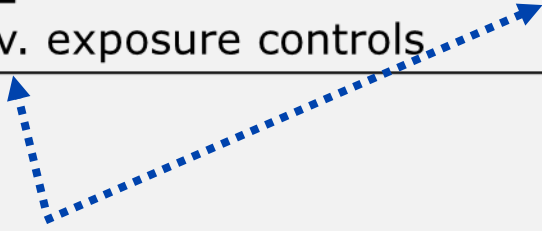
REACH defines format, content, when to provide, obligations upon receipt

Use-specific

- Operational conditions
- Risk management measures
- Exposure estimations (if relevant for recipient)

REACH defines when to provide, obligations upon receipt

Extending the safety data sheet

SDS section	SDS for substance	SDS for mixture
1.2	Functions of the substance	Technical purpose of mixture
7	Precautions for safe handling	Precautions for safe handling
8.1	Control parameters: OELs and DNELs and PNECs	Control parameters: OELs and DNELs and PNECs
8.2	Exposure controls <ul style="list-style-type: none"> • Engineering controls • PPE • Env. exposure controls 	Exposure controls <ul style="list-style-type: none"> • Engineering controls • PPE • Env. exposure controls
ES Annex	Operational conditions and risk management per use and contributing activity	

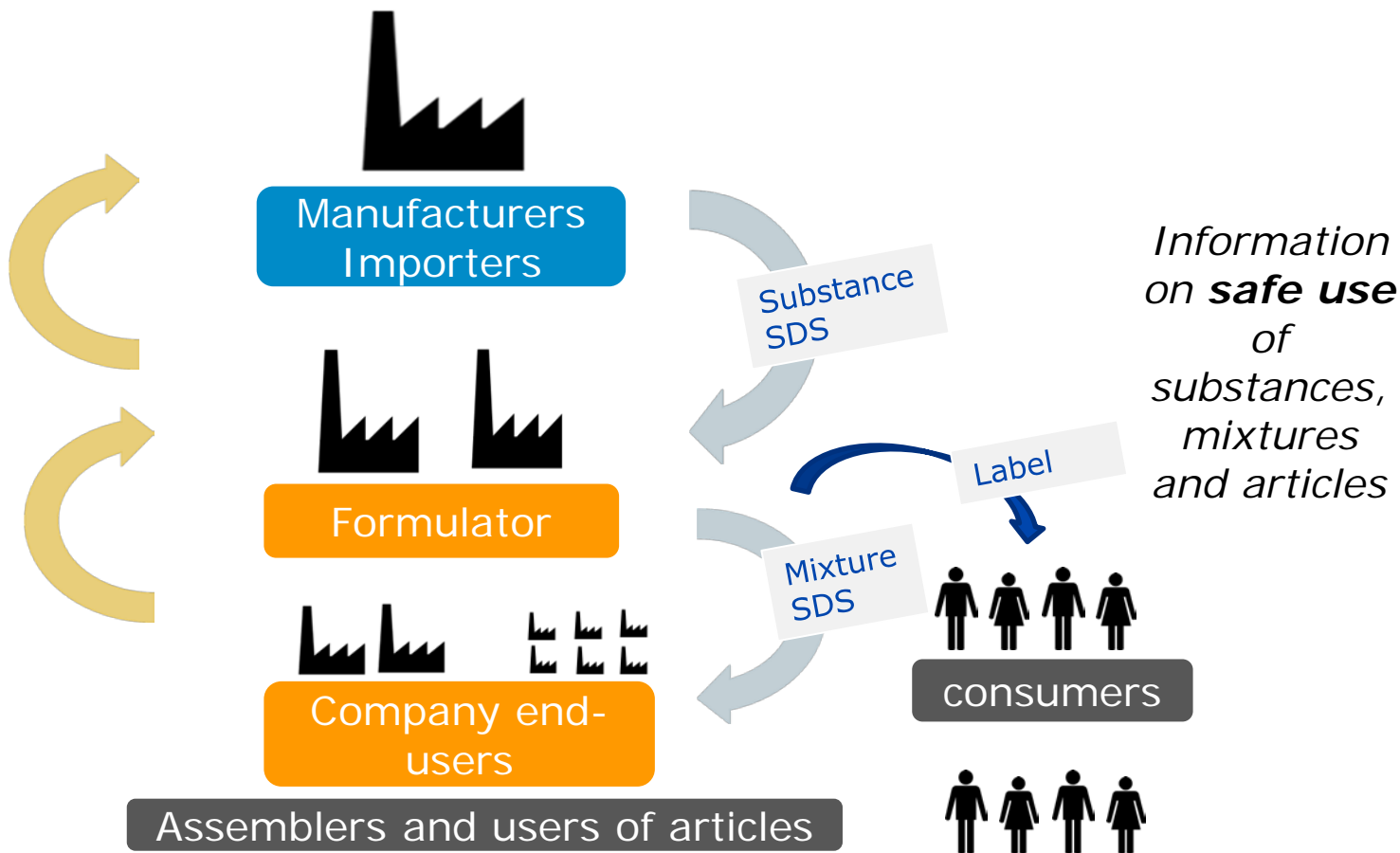
Article 31 (7)

Include ES and other relevant information

Supply chain communication

Sectors

Individual companies



Individual companies

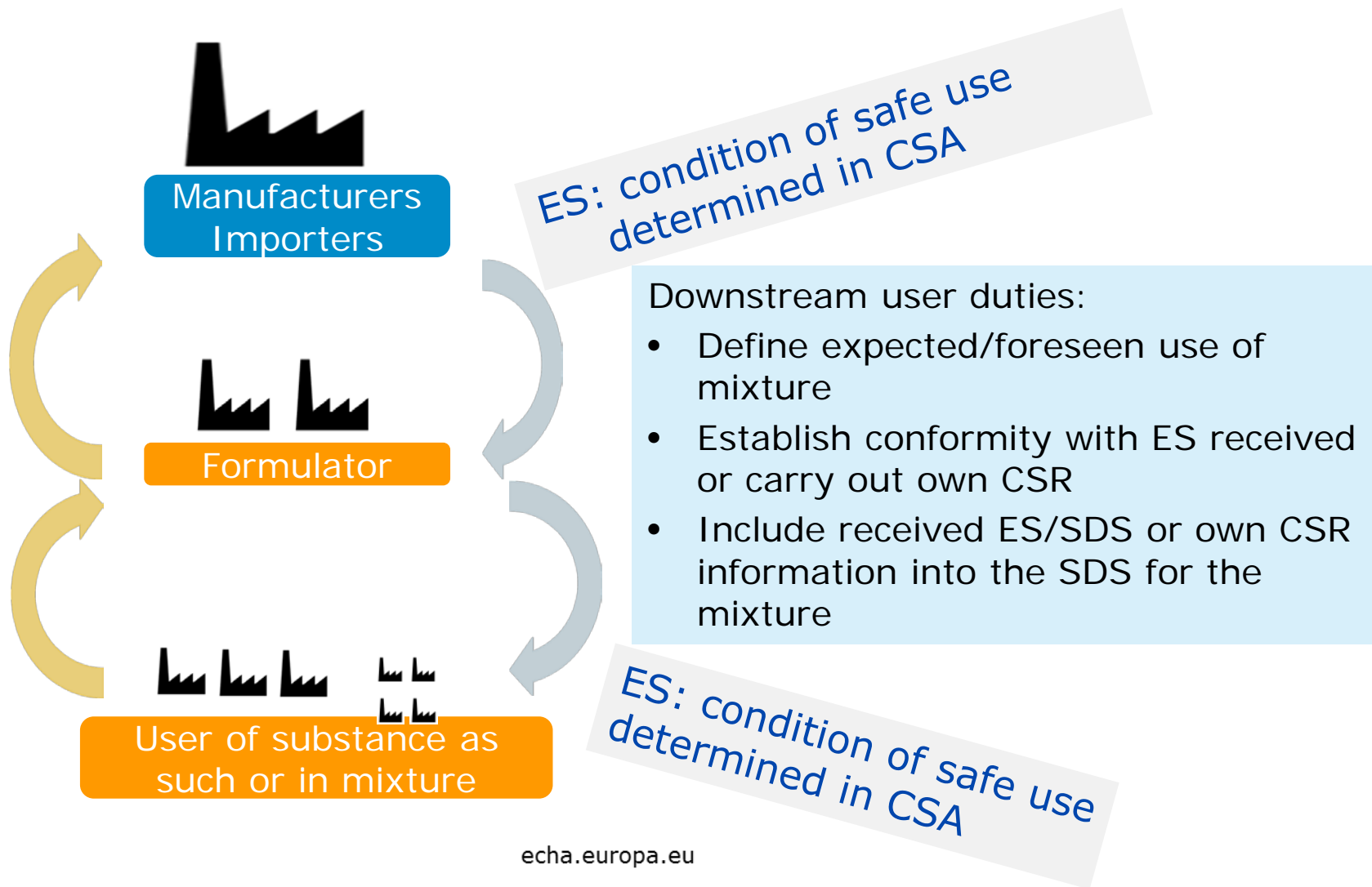
Information needs

“Assessment” tasks of companies

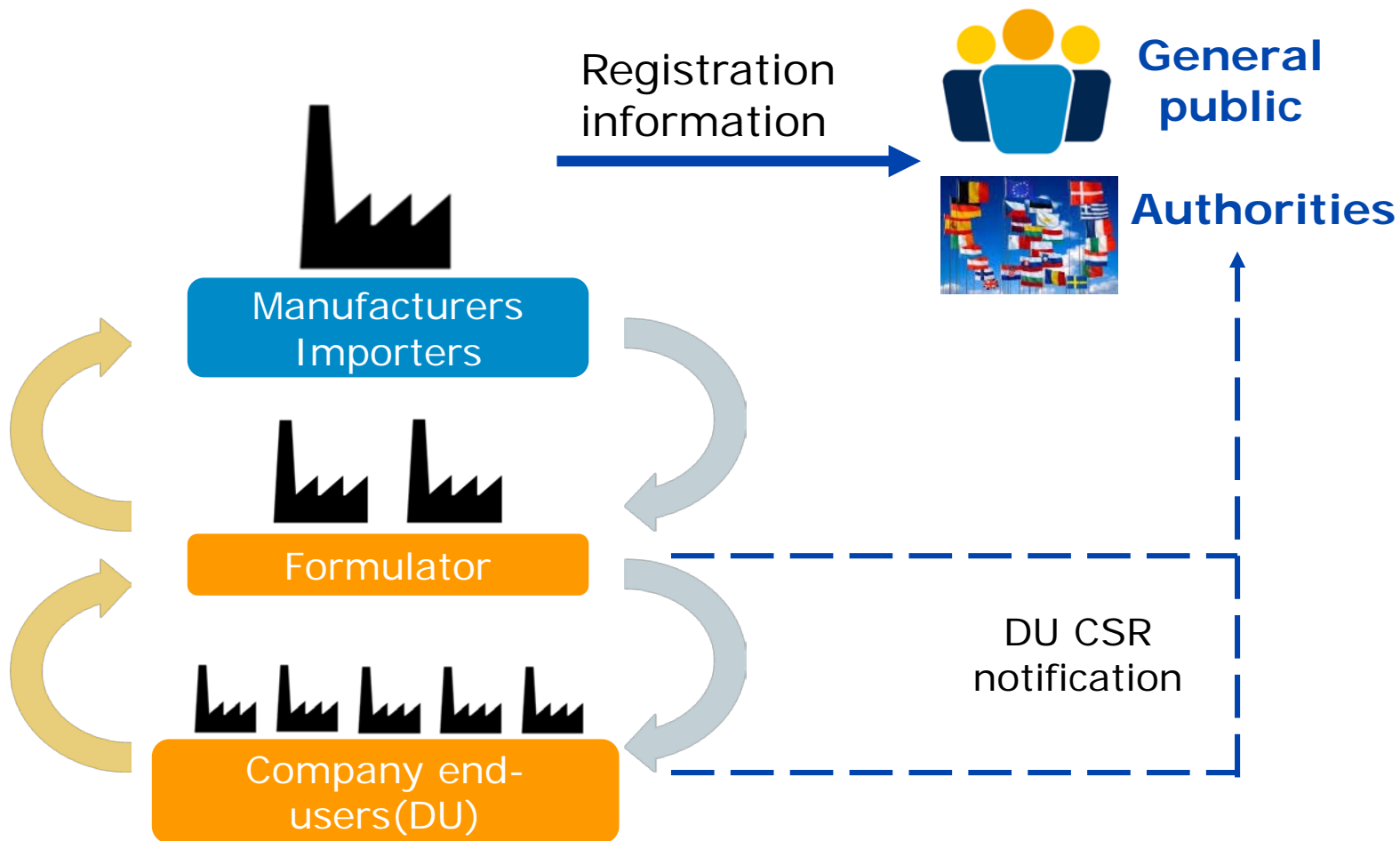
- Safe use of chemicals at own workplaces (OSH requirements)
- Control of emission to environment
- Chemical safety of own products and services
 - Use at customers' workplaces
 - Mixtures
 - Articles
 - Use by consumers
 - Mixtures
 - Articles



Downstream user response mechanism



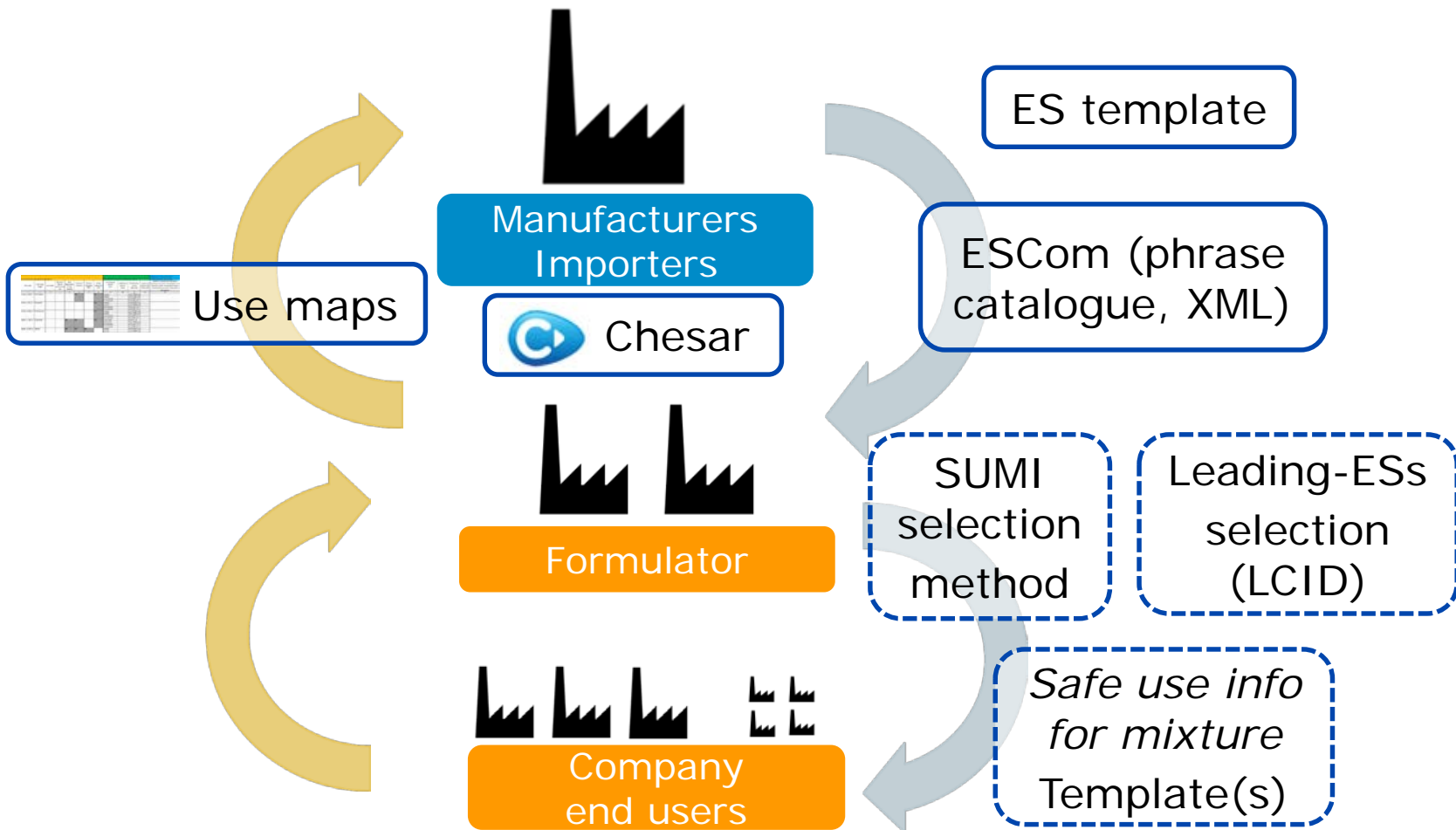
Authorities get informed



Methods and Tools



ENES Tools



Use map elements



Use description										
Use description	Life Cycle Stage	Use name	ES from the use description	Start/End of use	State of use	Product category (PC)	Active substance (AS)	Formulation name	Contributing active name	Concentration (g/kg)
worker_UACF	Production									
worker_UACF	Production									
worker_UACF	Professional									
worker_UACF	Consumer									
worker_UACF	Other									

SWED

Workers

Workers: Sector-specific Worker Exposure Description (SWED)

SCED

Consumers

Consumers: Specific Consumer Exposure Determinant (SCED)

SPERC

Environment

Environment: Specific Environmental Release Category (SPERC)

Use maps development status (1) 11/2018

Sector association	Products covered	Use map	SWED	SPERC	SCED	Chesar file
AISE	Cleaning products	PUB	PUB	PUB	PUB	PUB
EFCC	Construction chemicals	PUB	PUB	PUB		PUB
FEICA	Adhesives and sealants	PUB	PUB	PUB	PUB	PUB
I&P	Imaging and Printing products	PUB	PUB			PUB
Cosmetics Europe	Cosmetics and Personal care products	PUB	PUB	PUB		DEV
ECPA	Crop protection products	PUB	DEV	PUB		DEV
Fertilizers Europe	Fertilisers	PUB	DEV	PUB		DEV
CEPE	Paints and coatings products	DEV	DEV	DEV	DEV	DEV
ATIEL	Lubricants, metal working fluids, greases	DEV	DEV	DEV	DEV	INT
EuPC	Plastic compounds (and master-batches)	PUB	*			PUB
ECMA	Catalysts	INT	INT	DEV		INT
ESIG/ESVOG	Solvents	PUB	*	DEV		PUB
Concawe	Fuels	DEV			PUB	PUB

*Starting point for workers assessment provided, for possible iteration by registrants

Use maps development status (2)

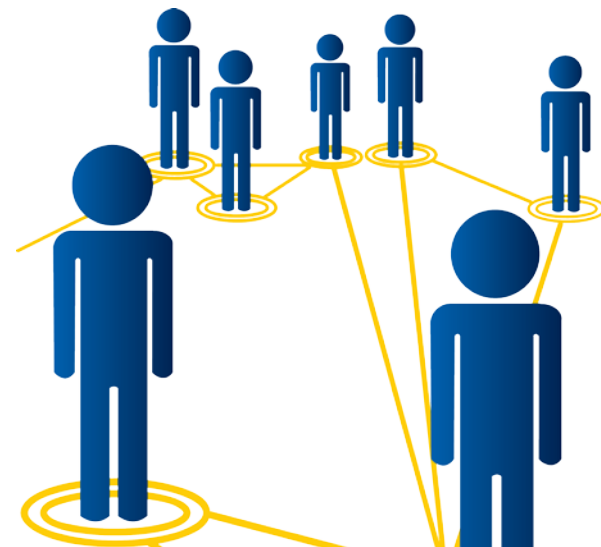


Sector association	Products covered	Use map	SWED	SPERC	SCED	Chesar file
	Rubber supply chain					
	Resin and foam supply chain					
	Textile finishing supply chain					
	Paper making supply chain					
	Metal compounding and conversion					
	etc.....					

ENES / ECHA achievements

- More than **50 %** CSRs are based on Chesar
- Significant number of industry sectors have generated or updated their sector use maps
- Tools/methods for generating, processing and communicating exposure scenario information available (ongoing “beta testing” under ENES)

However, quite some evidence that the communication through the supply chain is not properly working yet.



CHESAR - Introduction

- Chesar is a web application developed **to support registrants** in consistently:
 - carrying out chemical safety assessment
 - generating a chemical safety report (CSR) as part of their registration
 - generating exposure scenarios for communicating conditions for safe use (annex to extended safety data sheet)
- Available as desktop and server version
 - Chesar 1 was released in May 2010
 - Chesar 3.4 released in November 2018

<https://chesar.echa.europa.eu>



CHESAR provides opportunities for

- **Consistency**

- Within the CSA: substance properties, uses reported in IUCLID and the chemical safety report
- Information for the authorities (CSR) and for the supply chain (exposure scenario for communication)

- **Standardisation (efficiency gains for all actors)**

- Systematic workflow
- Incorporation of use maps and standard phrases (ESCom catalogue and ESComXML)
- Standardised format for Chemical safety report, Exposure scenarios for communication

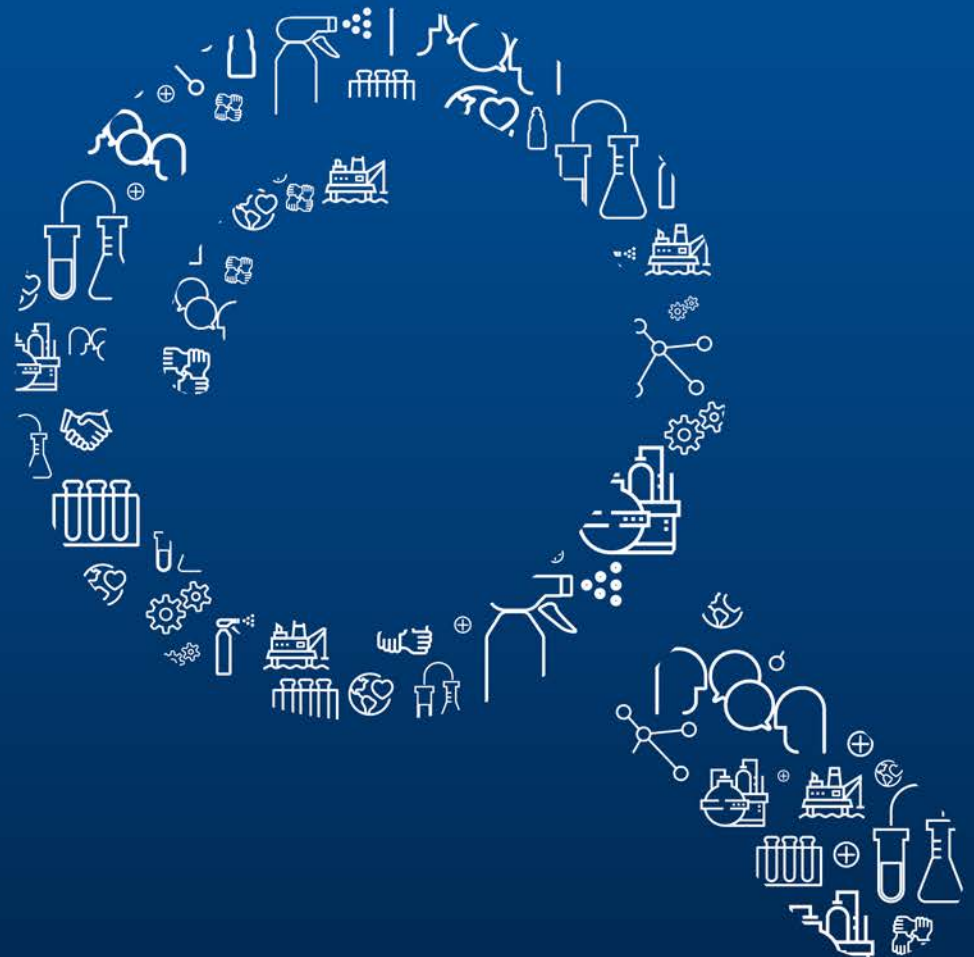


CHESAR provides opportunities for

- **Efficiency in single assessment**
 - Integrated exposure estimation tools
 - Re-use of information across substances
 - Automated generation of documents
 - Facilitated updates



Obstacles





Obstacles (1)

Limited explicit demand for safe use advice from the bottom of the supply chain

- Confusing and not sufficiently **targeted information**
- Unclear **value** of ES information for other obligations
- Lack of **capacity** to use/work with the information
- Lack of **trust** from MS OSH authorities in modelling based REACH exposure scenarios
- Recipients of mixture SDS don't recognise the "**status**" of exposure scenario information and associated duties



Obstacles (2)

Foreseen upstream communication mechanisms don't deliver (→ registrants and hence authorities lack sufficiently complete overview on uses of substances)

- **Unawareness** of downstream users of their duties
- Reluctance to communicate about “**innovative**” uses
- **Complex** supply chains
- Communication on identified (and hence assessed) **uses** of a substance in the extended SDS does not trigger response:
 - Use description too broad, too unspecific or not understandable for downstream user
 - Downstream user does not manage to get response from suppliers
- No upstream communication system established for single company to efficiently feedback to suppliers



Obstacles (3)

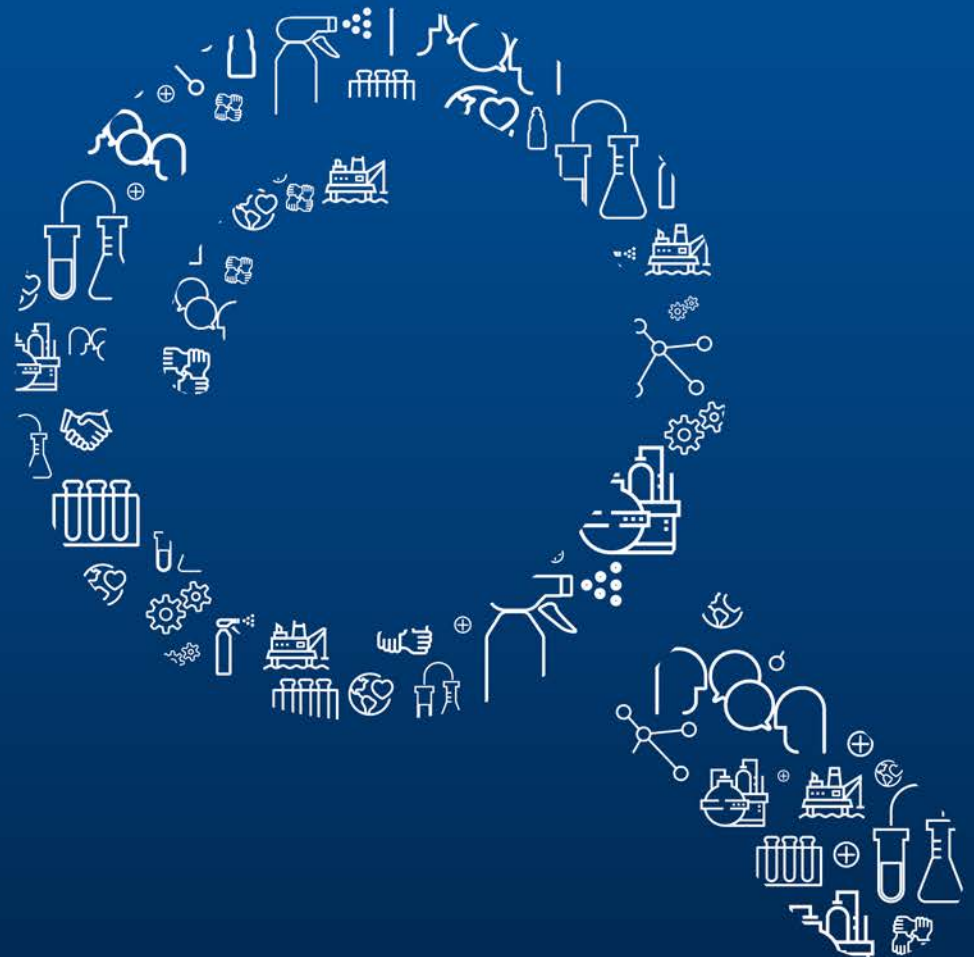
- Current legal requirements on exposure scenarios difficult to enforce (→ market forces do not properly work; → insufficient driver for harmonisation)
- Inertia of existing SDS systems and their underlying IT (global players reluctant to change their running SDS system)
- Limited uptake of available solutions
 - by registrants for CSR and SDS up-date
 - by downstream sectors making use-information available to registrants in an organised way



Consequences

- ES for communication still reflecting the registrants original objective to submit a complete dossier?
 - Over-reporting and under-reporting of uses
 - Conditions of use do not necessarily reflect reality in the supply chain
 - Terminology often not understandable to recipients
 - Risk management advice not derived by OSH practitioners
- Unassessed (potentially unsafe) uses remain undiscovered
- Multi-manual transfer of information through the supply chain (errors, takes resources, frustration, slow update)

REACH review action 3



ECHA's Strategic Objectives 2019-2023



Ensure risk management measures applied in European marketplace

Supply chain communication is an integral part of safe use

Sustainable management of chemicals through the implementation of EU legislation


Safe and sustainable use of chemicals by industry

Identification and risk management of substances of concern

Actions to invest in enabling components

REACH Review action 3

Four inter-related action areas

- 
- **3.1 Industry:** develop harmonised formats and IT tools to
 - provide more **user-targeted** information and
 - simplify extended Safety Data Sheets
 - preparation
 - use
 - facilitate their electronic distribution
 - **3.1 Industry:** use harmonised formats and IT tools
 - **3.2 Commission:** consider minimum requirements for the exposure scenarios for substances and mixtures in Safety Data Sheets
 - **3.2 ECHA:** develop a methodology for Safety Data Sheets for mixtures

Scoping process under action 3

Main themes

- **User targeting:** Characterise information needs (assessment tasks) of typical users of the extended safety data sheet
- **Define methodology** for extending safety data sheets for mixtures (with exposure scenarios and DNEL/PNEC information)
- Work out **potential minimum requirements** for exposure scenarios:
 - Simplification and Harmonisation (workability and efficiency)
 - Enforceability
- Collect proposals for embedding solutions in a **modernised IT concept** for the (user targeted) dissemination of information

Scoping process under action 3

Overall process

- Scoping phase (2019)
 - First Stakeholder workshop March 2019
 - Testing and exemplification of methods and tools for formulators under ENES
 - Dialogues with providers of IT solutions and services for safety data sheet authoring
 - Characterise information needs of SDS recipients (company perspective; inspectors perspective)
 - Second stakeholder workshop September 2019
 - Options for solutions to be discussed at CARACAL in November
- Development phase (2020)
- Consultation about proposed solutions (2021)



Summary

- Chemical Safety Assessment (CSA) and the resulting supply chain communication are essential to the safe use of substances
- Proper CSA relies on adequate information on hazard and use
- Tools/methods have been established to:
 1. gather and transmit the necessary information on use (ENES) and
 2. for the resulting CSA (Chesar)
 - Some gaps in both coverage (use map development) and uptake (implementation in the registration dossiers)
- Several obstacles identified in generation and transmission of safe use advice
- REACH Action 3 (and related Action 12) aims to tackle these obstacles



Thank you!

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