"Machinery" for assessment and communication on *safe use* in the supply chain

ENES 11

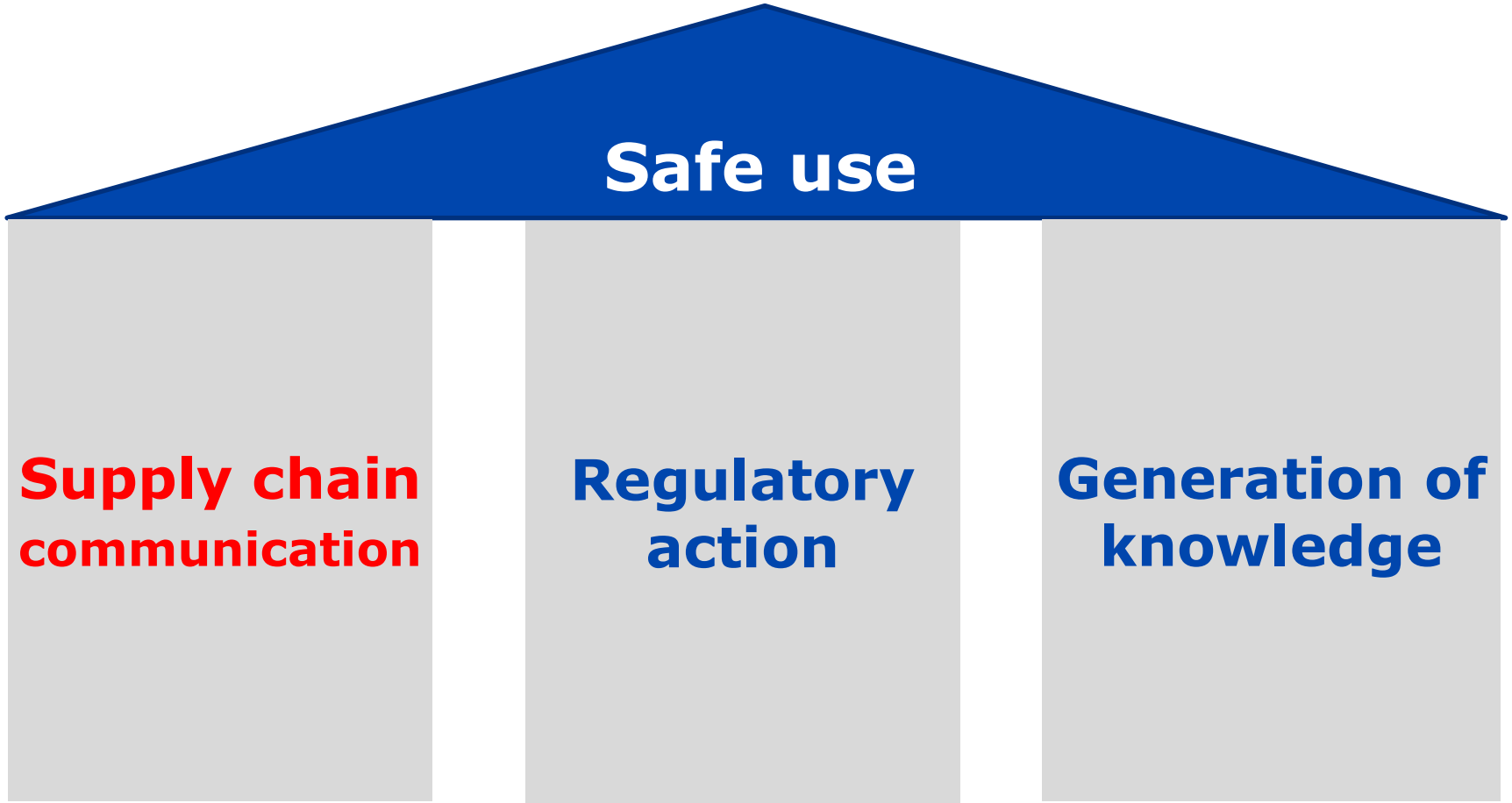
23-24 November 2017

European Chemicals Agency

Reminder on the machinery

Andreas Ahrens
ECHA

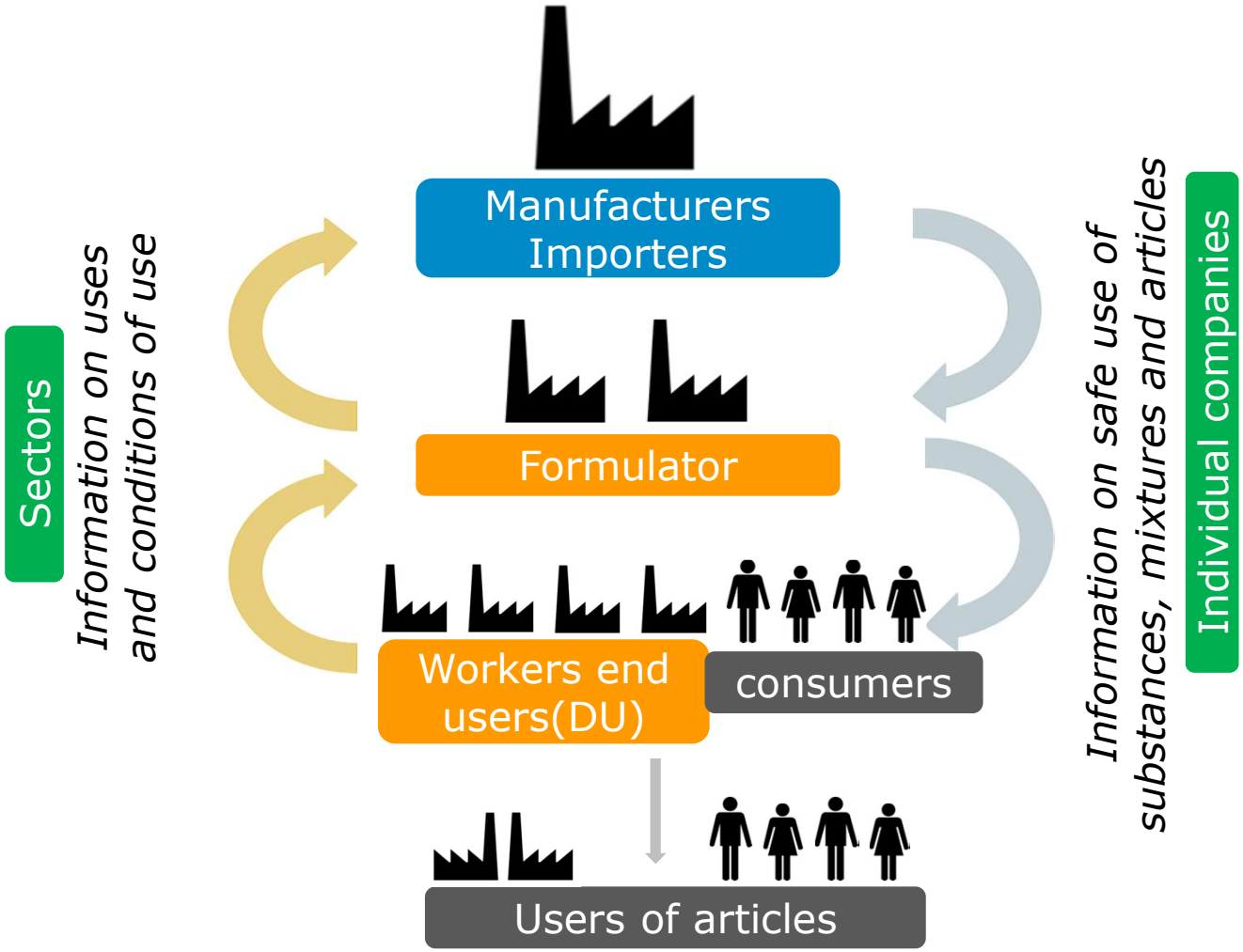
Basic pillars of chemicals legislation



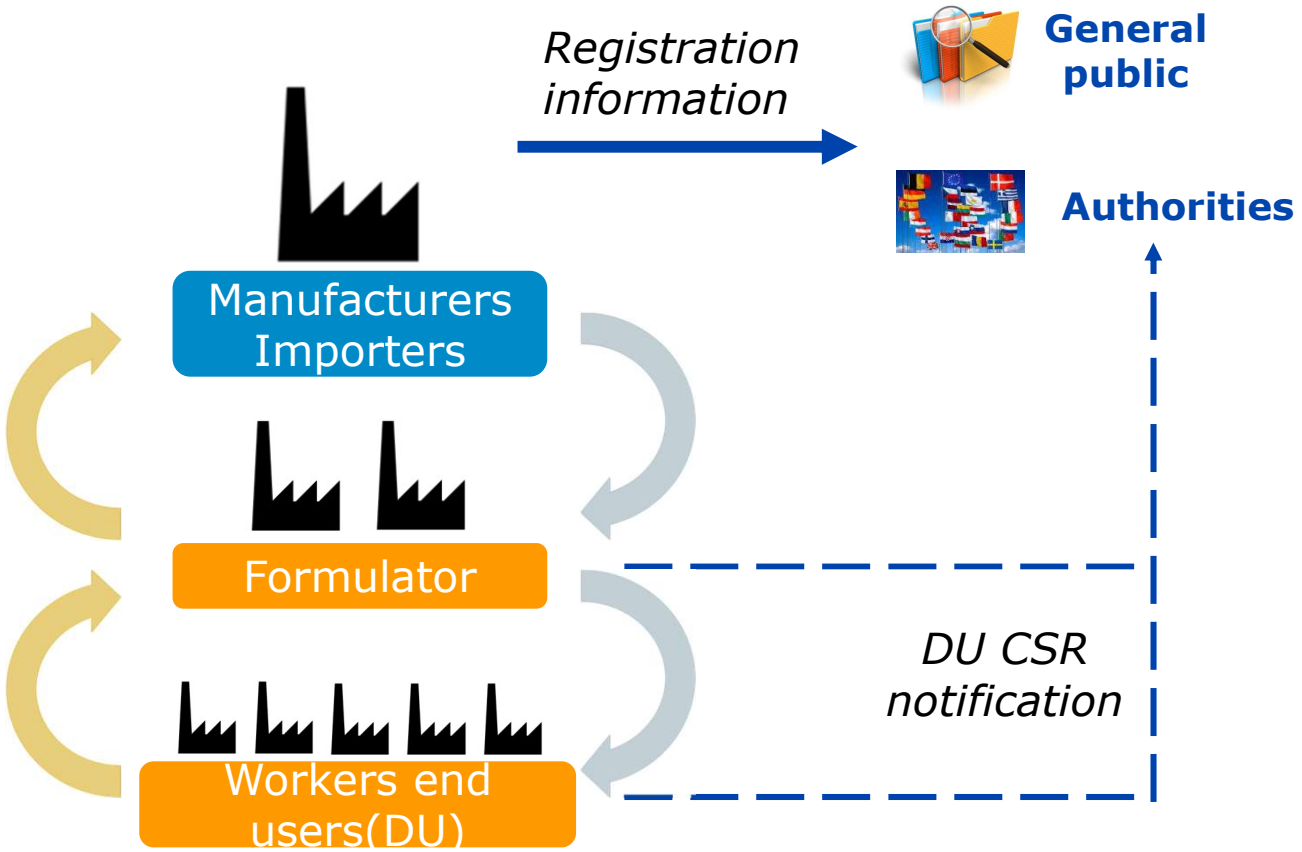
Reminder on basic principles

- REACH CSA and ES for communication to cover all uses and the whole life cycle of the substance.
- Registrant carries out the CSA (based on use-information received), and DU complements or "overwrites" it, if working outside the assessed conditions.
- Downstream users receive the *safe use* information resulting from a CSA in an extended SDS
  - for single hazardous substances
  - integrated across the hazardous substances in a mixture
- Downstream users are required to
  - Ensure that own on-site activities and products are safe. For that, check against the *safe use* information received (exceptionally undertake own CSA)
  - If a formulator: communicate relevant information to their customers
- Authorities receive use information via the registration dossier (main route) or the notification of DU CSR (exceptional)

Supply chain communication



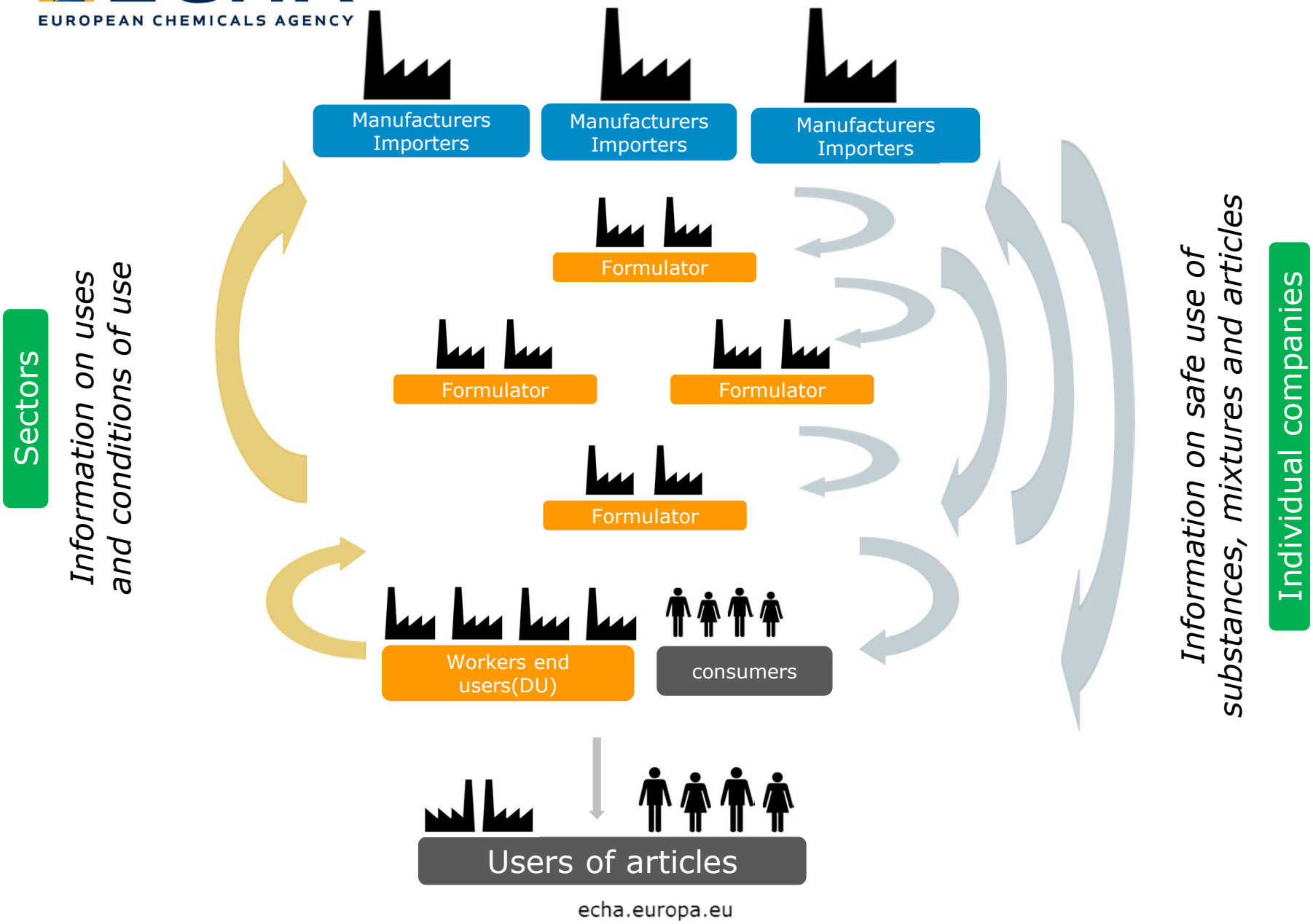
Authorities get informed



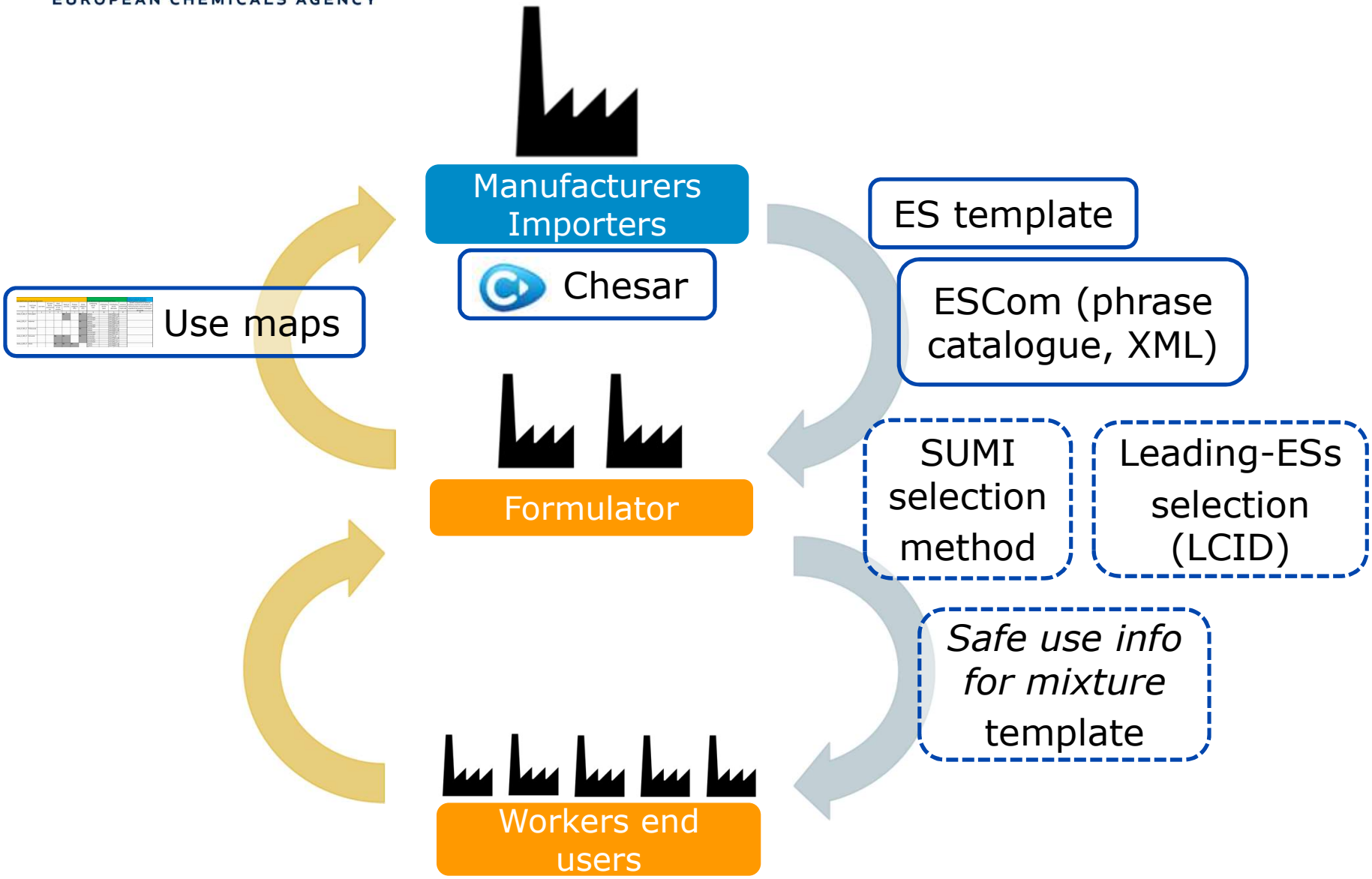
Resulting Challenges

- Registrants to obtain realistic information on condition of use of substances at the end of their supply chains
- One formulator manages information on multiple raw materials and multiple products; efficient system for information processing is key.
- Connect the REACH CSA data (tools) to the existing EHS and SDS authoring systems at single company level, to ensure consistency between safety assessment and communicated conditions of safe use
- End users of substances (in mixtures) should receive useful information in a digestible format
  - Checking own activities and article produced (when relevant) are safe
- Efficient integration with obligations from other legislations
  - workplace safety assessment, emission control from industrial sites, product/article safety, ……

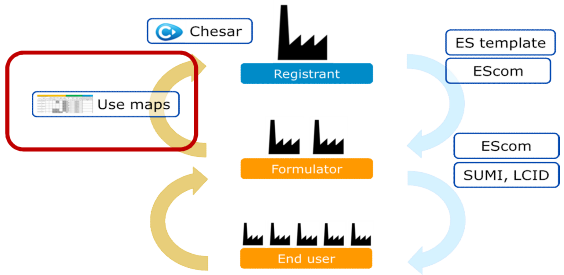
Complexity of supply chain



ENES tools

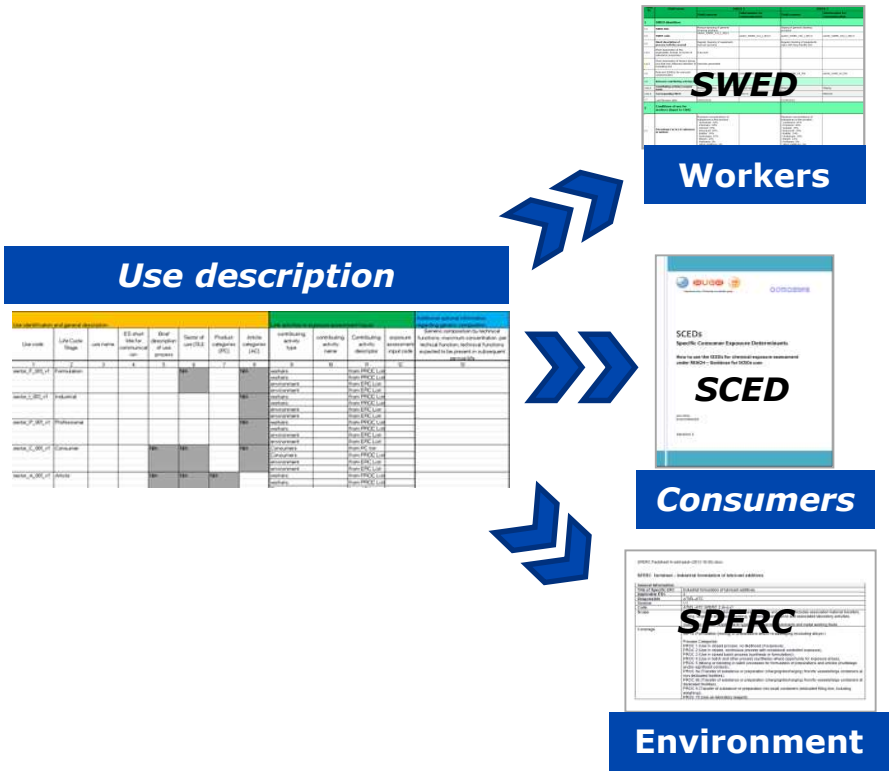

Manufacturers
Importers
Chesar
Use maps
ES template
ESCom (phrase catalogue, XML)
SUMI selection method
Leading-ESs selection (LCID)
Formulator
Safe use info for mixture template
Workers end users

Sector Use maps



- Developed by (DU) sectors: input to registrants for i) their CSA and ii) for generating the ES for communication annexed to the SDS.
- Benefits:
  - For registrants: ready made input for assessment
  - For formulators: harmonised description of use/CoU for all substances in a mixture. Facilitate tasks of checking/processing ES received.
- Use maps can also be used after the 2018 registration deadline to update the registration dossier and ES for communication

Use map elements



Workers: Sector-specific Worker Exposure Description (SWED)

Consumers: Specific Consumer Exposure Determinant (SCED)

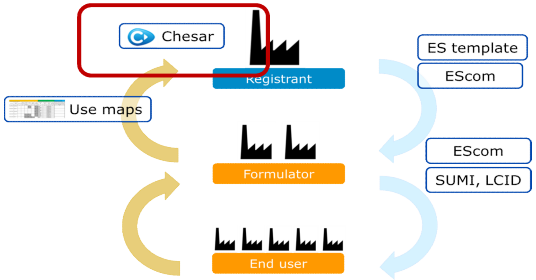
Environment: Specific Environmental Release Category (SPERC)

Use maps

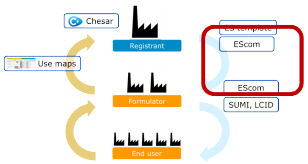
- State of play on use map development
- Registrants' sector use maps (GES) and DU sector use maps
- Cefic's pilot project on applying DU sector use maps in practice

See later presentations

Chesar



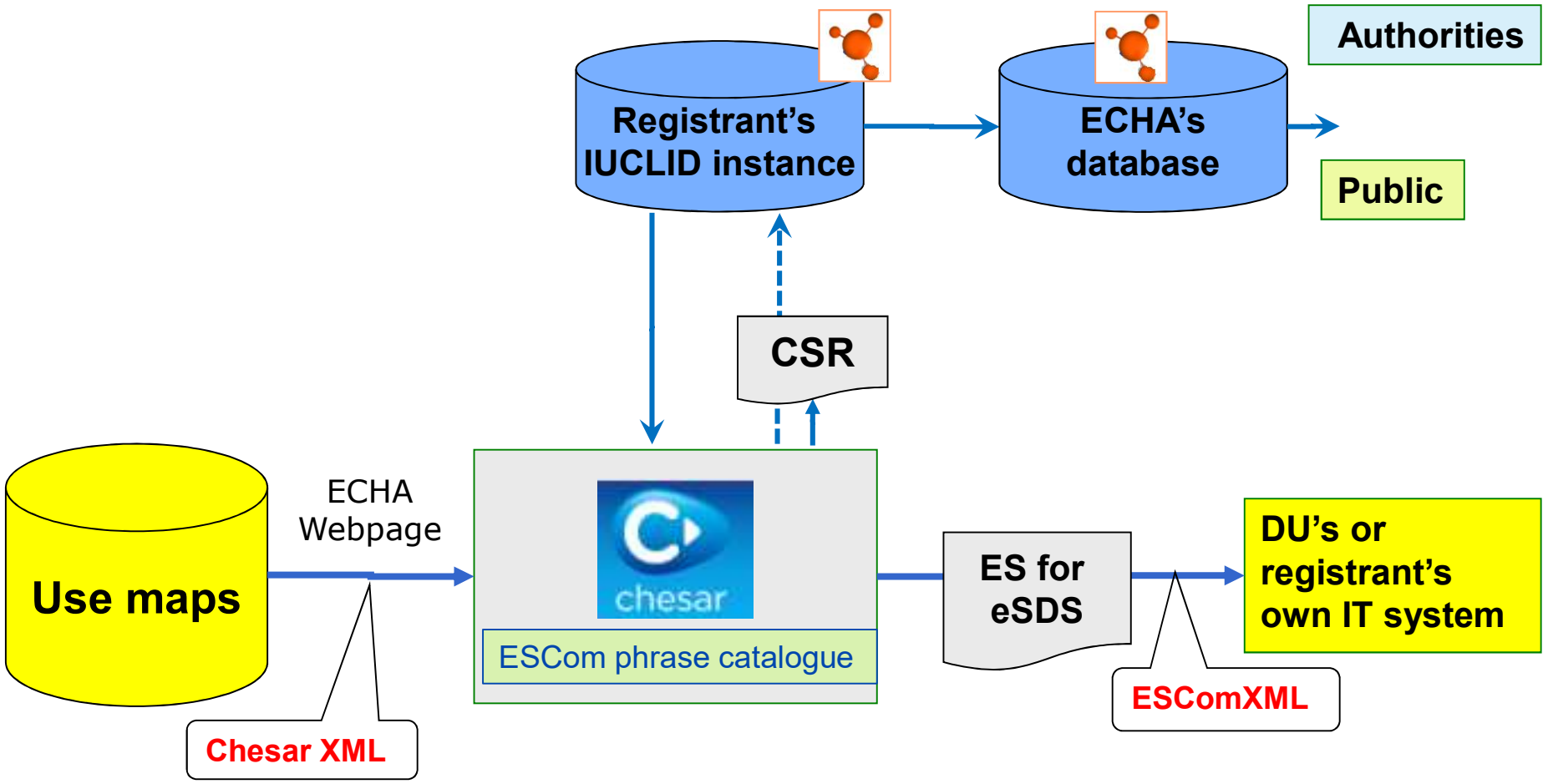
- Supports registrants for
  - Preparing their chemical safety assessment, including automatic loading of use maps
  - Generating their CSR and a consistent ES for communication
  - Extracting key information from their CSR for a consistent registration dossier in IUCLID (for the Authorities)
- Supports sectors
  - to generate/update their use maps
  - To export their use maps in XML format, for upload by registrants
- Supports registrants to import/update use-map information in their dossiers

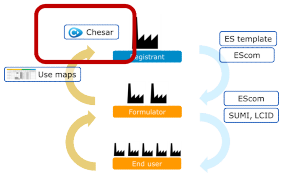


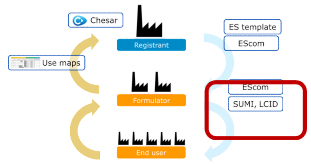
ESCom package

- **ESComXML**: standard to facilitate exchange of data (ESs) between IT systems
  - From the CSA tool to the SDS authoring system
  - Between supplier and customer systems, to ease the processing (automation) of the information, such as
    - compare with on-site conditions and product design (document "compliance")
    - generate relevant information for customer in suitable format and language
- **ESCom standard phrase catalogue**: harmonise the way for expressing conditions of safe use
- *See later presentation on ESCom pilot*

Tools and information flows



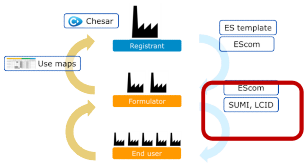




Tools/mechanisms for the formulator

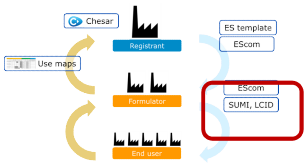
- To document "compliance" **or**
- To carry out own CSA and notify to ECHA
- To generate information on safe use (via extended SDS) for the customers, where required
  - SUMI Selection Method
  - LCID (Lead Component IDentification) method
- To generate labels for consumer products/ articles

SUMI selection method



- DUCC sector-specific "bottom up" approach to generate and communicate information on safe use for the customers
- It is suited to end-use **mixtures** with clearly defined markets and uses
- It includes two different elements, for communication upstream (SWED) and downstream (SUMI)
- **SUMI Format**: Format to communicate safe use information for mixtures to downstream end-users
- **Pre-defined set of SUMIs** (based on SWEDs)
  - Relevant SUMIs to be 'selected' by formulators
  - SUMIs reflect uses and CoUs described in the sector use map: harmonised content

LCID method



- To generate information on safe use for mixture
  - LCID (Lead Component IDentification) method to identify one or more lead substance(s) in the mixture
  - Lead substance(s) drives the conditions for safe use
  - No harmonised method yet to consolidate across exposure scenarios in case of different lead substances (for different exposure routes)
  - No harmonised format (yet) for communicating the conditions for safe use for the mixture SDS
    - Format for integration into section 8
    - Format for attachment

State of play on use map development

Upstream communication to registrants

Laure-Anne Carton de Tournai
ECHA

Use maps developers network

- Set in place after ENES10 to facilitate exchanges between sectors and support from ECHA
- Regular WebEx/Workshops. Focus on:
  - Use maps and Chesar files creation + testing
  - Adaptation of Chesar to use maps
- 13 active sectors covering a wide range of products
  - Elements published in the library for 6 sectors
  - Information from 5 other sectors to be published soon
  - Most sectors currently developing Chesar files
- To join the network: echa_enes@echa.europa.eu

Use maps development

- Sectors work according to their specificities/priorities
  - 'full' use maps package (AISE, FEICA, CEPE, EFCC) or priority to some elements (ECPA, Fertilisers Europe: SPERCs, I&P: SWEDs; Concawe: SCEDs)
  - EuPC-EuMBC: focus on use description and input to the conditions of use for workers (including concentration per additives types, process t°)
  - ESIG: transfer of GESs into Chesar input/upload files and connect with DU sector use maps

- Limited review process of use maps elements by ECHA before publication: comments to sectors who then decide which to implement before publication

- Recently initiated by ECHA: Cross-sector analysis
  - approach to differentiate among uses
  - overlaps between sectors

Use maps development (11/2017)

PUB: Published in use maps library
DEV: Under development
INT: Intention
NO: No intention

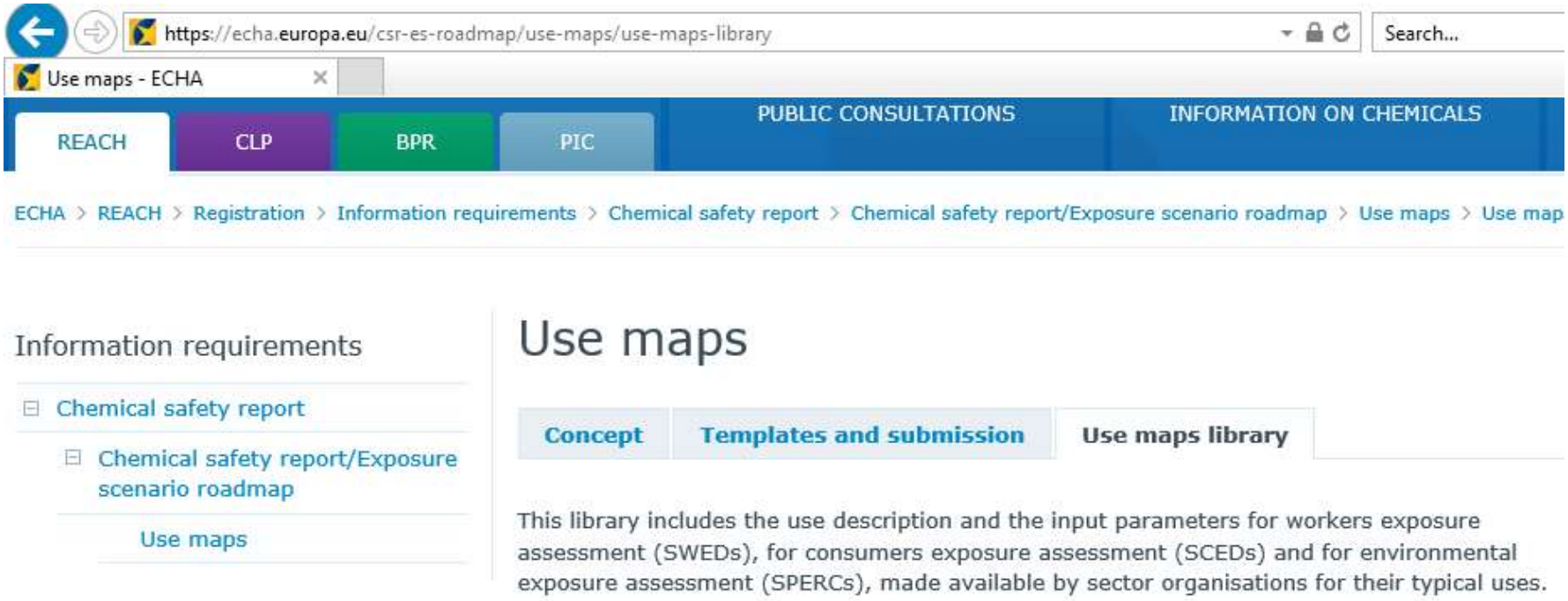
Sector	Products covered	Use maps	SWEDs	SCEDs	SPERCs	Chesar file
AISE	Cleaning products (Soap, detergents, maintenance)	PUB	PUB	PUB	PUB	DEV+
EFCC	Construction chemicals	PUB	PUB		PUB	DEV+
FEICA	Adhesives and sealants	PUB	PUB	PUB	PUB	DEV+
I&P	Imaging and Printing products	PUB	PUB	NO	NO	DEV+
Cosmetics Eur	Cosmetics and Personal care products	DEV+	PUB	NO	PUB	DEV+
ECPA	Crop protection products	PUB	DEV		PUB	DEV+
Fertilisers Eur	Fertilisers	DEV+	DEV		DEV+	DEV+
CEPE	Paints and coatings products	DEV+	DEV+	DEV+	DEV	DEV
ATIEL	Lubricants, metal working fluids, greases	DEV	DEV	DEV	DEV	INT
EuPC/EuMBC	Plastic additives	DEV+	*	NO	NO	DEV+
ECMA	Catalysts	INT	INT	NO	DEV	INT
ESIG/ESVOG	Very broad product types Overlapping with a number of sectors	DEV+	*		DEV	DEV+
Concawe	Fuels	DEV		DEV+		DEV+

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

Use maps library

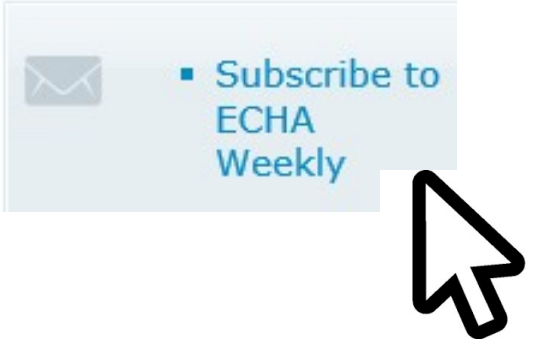
https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library

- One stop shop for use maps on ECHA website
- One section per sector
- Files directly downloadable



Use maps library

- Library widely consulted
- As of 6 November 2017 more than **12 000** files downloaded
  - AISE 5 796 since Oct. 2016
  - FEICA 3 580 since Nov. 2016
  - Cosmetics Europe 1 334 since Nov. 2016
  - EFCC 747 since Dec. 2016
  - I&P 617 since Jan. 2017
  - ECPA 273 since Sept. 2017
- Stakeholders informed about any new publication in the library via the *ECHA weekly* (~ 15 000 subscribers)



GES and DU sector use maps

Upstream communication to registrants

by Cornelia Tietz, ESIG

ESIG/ESVOC Generic Exposure Scenarios (GES) Overview of Use Map Update and Application

Conclusion from ESIG‘s mapping comparison

Cornelia Tietz
ESIG Secretary General

Outline

- Why Generic Exposure Scenarios (GES)?
- GES v DU Sector Use Maps

TOP – DOWN approach

*"Companies are responsible for collecting information on the properties and uses of the **substances they manufacture or import** above one tonne a year. **They** also have to assess the hazards and potential risks presented by the substance."*

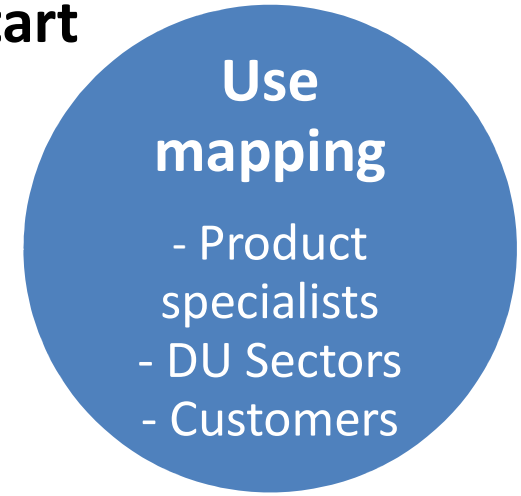
- **100's different solvents, with majority >1000 tonnes**
  - **684++** Number of solvent Registrations to date 70% >1000 tonnes
  - **++** Solvent-type substance registrations, e.g. LOA, Concawe
- **Widespread uses** with most having **different applications across all market sectors** & numerous different combinations of exposures

➢ **How to manage to assure registration of the majority of uses for all solvents of relevance to the supply chain**?

➢ And assure continuity of supply with minimal churn in the supply chain due to missing uses

GES approach

start



Early in the REACH process (2008)

ESIG started to reach out to its downstream users by addressing them directly about their uses and collecting the answers.

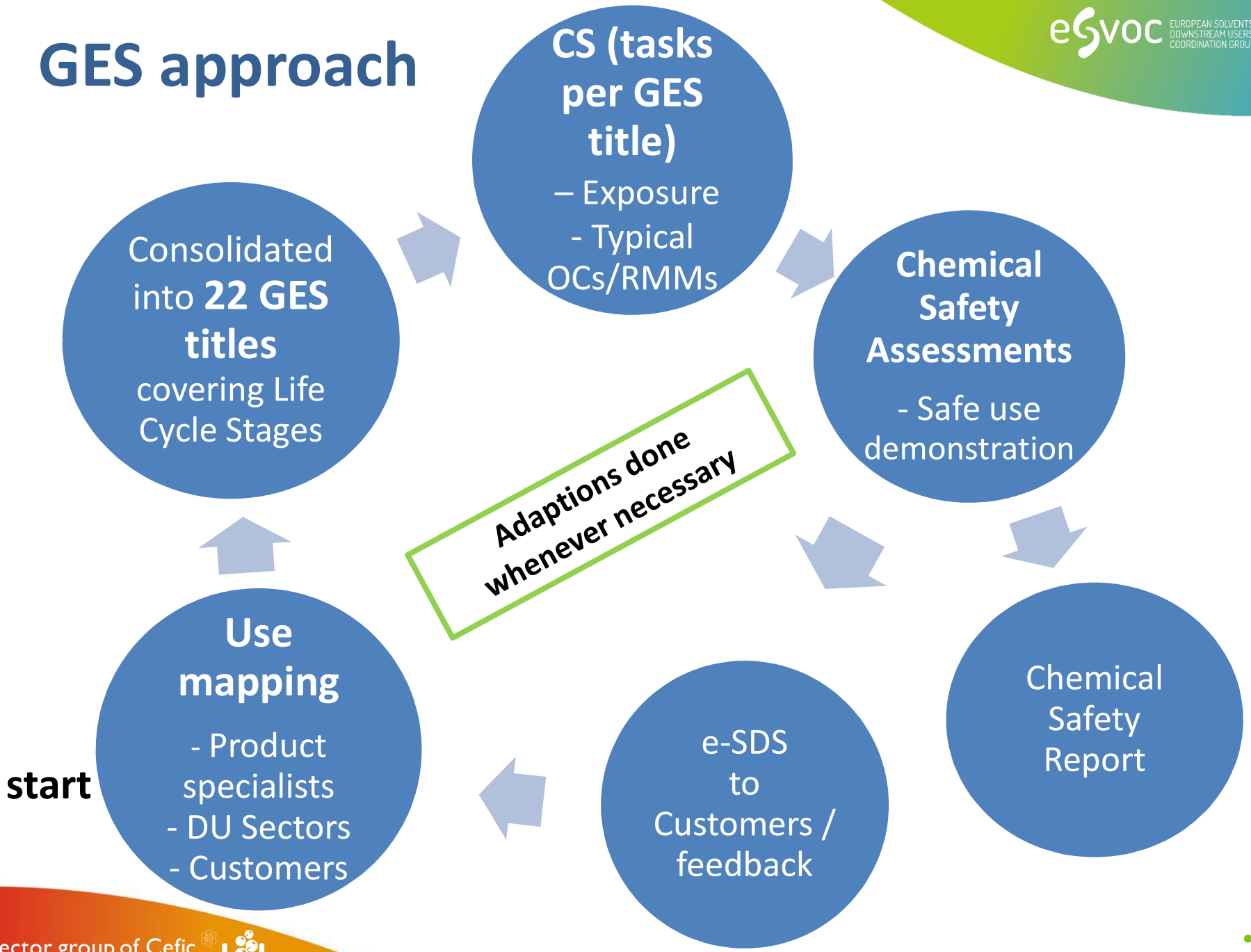
Responses received were

- frequently different in wording,
- not always conclusive and, in the end,
- often referred to similar uses.

As a next step, the collected uses from over 15 different DU groups were brought together (under the umbrella of ESVOC) into Generic Exposure Scenarios (GES)

☝ allowing, for example, a registrant or formulator to identify and describe a “coating scenario” regardless of any sectoral jargon.

GES approach



Index of GES Titles for Solvents

- Manufacture of substance ~~incl. use as process solvent and extraction agent~~ (LCS - Manufacture)
- Formulation & (re)packing of substances and mixtures (LCS - Formulation)
- ***New*** - Use in process chemicals (LCS - IS)
- Use as an Intermediate (LCS - IS)
- ~~Distribution (I)~~
- Use in coatings (LCS - IS, PW & C)
- Use in cleaning agents (LCS - IS, PW & C)
- Use in lubricants (LCS - IS, PW & C)
- Use in functional fluids (LCS - IS, PW & C)
- Use in oil and gas field drilling and production operations (LCS - IS, PW)
- Metal working fluids / rolling oils (LCS - IS, PW)
- Use in blowing agents LCS - IS)
- Use in fuels (LCS - IS, PW & C)
- Use as binders and release agents (LCS - IS, PW)
- Use in agrochemicals (LCS - PW & C)
- Use in road and construction products (LCS - PW)
- Uses in cosmetics/personal care products, perfumes and fragrances ~~Other consumer uses~~ (LCS - C) – *no human health assessment required*
- De-icing and anti-icing fluids (LCS - PW, C)
- Use in polymer processing (LCS - IS, PW)
- Use in rubber production and processing (LCS - IS)
- Use in water treatment agents (LCS - IS, PW & C)
- Use in Explosives (LCS - PW)
- Use in mining chemicals (LCS - IS)
- Use in laboratories (LCS - IS, PW)
- **Titles allow integration of Human Health and Environmental assessments within one ES**

- **22 potentially relevant GES titles**
- **42 potentially relevant ESs for any solvent (consolidating 5 – 10 Contributing Scenarios per ES)**

Alignment of GES with DU Sector Use Maps/SWEDs

- Alignment checking against the available DU Sector Overview Use Maps and supporting SWEDs in hand:
  FEICA - AISE - EFCC - CEPE - EUPIA
- Some clarification on GES v DU Sector Use Map/SWED approach were searched for
- Documenting details within ECHA Overview Use Map template to be published
  - Also includes all GES Titles, supporting Contributing Activities/Scenarios, typical OCs/ RMMs

Alignment of GES with DU Sector Use Maps/SWEDs

- ✓ **Initial review shows good alignment**
- ? **Some questions – continued liaison**
- ✓ **Solvent sector feels very confident in rightness and application of information provided in GES**
- ✓ **ESIG/ESVOC use map comparison to be published soon on ECHA and ESIG website**
- ✓ **ESIG will continue to compare with any new sector use map out there so that DU Sectors are able to identify their related SWED and support the linkage to their associated Sector SUMIs**

+ GES solvent use maps to be transferred into CHESAR to allow assessment

Conclusion

ESIG

- acknowledges the ongoing developments to improve the utility of Human Health Exposure Scenarios/safe use communication in the supply chain.
- remains committed to this aim and to reviewing its approach in the light of these new developments.
- considers that the concept, structure and relevance of the GES remain valid and hence need to be kept aligned with parallel regulatory approaches such as sector use maps.

Thank you for your attention

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Cefic pilot on applying use maps in practice

Upstream communication to registrants

Alejandro Garabatos
Cefic

Cefic's Pilot project on Use Maps
ENES11 – Session1

Agenda

1. Background
2. Objectives
3. Settings
4. Description
5. Outcome – Strengths and weaknesses
6. Next steps and actions identified

1. BACKGROUND

- Under the CSR/ES Roadmap (joint action plan of authorities and industry) several tools have been developed to support registrants chemical safety assessments and the communication of safe use conditions for substances and mixtures in the supply chain.

- To raise awareness of the tools, it is essential to demonstrate that the concepts work in practice and in combination, and provide added value.

- For doing that, relevant parameters and work steps are intended to be documented, recommendations and obstacles to be collected and reported.

2. OBJECTIVES

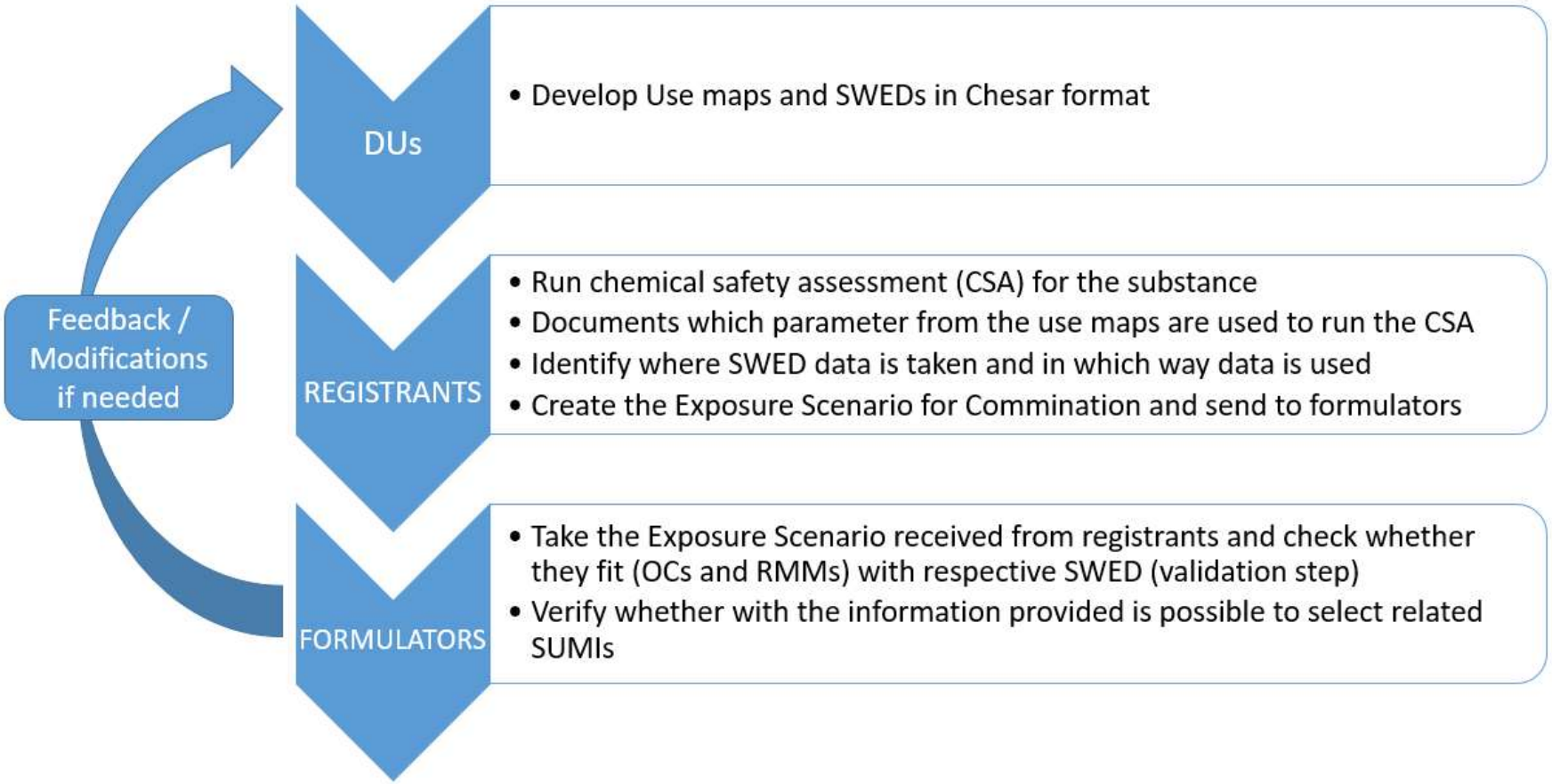
- To demonstrate how sector Use Maps' and related SWEDs and SUMIs support registrations and supply chain communication.
- Registrants to use the use maps generated by DUs.
- DUs to publish updated use-maps in Chesar format in ECHA's Use maps library.
- Getting new sectors on board.

3. SETTINGS

- FEICA and EFCC use maps and SWEDs in CHESAR format
- Registrants represented by 5 companies and 4 consultants
- Phase 1 limited to workers activities and Tier1 assessment based on ECETOC TRA
- CHESAR version 3.2

Substance	Uses
Cyclohexane, CAS110-82-7 **Xylene**, CAS 1330-20-7 **C9-C12 Hydrocarbons, 2-25 % aromatics**, EC 919-446-0, CAS 64742-82-1 and CAS 64742-88-7 **Benzyl alcohol**, EC 202-859-9, CAS 100-51-6	**FEICA_PW_001** (Low energy distribution of adhesives and primers on large areas outdoors by professionals) **FEICA_PW_005** (Professional small scale application of adhesives, sealants or primers) **FEICA_IS_002** (Industrial large scale spray application of adhesives in containment)
	EFCC_PW_11-o_v1 "Use of construction chemical products by spray application (high energy), outdoor" **EFCC_PW_11-i_v1** "Use of construction chemical products by spray application (high energy), indoor"
	EFCC_PW_L-10-o_v1 "large-scale use of construction chemical products by roller or brushing application, outdoor" **EFCC_PW_L-10-i_v1** "large-scale use of construction chemical products by roller or brushing application, indoor"

4. DESCRIPTION



5. OUTCOME - STRENGTHS

- The uploading of use-map information, the chemical assessment done by registrant and the generation of the ES for communication do work. (registrants spent between *1 to 3h* for the exercise).
- ES prepared based on use maps simplifies the compliance check of the formulator significantly.
- Relatively good harmonization of phrases (different substances, different suppliers and the same phrases).
- Chesar 3.2 is helpful to process use maps

Note: *Assessment time may be longer, since there are many use maps being published and more are expected, so it will require a significant time in practice to identify the uses and concentration for a substance registration.*

5. OUTCOME - WEAKNESSES

- Some unexpected differences between registrants for the same assessment are observed, but the route cause has not yet been analysed.
- There are some difficulties for registrants to select the contributing activities based on the properties of the substance.
- The way sectors have differentiated uses in their use map can lead to too long ESs with repetitive CSs.
- Clarifications needed on how can a single formulator connect the incoming ESs (based on SWEDs) with right SUMI.

6. Identified needs for further work

1. Guidance for use maps developers to create more consistency in the description of uses and conditions of use
2. Guidance for registrants implementing use maps to help selecting appropriate contributing activities
3. Support for formulators to put in place methods/tools to process the incoming information on routine basis
4. The applicability of alternative Tier2 assessments using ART instead of ECETOC TRA v3, and address the findings
5. Identification of adaptations needed in Chesar to better support the use maps.
6. More sectors to develop/update their use maps


thank you
danke
謝謝
ngiyabonga
teşekkür ederim
gracias
tapadh leat
спасибо
Баярлалаа
рахмат
dank je
mochchakkeram
go raibh maith agat
dziękuję
bedankt
obrigado
sukriya
kop khun krap
terima kasih
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ESCom

Downstream communication to customers

Dook Noij
Dow

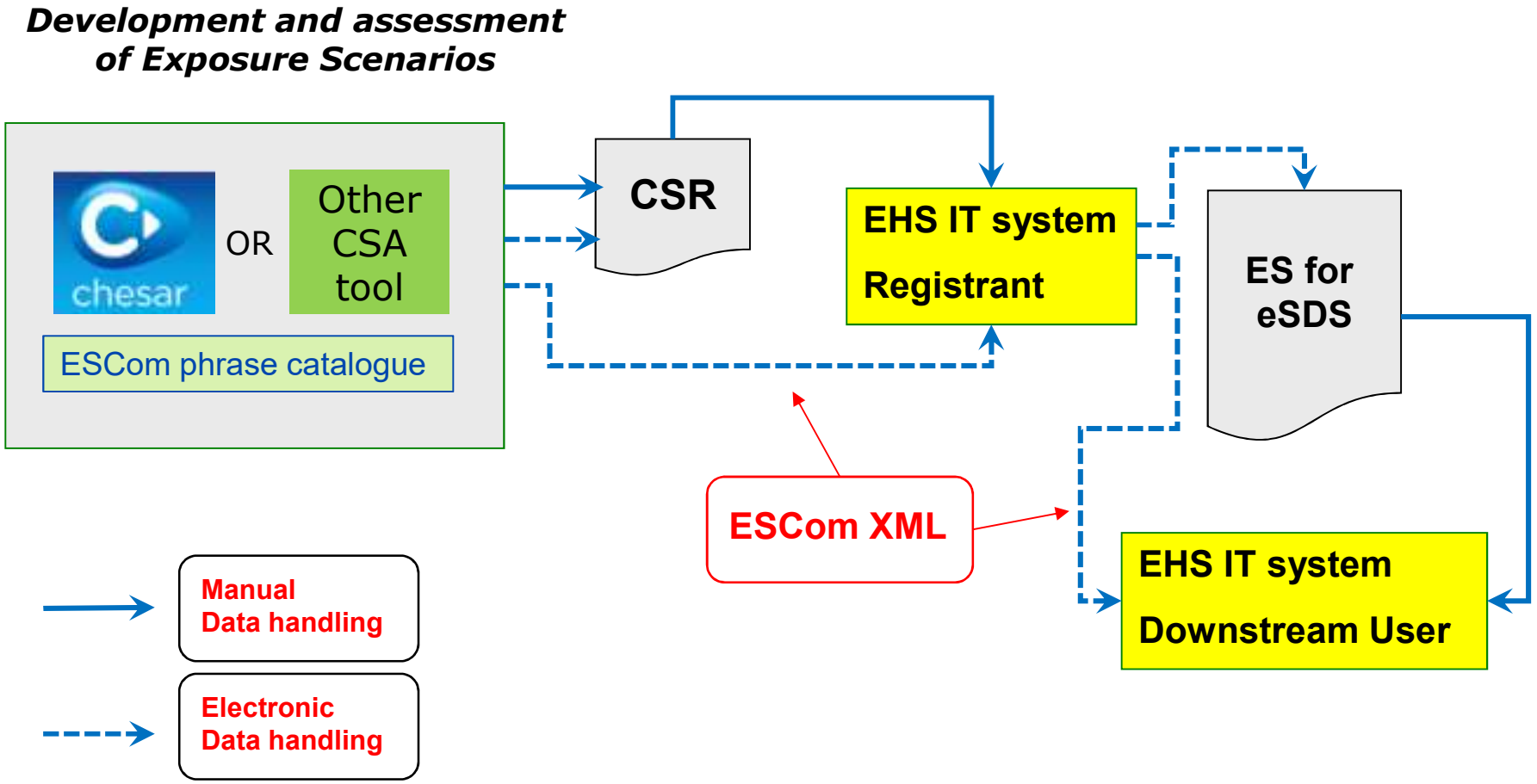
ESCom: communication with customers

Results of a pilot with ESCom XML

Benefits of and prerequisites for using ESCom

Dook Noij (Dow)
On behalf of the ESCom Working Groups
(Standard Phrases and XML)

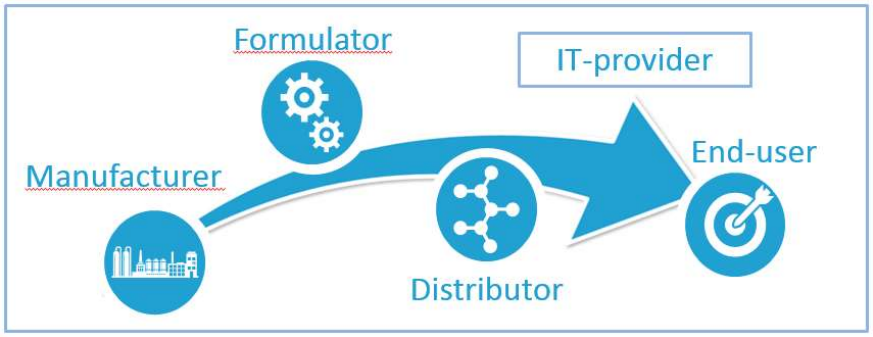
Data exchange in the chemical supply chain



Piloting the ESCom package

Although benefits of ESCom are recognized, implementation of electronic data exchange via ESCom XML is not yet implemented

Initiative: pilot project with ESCom XML, involving key players within the chemical supply chain



Objectives:

- Demonstrate that the ESCom Package is fit for purpose and works
- Collect information on pro's/con's, implementation lessons

The pilot

Participants: 1 manufacturer, 1 distributor, 2 IT-providers, 1 end-user

Exposure scenarios created by IT providers (ESCom XML format)

Testing with 10 Exposure Scenarios (ES; mainly worker scenarios) with on average 7 Contributing Scenarios (CS)

Testing XML exchange:

- Chesar => IT provider
- IT provider => Manufacturer
- Manufacturer => Distributor
- IT provider, Manufacturer, Distributor => End user (on-going)

Preliminary results

Successful import/export of ESCom XML files between participants

Main attention items:

- Initial effort for interface implementation and data migration (depending on type of EHS system and company specific data formats)

- Free text (non-ESCom phrases) in Exposure Scenarios (not supported by ESCom XML)

Estimation of time savings*

Entering ES data in EHS IT system of Registrant or DU

- Manual ES data input in EHS IT system (including creation of ES/CS in EHS IT system): 2-4 hrs (120 - 240 min) per ES (depending on level of experience of employees)

- Electronic ES data input in EHS IT system:
  - Without missing phrases (non-ESCom phrases): ~5 min per ES (quality check/review)
  - With missing phrases (manual replacement by non-ESCom phrases): 30 - 60 min per ES (assuming 25 % of the phrases have to be replaced by non-ESCom phrases), plus ~5 min per ES (quality check/review)

** NOTE: initial effort to implement ESCom XML (interfaces, data migration) not taken into account*

Time saving per ES by electronic data entry

- Case manual vs electronic data entry (no missing phrases):

  (120 - 240 min) – (5 min) = **115 – 235 min**

- Case manual versus electronic data entry (25 % missing phrases):

  (120 - 240 min) – (30 - 60 min) – (5 min) = **85 - 175 min**

- Worst case: identical to full manual entry: **0 minutes**

To optimize the time savings, it is critical to maximize the use of ESCom phrases!!!

Conclusions from the pilot so far

Initial implementation of ESCom XML requires significant effort

Efficiency improvement can be high, provided mainly (if not only!) ESCom phrases are used in ES communication:

- Less resources needed, no special expertise required
- Faster processing of data due to automation

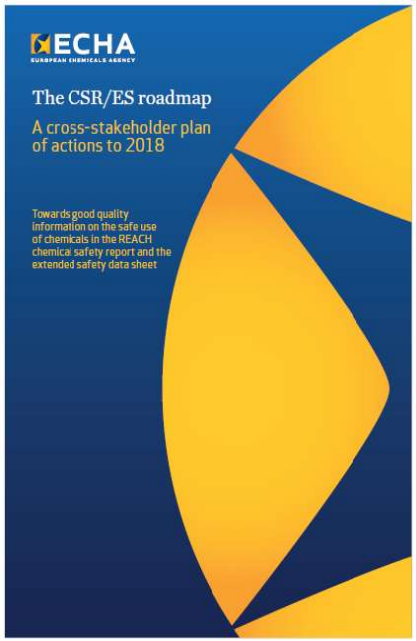
Other benefits:

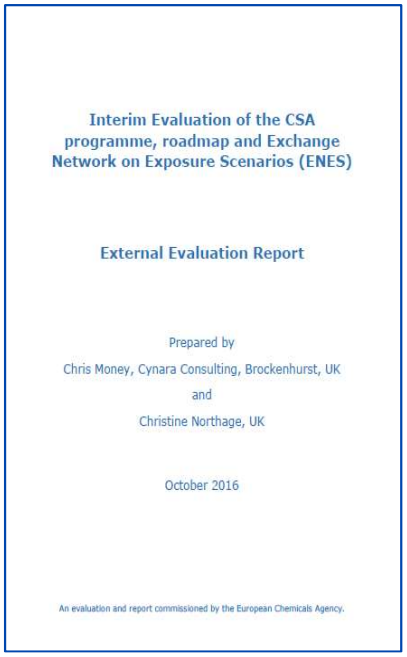
- Higher accuracy of data entry:
  - Eliminated risk of human error while copy-paste data at every stage
  - Automated selection of correct version of the phrase (ESCom version)
- Ensured compliance (fully consistent with CSR)
- Automated translation of standard phrases

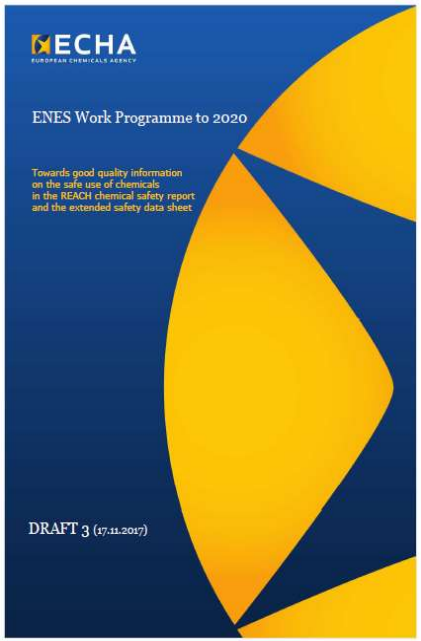
Introduction to the ENES Work Programme

Erwin Annys
Cefic
on behalf of ENES Coordination Group

Evolution





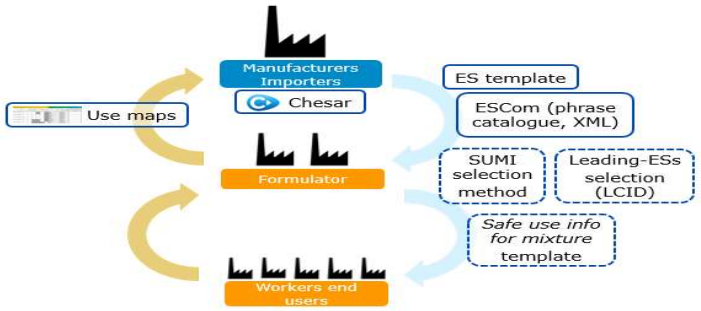


CSR/ES Roadmap 2013

Evaluation 2016

ENES Work Programme to 2020

Objective



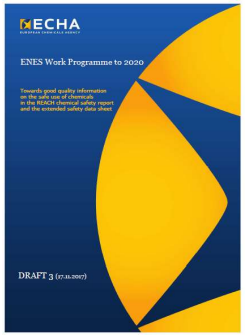
Make communication in the supply chains on uses and conditions of *safe use* work in practice

- Determine information needs of the different actors (content and form of information).
- Connect practices under REACH with practices under other legislation (OSH, environment, consumer safety).
- Develop/maintain methods and tools to collect, process and communicate this information.
- Adapt exposure assessment methods/tools to support the REACH Safety Assessment Framework.
- Convince companies (and authorities) that it is worth the effort (demonstrate usefulness and feasibility).

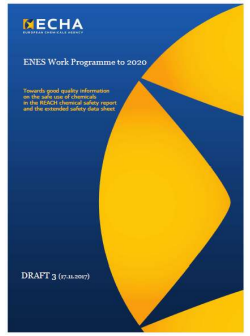
Noteworthy features moving forward

- More focus on the information **needs** of downstream end-users.
- More focus on REACH information processing at the single formulator's level.
- Better connect REACH information with the authoring systems for safety data sheets for substances and for mixtures.
- Integrate REACH "safe-use" within business information systems.

ENES Work Programme



1. Strategy and promotion.
2. Information from downstream users to registrants.
3. Information processing by registrants.
4. Information processing by formulators.
5. Information processing by end users.
6. Coherence between REACH CSA, SDS information and local workplace risk assessment (research)



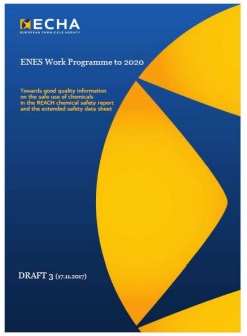
Action tables

2. Information from downstream users to registrants.
Covers all actions around sector use maps.

	Action type	Action	Description of actions	Expected impact from action	Timeframe	Responsible lead organisation
2.1	Content development	Develop use maps elements by individual sectors.	Developing new use maps. Completing/updating existing use maps (including SPERC, SCEDs, SWEDs); including standard phrases for communication and Chesar files. *Note: See also promotional action above to activate inactive sectors.*	More complete use maps available for registrants.	2017-2020	DU sectors
2.2	Content development	Support to sectors developing/ updating use maps.	Regular exchanges among use maps developers and ECHA. High-level feedback from ECHA prior to publication. Development of support material. Identification of improvement/ harmonisation needs.	Increased harmonisation and consistency of use maps available (including in Chesar format).	2017-2020	ECHA
		review process on the	Set up a (third party) review mechanism to ensure that published use maps are complete, understandable and that	Increased quality and buy-in by the authorities (e.g. via	For SPERCs, 2018: qual-	Member State lead

- Action types: generation of content, testing, development of tools/methods, research, monitoring of progress.
- All stakeholders to be, as far as possible, represented in all actions (with more or less intensity).
- Yearly work programmes to be documented.

Steering the programme

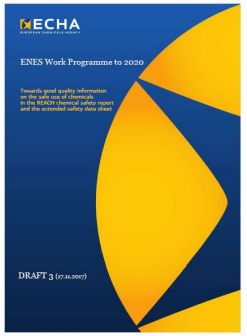


High level commitment of parties

ENES Coordination Group

Action lead | Action lead | Action lead

ENES



Next steps

- Draft programme at ENES11:
  - Working sessions discuss action areas;
  - Propose changes / additions / deletions / priorities;
  - Identify volunteers to contribute in action groups;
- Revise draft after ENES11.
- Finalise document by end 2017.
- Organisational commitments (re)confirmed early 2018.
- CARACAL informed (March 2018).

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EUROPEAN CHEMICALS AGENCY

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