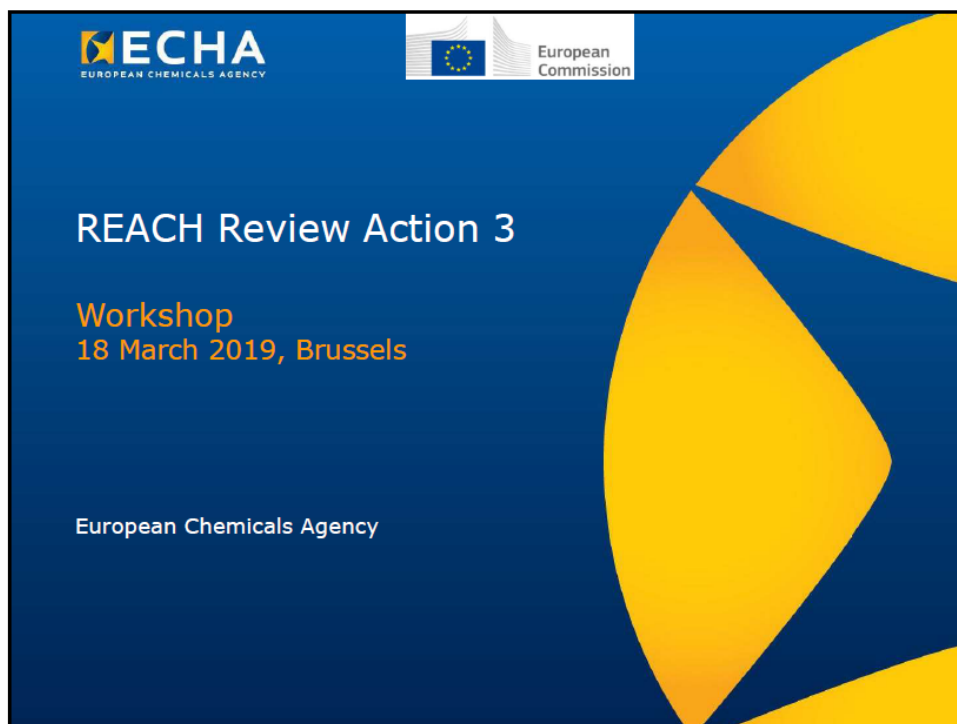


## Appendix 4. Presentations



The slide has a white background with a black border. In the top left corner is the ECHA logo. To its right, the word 'Agenda' is written in a large, bold, blue font. Below the title is a list of agenda items, including welcome, scene setting, workshop approach, coffee and lunch breaks, group discussions, reports, and conclusions. At the bottom right, the website 'echa.europa.eu' and the page number '2' are listed.

- Welcome by Commission and ECHA
- Set the scene: Why is Action 3 needed?
  - The state of supply chain communication after 10 years of REACH (Jack de Bruijn, ECHA)
  - ECHA's analysis on shortcomings (Andreas Ahrens, ECHA)
  - Current status of REACH Review Action 3 and main comments received from CARACAL (Gert Roebben, COM)
- Explanation and set up of workshop approach
- Coffee break*
- Discussion in small groups, rotating (Part 1)
- Lunch break*
- Discussion in small groups, rotating (Part 2)
- Coffee break*
- Reports of rapporteurs
- Plenary roundtable discussion
- Conclusions and discussion on next steps
- Closing 17h00*

echa.europa.eu 2



## Action 3: Improving the workability and quality of extended Safety Data Sheets

- **Action 3(1):** The Commission encourages more industry sectors to develop and use harmonised formats and IT tools that would provide more user-targeted information and simplify the preparation and use of extended Safety Data Sheets as well as facilitate their electronic distribution;
- **Action 3(2):** The Commission will consider including minimum requirements for the exposure scenarios for substances and mixtures in Safety Data Sheets and request ECHA to develop a methodology for Safety Data Sheets for mixtures

echa.europa.eu

3




## Four interrelated action areas

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

echa.europa.eu

4



## REACH Review & ENES Actions


REACH Review Action	Relevant ENES Actions
<p><b>3. Workability and quality of ext. SDSs</b> – potentially minimum requirements for ESs, &amp; develop a methodology for mixtures Actors: COM, ECHA, industry</p>	<p>1.4 Consistency of safe-use info 3.3b Further development of ECom package 4.1 &amp; 4.2 Methods to generate safe-use info. (SUMI &amp; LCID) 5.2 Market research</p>
<p><b>12. Interface of REACH and OSH</b> - aligning methodologies &amp; coordinated enforcement by Q1 2019 Actors: COM</p>	<p>3.2 Consolidate user exposure tools 5.2 Market research 6.1 Communication practices in the supply chain</p>
<p><b>14. Support to SMEs</b> - best practice, sector-specific solutions &amp; other support in national languages Actors: COM, ECHA, MSs &amp; NEAs</p>	<p>1.2 Promotion of ENES tools 5.2 Market research 6.1 Communication practices in the supply chain</p>

echa.europa.eu 5



## Supply chain communication after 10 years of REACH


Jack de Bruijn, ECHA

 **ECHA**  
EUROPEAN CHEMICALS AGENCY

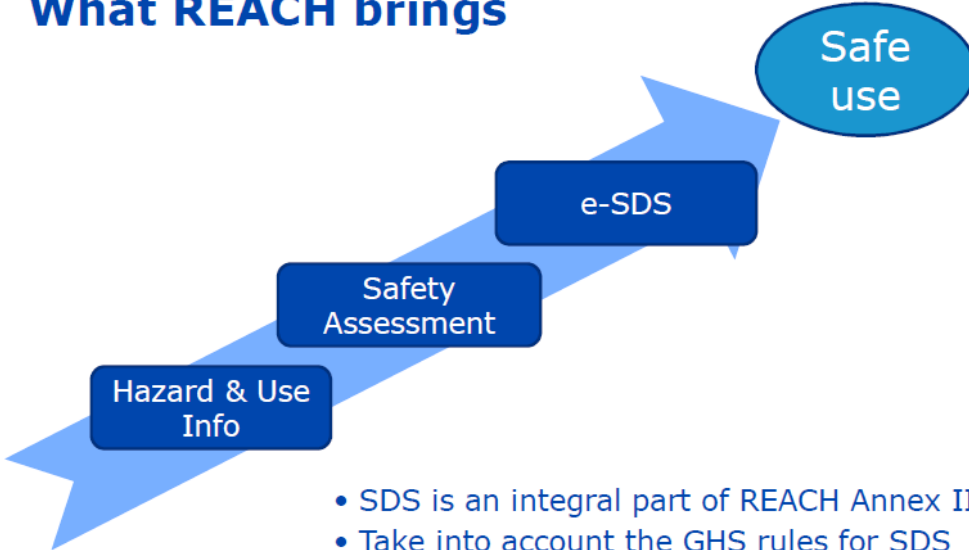
## Content

- Setting the scene (at high level)
  - Importance of supply chain communication
  - ECHA work on topic - ENES
  - Reflection and analysis - lessons learnt
  - REACH Review Action 3 way forward - commitment

echa.europa.eu 7

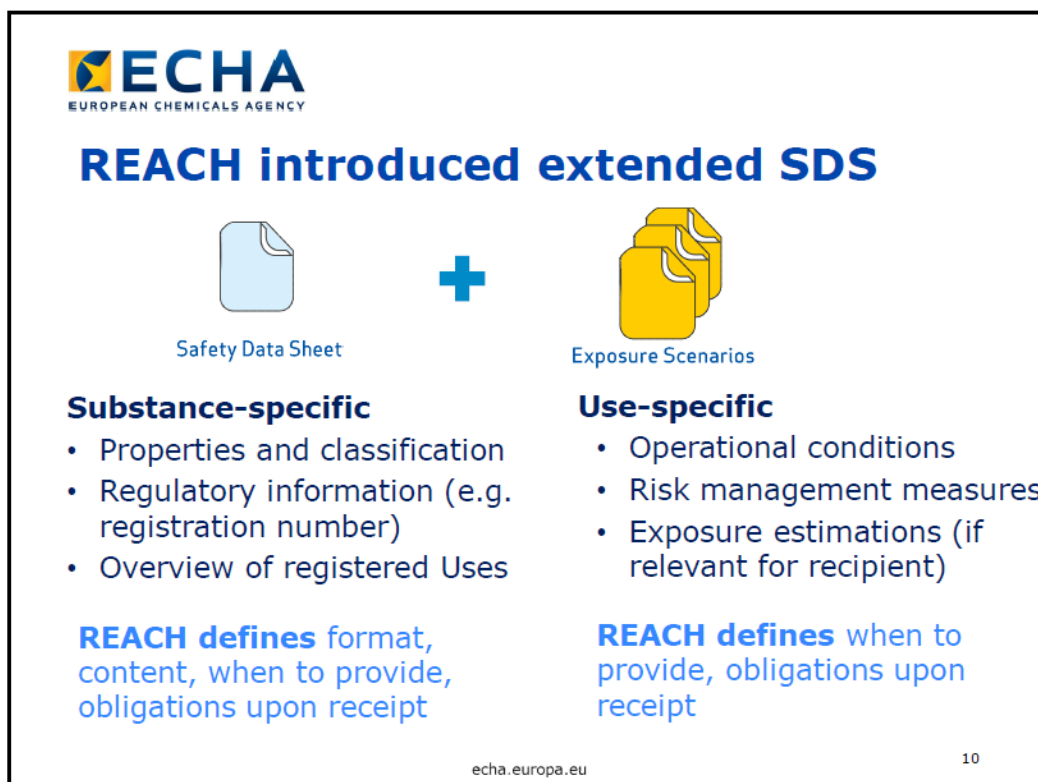
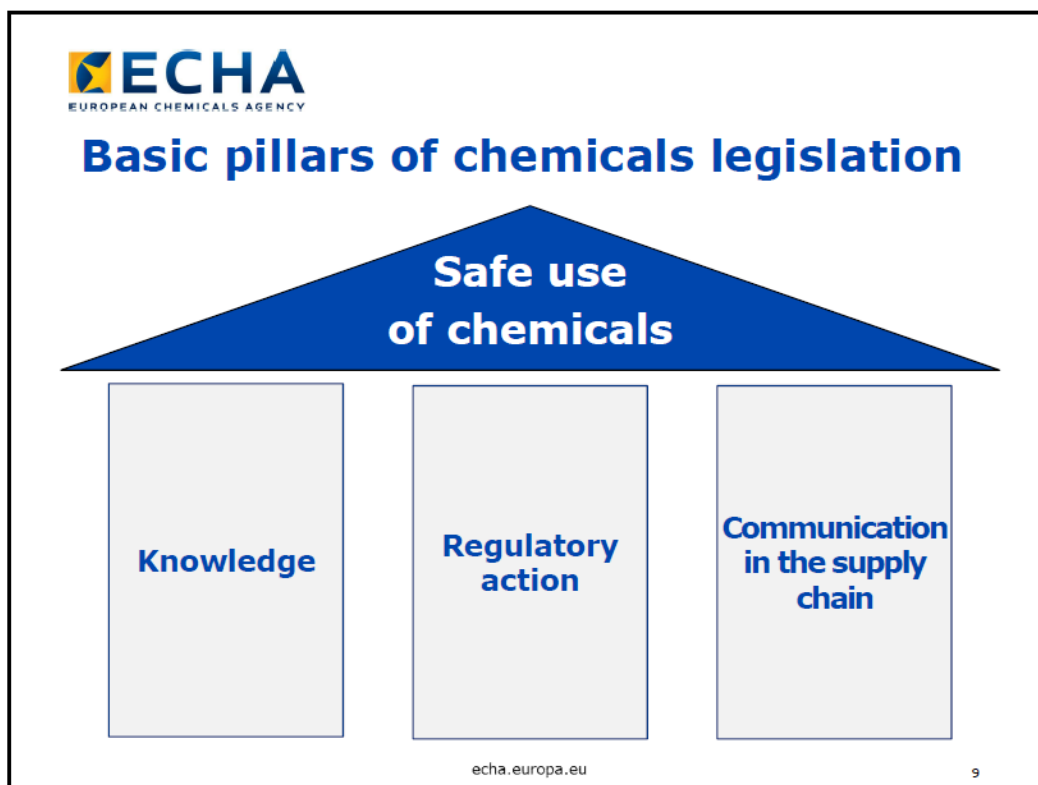
 **ECHA**  
EUROPEAN CHEMICALS AGENCY

## What REACH brings



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

echa.europa.eu 8



**ECHA**  
EUROPEAN CHEMICALS AGENCY

## ECHA is working together with partners to enhance supply chain communication

ENES Programme 2020

- Tools for improving communication in the supply chain
- Key actors involved ECHA, chemical and downstream user industries

Improving communication on the safe use of chemicals

<https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios>


echa.europa.eu 11

**ECHA**  
EUROPEAN CHEMICALS AGENCY

## ENES: many positive aspects

1. CSR/ES Roadmap launched in 2013 as a **collaborative** stakeholder programme to improve supply chain communication.
2. ENES is of **unique** and of **high value** to industry to develop and share practical solutions. ENES to continue....
3. Suite of tools developed for CSA/ES generation and communication.
4. However, to address shortcomings identified change / **adaptation** is needed (this is natural) in moving towards 2018 and then 2020.


echa.europa.eu 12



## Evaluation of ENES programme

- **Raising awareness:** Broadening engagement and implementation beyond the current (ENES) community: industry sectors & Member States.
- More pronounced emphasis on needs of the **end users** of chemicals.
- Strategic positioning of the extended safety data sheets as a means of **supporting compliance** with closely related legislation (*environment, OSH, product safety*).
- Manufacturers, formulators and end users should take (ENES) tools into use.
  - Feedback mechanism to ensure developers of tools know how to improve.

echa.europa.eu 13



## Lessons learned in various studies

### Exposure scenarios need further development

**Views of the Finnish companies and the labour inspector on the shortcomings of exposure scenarios.**

Reasons	Companies	Labour inspectors
Unclear information / Too many acronyms information	✓	✓
Too long / Difficult to identify relevant	✓	✓
For specialists	✓	✓
Not in line with the terminology and assessment requirements in OSH/Environmental legislation	✓	✓
Poor layout (no index, page numbers and / or version numbers)	✓	✓
Too much repetition / information scattered across the safety data sheet and exposure scenarios / information refers to other sources	✓	
Information is overlapping or contradicting with the body of safety data sheet	✓	✓
Poor translations	✓	✓

echa.europa.eu 14



The slide features the ECHA logo and 'EUROPEAN CHEMICALS AGENCY' at the top left. The main heading is 'REACH Review Action 3'. Below it is a bulleted list of points regarding the workshop's purpose and the need for stakeholder input. The text 'echa.europa.eu' is at the bottom left and the number '16' is at the bottom right.

**REACH Review Action 3**

- Is an opportunity to make the ext.SDS system work better for all. This Workshop is the starting point....
- Your input is critical, e.g.:
  - What do you see as the main root causes (obstacles) negatively impacting the workability and quality of extended safety data sheets?
  - Do the various guidelines and tools that have already been developed help companies with the extended safety data sheets?
  - How to coordinate with other REACH Review Actions?
  - What should be the role of OSH, Environment authorities?





## Commitment

- ECHA supporting and resourcing work on supply chain communication.
- But Improvements cannot be achieved by ECHA (COM) alone.
- Stakeholders' participation is key
  - How can we best involve you?
- Where is your organisation ready to contribute to the work process in 2019 and beyond?



[echa.europa.eu](http://echa.europa.eu)


17





## Supply chain communication Achievements and obstacles

Andreas Ahrens  
European Chemicals Agency



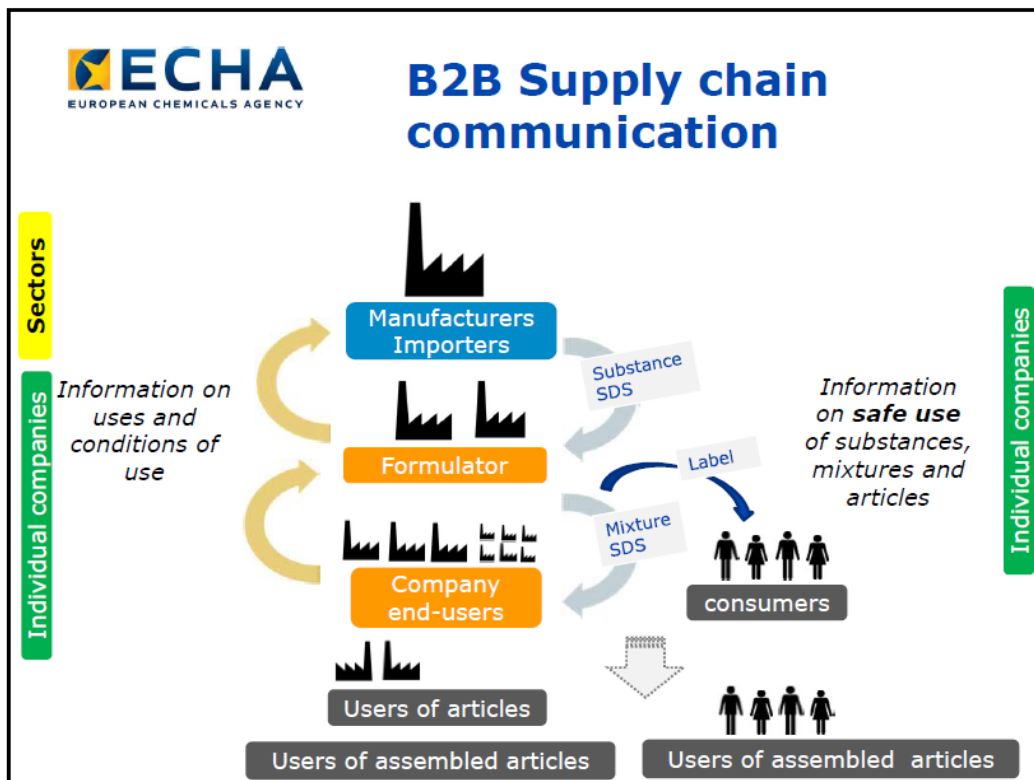
  
EUROPEAN CHEMICALS AGENCY

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

<p><b>Manufacturer</b></p>  <p><b>Knows the properties of the substance</b></p>	<p><b>Downstream user</b></p>  <p>Knows how the substance is used</p> <ul style="list-style-type: none"><li>• Foreseen products and processes</li><li>• Concentrations and amounts</li><li>• Operational conditions</li><li>• Risk management measures</li></ul>
--	--

→ Exchange of information (via supply chain or other means)  
→ Allocation of assessment responsibilities  
→ Capacity to carry out the assessment

echa.europa.eu •20



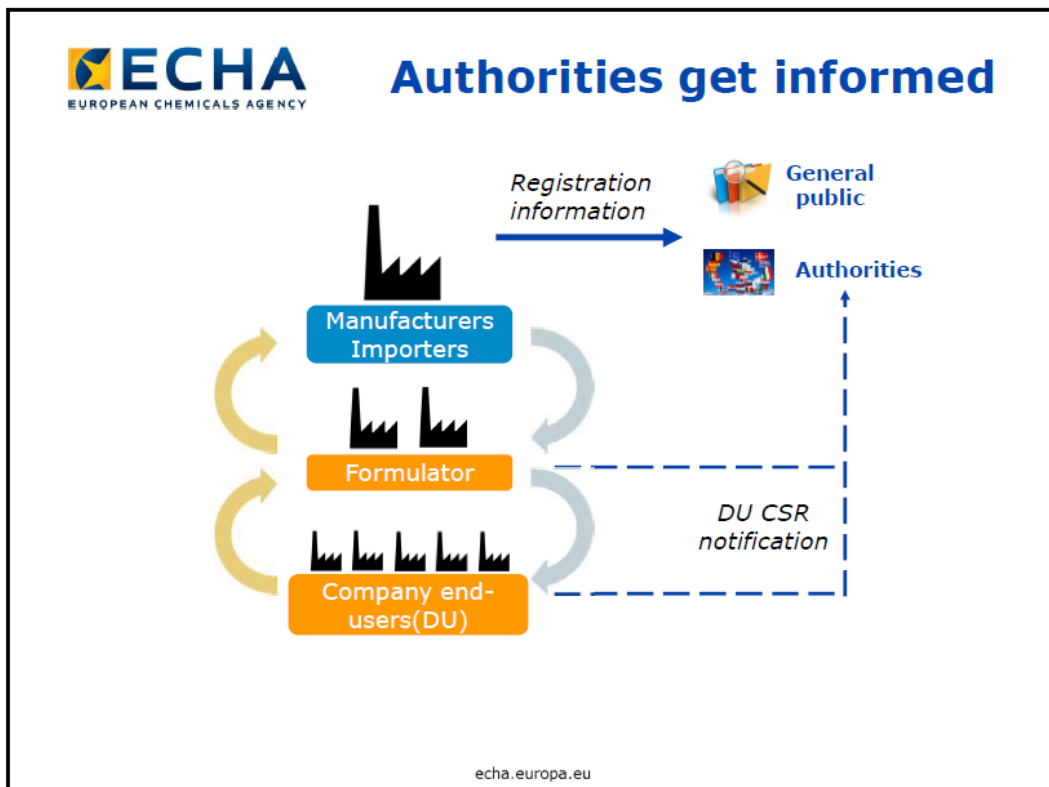
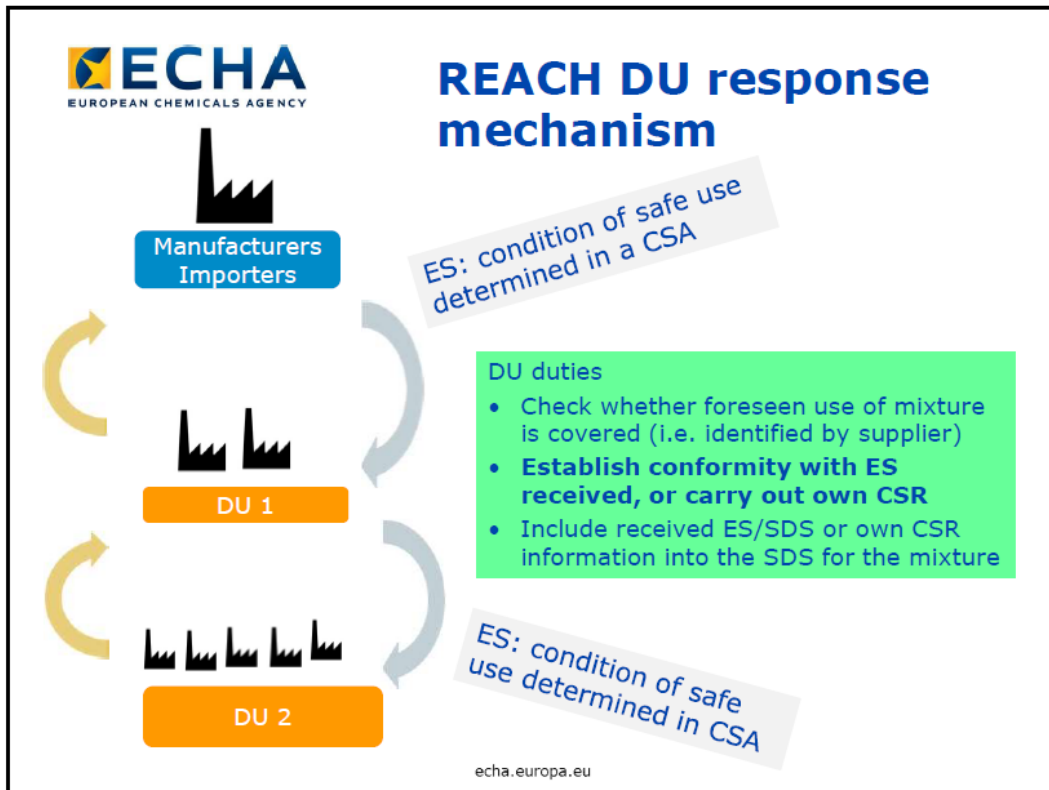
**ECHA**  
EUROPEAN CHEMICALS AGENCY

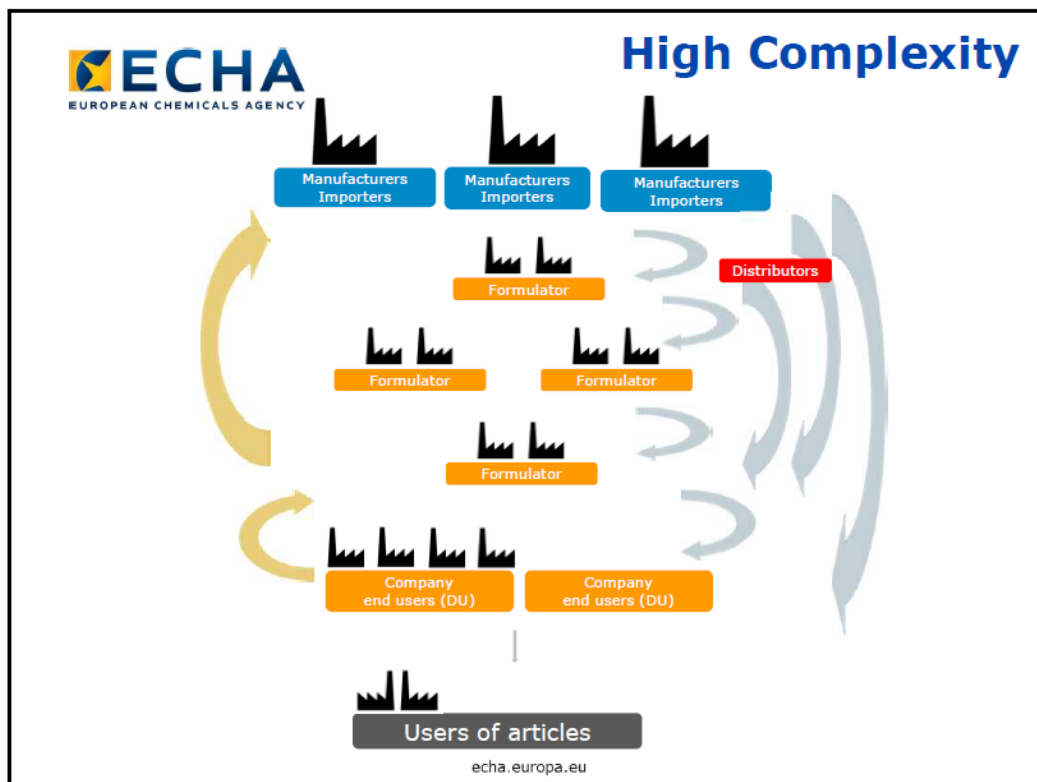
## Number of substances and safety data sheets

Documents	Number
Substance (by lead dossiers) requiring exposure assessment	4,300
Extrapolated number of SDS with exposure scenarios:	30,000
Extrapolated SDS for mixtures containing these substances	300,000

echa.europa.eu

22





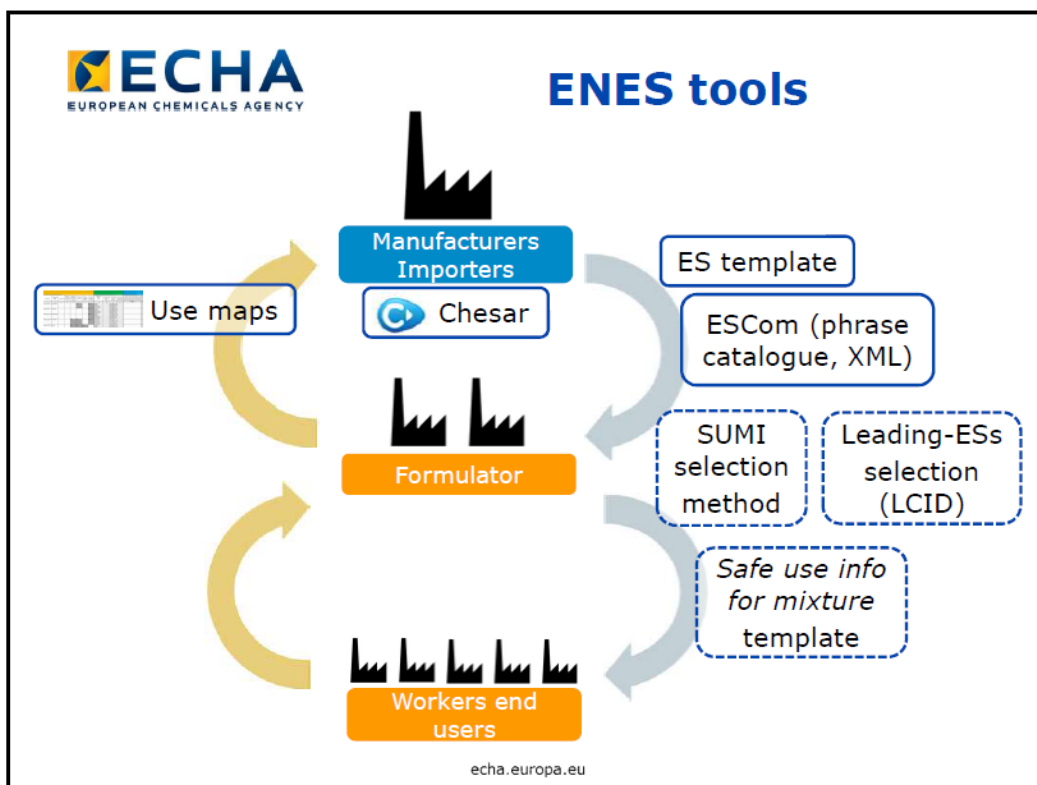
**ECHA**  
EUROPEAN CHEMICALS AGENCY


## The exposure scenario challenge

Top down system (with limited feedback)

- An assessor at the top of the supply chains is expected to
  - differentiate safe use advice for his substance according to
    - to the identified uses in the life cycle of the substance
    - the variety of the operational conditions existing for a use
    - risk management measures available to the user
  - demonstrate control of risk based on exposure quantification
  - communicate relevant and targeted advice in a terminology understandable to recipients
  - all this, based on information to be obtained from a complex, diversified and competitive market (for initial extending of SDS and subsequent feedback)
- Set to front-end of existing SDS systems having emerged over decades

echa.europa.eu 26






## ENES/ECHA achievements

- At present more than 50% of companies generating or updating a CSR use Chesar.
- A significant number of industry sectors have generated or updated their sector use maps.
- Some tools/methods for generating, processing and communicating exposure scenario information available (ongoing "beta testing" ).

echa.europa.eu
29




### Use maps development status (1) 11/2018

**PUB:** Published in use maps library     **INT:** Intention  
**DEV:** Under development

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

echa.europa.eu

 **Use maps development status (2)**  
EUROPEAN CHEMICALS AGENCY

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.....					

echa.europa.eu

 **Ongoing "Beta Testing"**  
EUROPEAN CHEMICALS AGENCY

3 ENES projects

- 10 registrants testing exposure scenario generation based on sector use maps
- x formulators going to test the processing of the ES generated by registrants (based on SUMI selection method)
- VCI/CEFIC taskforce exemplifying safe use information for mixture based on LCID method

echa.europa.eu

32





## Why is it not working (1)

No explicit demand for safe use advice from the bottom of the supply chain (=> market forces do not properly work)

- 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


## Why is it not working (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
- 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 DU
  - DU don't manage to get response from suppliers
- No upstream communication system established for single company to efficiently feedback to suppliers


## Why is it not working?

3. Current legal requirements on exposure scenarios difficult to enforce (=> market forces do not properly work; => insufficient driver for harmonisation)
4. Inertia of existing SDS systems and their underlying IT (global players reluctant to change their running SDS system)
5. 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
  - 70% of SDS annexes are a copy and paste of CSR section 9 into ES for communication
  - Conditions of use do not reflect reality in the supply chain
  - Terminology 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, waste of resources, frustration, slow update)

echa.europa.eu 37

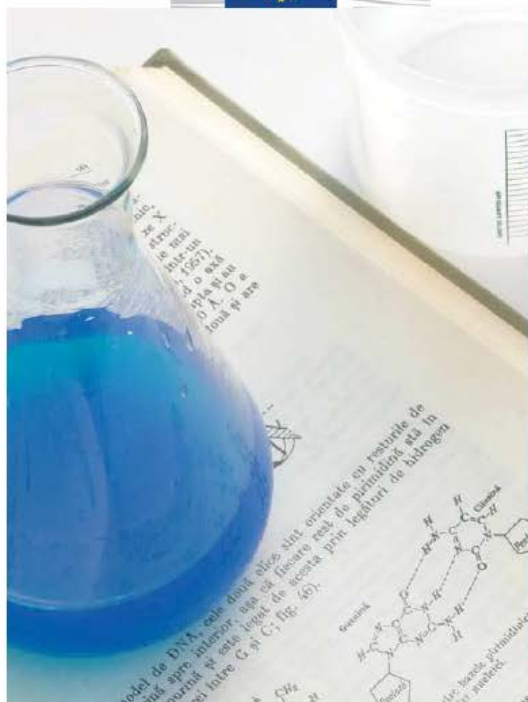
**Summary**

- Exposure scenario concept challenging by nature
- Solutions largely available, partly still under testing and partly already implemented

**Obstacles**

- Lack of explicit demand from customers and authorities (feedback circles don't work; insufficient user targeting)
- Upstream communication does not work at single company level
- Requirements leave room for flexibility: enforcement difficult; insufficient harmonisation;
- Only limited uptake of available solutions regarding improvement of use-related information
- Companies do not change existing safety data systems for systematic integration of CSR based information

echa.europa.eu 38



## REACH review Action 3

- Current status

- Main comments received from CARACAL

*Brussels, 18 March 2019*

Disclaimer

*All views expressed are purely personal and should not be considered as representative of the European Commission's official position. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the following information.*



## ACTION 3

### Improve workability and quality of extended safety data sheets

**Too lengthy**  
**Information not targeted to users**

**Expand the use of harmonised formats and IT tools**

**Deficiencies on information in the exposure scenarios**

**Actors involved : Commission and ECHA with industry. ECHA to develop a methodology of SDS for mixtures.**



## Related actions

### **ACTION 12: Interface REACH and OSH legislation. *Why?***

- 1) Need to clarify some overlaps
- 2) **Better use of REACH tools under the OSH legislation**
- 3) Improve the coordination between REACH and OSH national authorities
- 4) Alignment of the methodologies
- 5) Enhance the role of RAC to provide scientific opinions under OSH legislation

**Actors involved : Commission, ECHA and Member States.**



## Related actions

### **ACTION 14: Support SMEs compliance.**

- 1) Specific vulnerability compared to large companies in view of limited human and financial resources/capacity to absorb costs
- 2) Need to monitor possible impact for the registration deadline 2018
- 3) Support measures provided so far considered useful but need for practical and user-friendly information, available in national languages

**Actors involved: Commission, ECHA and Member States.**



Main REACH Review Action 3 events	
Adoption and publication of second REACH review	5 March 2018
Discussion REACH review action 3 in CARACAL	21 November 2018
<b>Scoping Workshop</b>	<b>18 March 2019</b>
<i>Interviews, smaller meetings per sector, consult ENES + FORUM, ...</i>	<i>April-June 2019</i>
<i>Interim progress report to CARACAL</i>	<i>July 2019</i>
<i>Broad stakeholder workshop, Helsinki</i>	<i>End of September 2019 (tbc)</i>



## Main feedback to CA/98/2018

### General

- 1) Support for proposed follow-up actions (incl. workshop)
- 2) Need for changes in REACH (Annex II + more)?
- 3) Improve compatibility of tools used in different sectors



## Main feedback to CA/98/2018

### ENES tools

- 1) Useful
  - Use Maps, SUMI, LCID, ESCom, CHESAR, ...
  
- 2) Not used enough - reasons to be examined
  - Involve more industry sectors
  
- 3) To be promoted more
  - Also to avoid duplication of efforts



## Main feedback to CA/98/2018

### (More) guidance requested on

- 1) Orientation of information to user needs
  
- 2) Specific ES requirements
  
- 3) Acceptable formats



## Main feedback to CA/98/2018

### Minimum ES requirements

- 1) As a way to facilitate the 'logistics' of supply chain communication
- 2) To improve quality and comprehensibility
- 3) As for SDS main body (index) or beyond (template)



## Main feedback to CA/98/2018

### Mixtures

- 1) Need for more clarity on requirements for mixtures
- 2) Take inspiration from ENES (SUMI), OSH, ...
- 3) Effects of combined exposure  
- Beyond scope of REACH Review Action 3?





## Main feedback to CA/98/2018

### Complexity / length of eSDS

- 1) More user-targeted information
  - Often unrealistic risk management measures
  
- 2) Consider 'basic' SDS (2 pages) with links to more info
  - More modular approach?



## Main feedback to CA/98/2018

### Linguistic problems

- 1) Important issue for SMEs and smaller Member States
  
- 2) High expectations from more harmonisation / standardisation of requirements and from use of electronic tools (e.g. ECom)



## Main feedback to CA/98/2018

### Electronic eSDS

- 1) Carries the hope of many for a more efficient preparation, translation, distribution and use of eSDS

- Existing tool: ECom



## Main feedback to CA/98/2018

### Occupational Safety and Health

- 1) Need synergy between SDS and workplace safety rules
- 2) Link with REACH Review Action 12  
« How to use REACH tools to enhance effectiveness of OSH legislation »
- 3) Value of measured data vs modelled data



## RCOM document CA/16/2019

**- Provides initial COM/ECHA response to CARACAL comments**

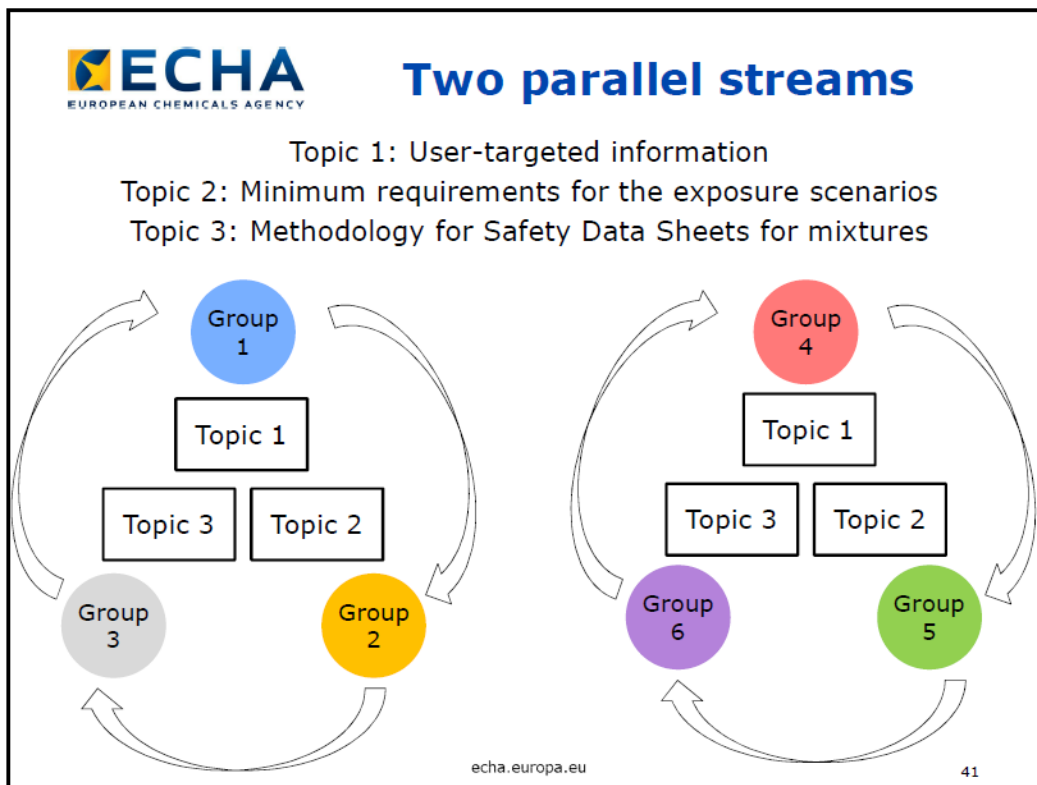
**- To be further developed based on additional input collected today and in the coming months**



For further information on REACH and the REACH evaluation, please visit:

[ec.europa.eu/growth/sectors/chemicals/reach/](http://ec.europa.eu/growth/sectors/chemicals/reach/)  
[ec.europa.eu/environment/chemicals/reach](http://ec.europa.eu/environment/chemicals/reach)  
[echa.europa.eu](http://echa.europa.eu)  
[http://ec.europa.eu/growth/sectors/chemicals/reach/review\\_en](http://ec.europa.eu/growth/sectors/chemicals/reach/review_en)  
[http://ec.europa.eu/environment/chemicals/reach/review\\_2017\\_en.htm](http://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm)







## Questions for the plenary

- Do you agree that the themes discussed during the breakout groups provide an appropriate frame for Action 3?
- Which aspects are most important to you?
- Which aspects are of lower priority?
- Which aspects are missing in your view?

echa.europa.eu

43

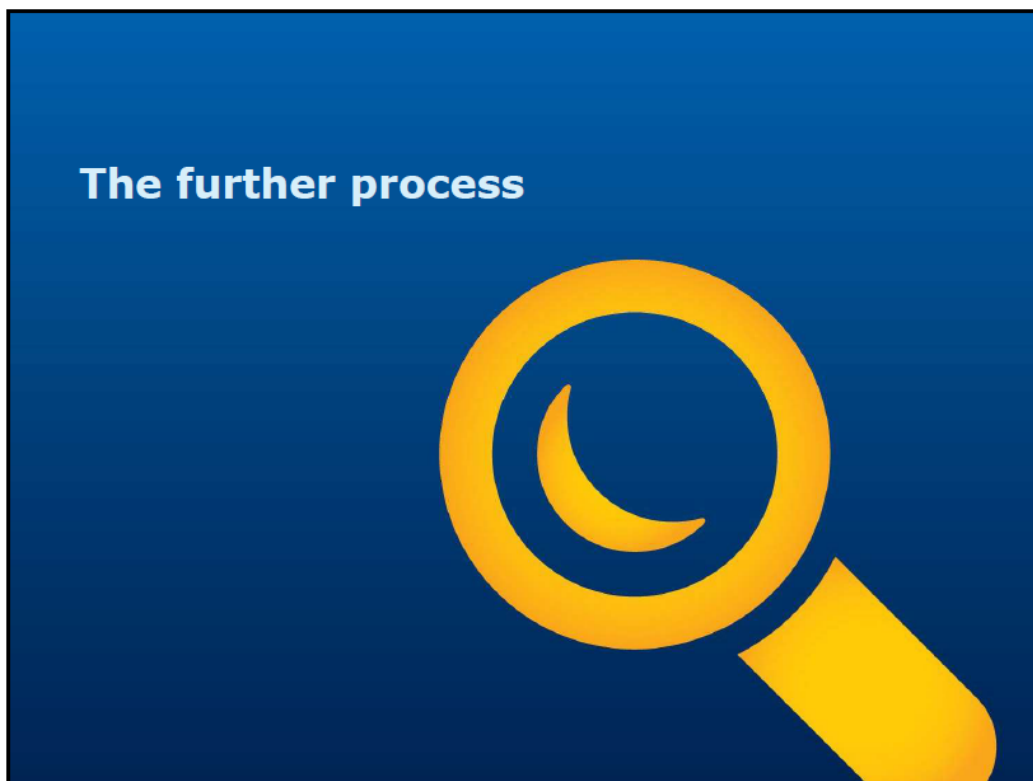


## Questions on the coordination of activities with other REACH Review actions

- Do you see opportunities to integrate REACH information e.g. in OSH tools for workplace chemical risk assessment or Environmental assessment frameworks?
- ECHA, Member States and industry has prepared various guidelines and tools to help companies with the extended safety data sheets. Is that material suitable to demonstrate the benefits of the new system?

echa.europa.eu

44



## Phases

- 1. Scoping** phase to identify issues/problems/potential solutions of priority importance.
  - Delivering to CARACAL in November 2019.
- 2. Development** phase for working out solutions, making choices between options and testing impacts.
  - One year's time after agreement on scope, 2020.
- 3. Consultation** phase on the proposed solutions (conceptual, regulatory, technical/tools/guidance)
  - Potentially another year, 2021.



## 2019 Objectives

**Harvest proposals** for solutions and to identify:

- a) Which solutions are (potentially with small adaptations) ready for implementation.
- b) Which solutions need to be (further) developed, which may include methods for generating and utilising information, tools and IT solutions, guidance, legal clarification.
- c) Who will carry out the development work
  - including a proposal for a revised work programme for the Exchange Network on Exposure Scenarios (ENES).

echa.europa.eu

47



## Process outline

- Gather more representative overview:
  - Interviews/Meetings with sector organisations & companies / April-May.
- Harvest proposals:
  - ENES Work Programme actions: beta testing /May-June
  - Forum initiatives / June.
- Current & future solutions in SDS authoring
  - Service providers / May.

echa.europa.eu

48





## Process outline

- Interim report/CARACAL-30/July
- Stakeholder workshop/ECHA/23-25 September
- REACH Review Action 3 Scoping document/  
CARACAL-31/November.

[echa.europa.eu](http://echa.europa.eu)

49



Thank you!

### Follow our news

Newsletter: [echa.europa.eu/subscribe](http://echa.europa.eu/subscribe)

Twitter: EU\_ECHA

Facebook: EUECHA

YouTube: EUchemicals

LinkedIn: European Chemicals Agency