



# Notifying hazardous mixtures to Member States

## Annex VIII to CLP and harmonisation of information

21 May 2019

Submission and Processing Unit  
Poison Centres Team

#SAFERCHEMICALS

# Welcome!

## **Part I – 10:00-11:10** (streamed live)

- Poison Centres notifications – Regulatory update
- Prepare and submit using ECHA tools
- Foreseen changes

### *Short break 11:10-11:30*

- ECHA Submission portal: introduction to the training

## **Part II - 11:45-16:00** (not streamed live)

- Training exercise (I)

### *Break 13:00-13:45*

- Training exercise (II)
- Close

## Practical info

- Wear your badge
- WiFi password: **GuestW1F1**
- **Coffee** served in the lobby 11:10-11:30
- **Lunch** (own cost) outside or ECHA restaurant 13:00-13:45
- Drinks, except water, or food are not allowed in the conference room
- Request for taking floor is done by pressing the microphone button on the panel in front of every seat





## Practical info

- Smoking: ground floor, take elevator to your left as you leave the room
- Toilets are located on the same floor on the left as you exit
- In case of emergency, follow green exit signs and assemble in the park outside



# Poison centre notifications – Regulatory update

Safer chemicals – ECHA conference

21 May 2019

Daniele Ape

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# Table of contents

- Background – Article 45 and Annex VIII
- Duty holders – who?
- Timing – when?
- Information requirements – what?
- Action points and key messages

# Background – Article 45 and Annex VIII



# Article 45 of CLP

"Member States shall appoint a body... responsible for receiving information ... **for formulating preventative and curative measures**, in... the event of emergency health response, from **importers and downstream users** placing mixtures on the market. This information shall include the **chemical composition** of mixtures...**classified as hazardous on the basis of their health or physical effects** [...]"

**Why** ✓ **Who** ✓ **What** ✓ **How** ?

- ➔ Different information requirements in each Member State
- ➔ Different submission systems
- ➔ Issues with identification of poisoning agent/mixture



## It's about harmonisation

- Same information requirements in all EU Member States
- Preparation of data in a harmonised format
- Submission of data possible via central system (ECHA portal) [Optional]

# Duty holders – Who?



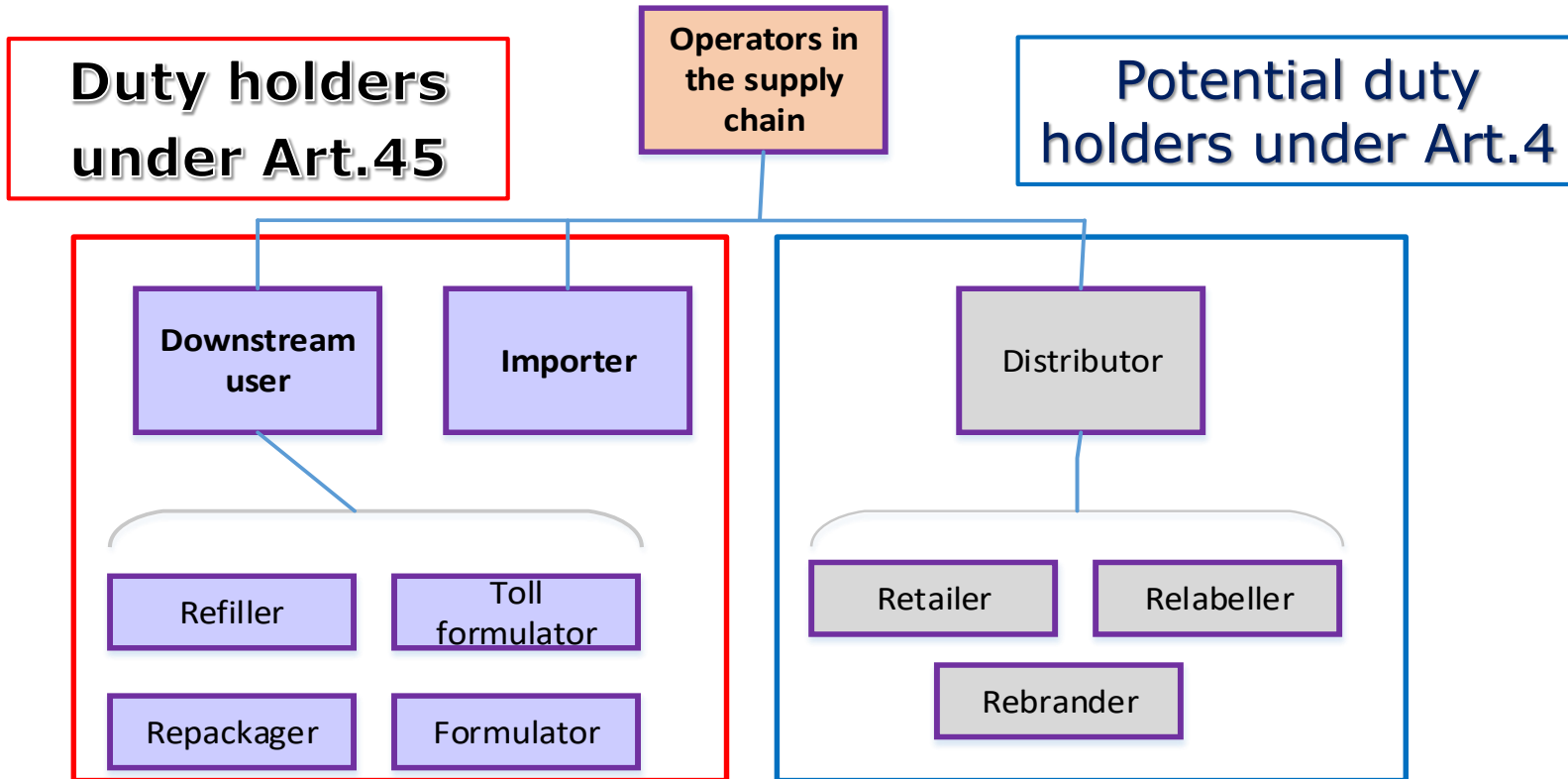
## Who has submission obligations?

- Companies placing **mixtures** on the **market** (*before!*)
  - Mixtures classified as **hazardous** on the basis of their health or physical effects
- In each Member States where the mixture is placed on the market

### **NOT:**

- Substances
- Mixtures not covered by CLP
- Mixtures classified only for environmental effects
- Mixtures used for R&D; PPORDs
- Gases under pressure
- Explosives (unstable explosives and divisions 1.1 to 1.6)

# Who has to submit information?

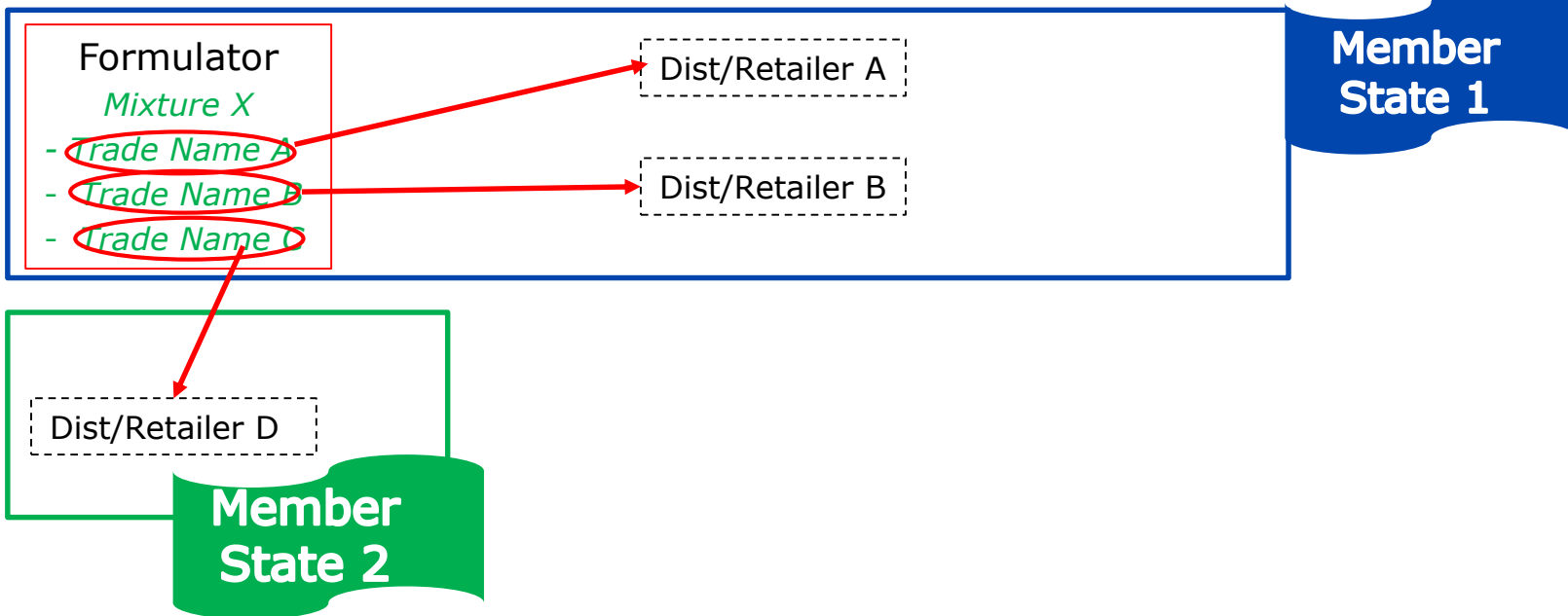


**Article 45** - Direct obligations → Importers/Downstream user

**Article 4(10)** – Mixtures placed on the market have to be CLP compliant → All actors (*including distributors!*)

Shared responsibility to prevent non-compliance (i.e. Annex VIII information available to relevant ABs)

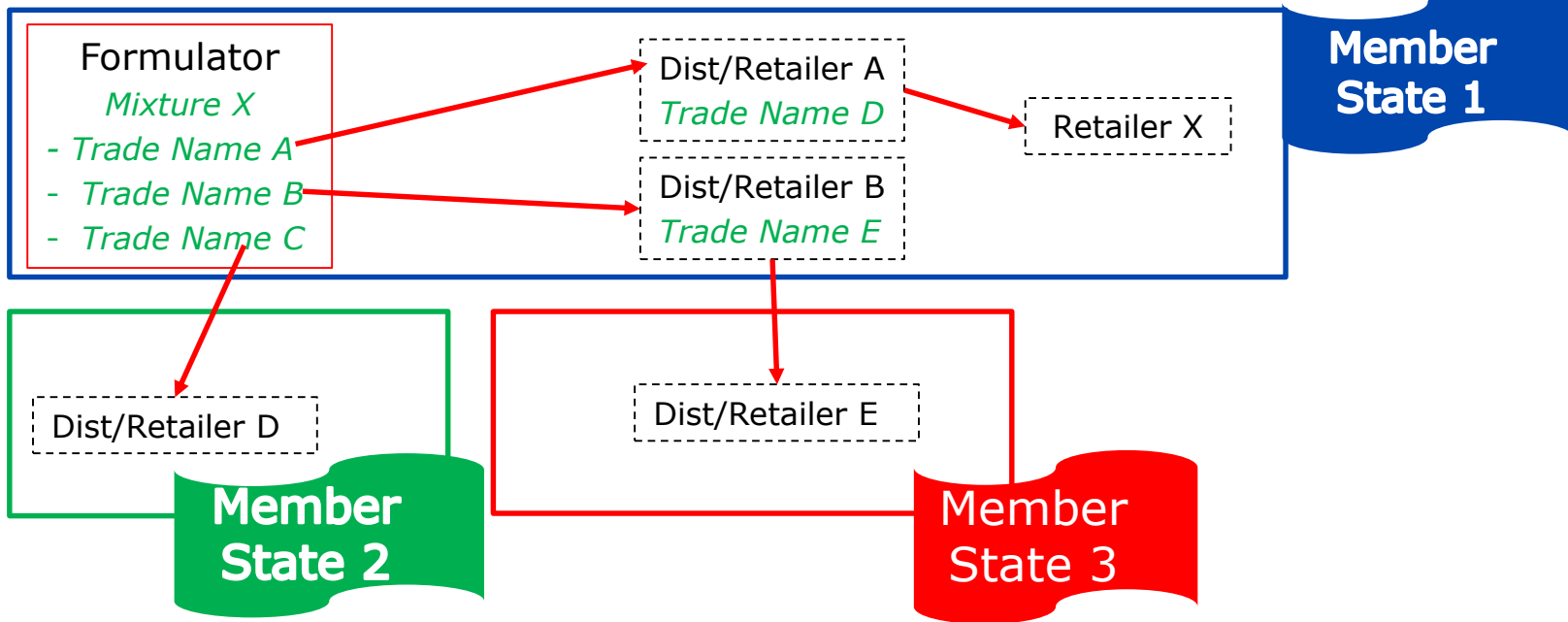
# Who has to submit information?



(Art.45) **Formulator** submits to appointed bodies in:

- Member State 1: Trade Name A and Trade Name B
- Member State 2: Trade Name C

# Who has to submit information?



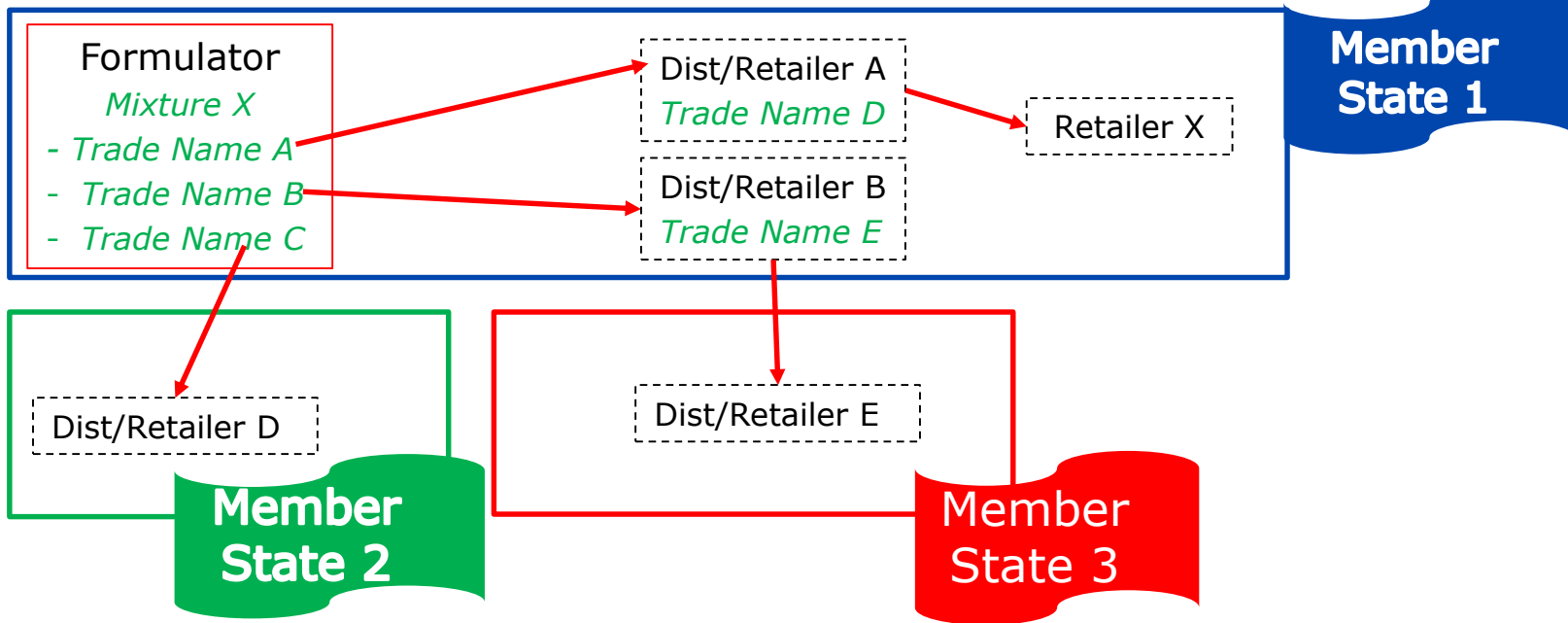
(Art.45) **Formulator** submits to appointed bodies in:

- Member State 1: Trade Name A and Trade Name B
- Member State 2: Trade Name C

(Art. 4(10))

- **Distributor A** submits to appointed body in Member State 1 (Trade Name D)
- **Distributor B** submits to appointed body in Member State 3 (Trade Name E)

# Who has to submit information?



- (Art.45) **Formulator** submits to appointed bodies in:
- Member State 1: Trade Name A and Trade Name B
  - Member State 2: Trade Name C

- (Alternatively)
- **Distributor A** informs formulator about Trade Name D;
  - **Distributor B** informs formulator about Trade Name E in MS 3

**and**

- Includes Trade Name D in submission to appointed body in Member State 1
- submits to appointed body in Member State 3 (Trade Name E)

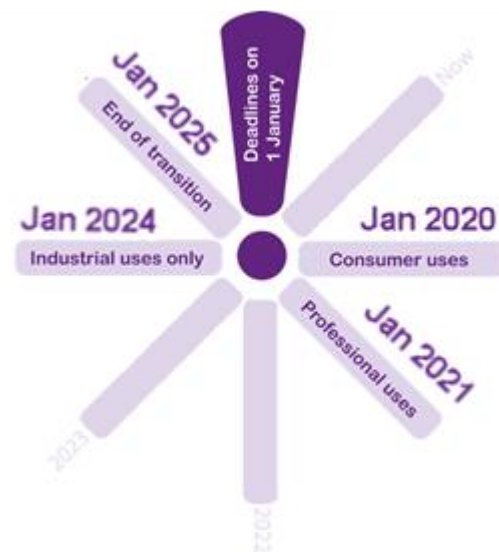
# Timing – When?



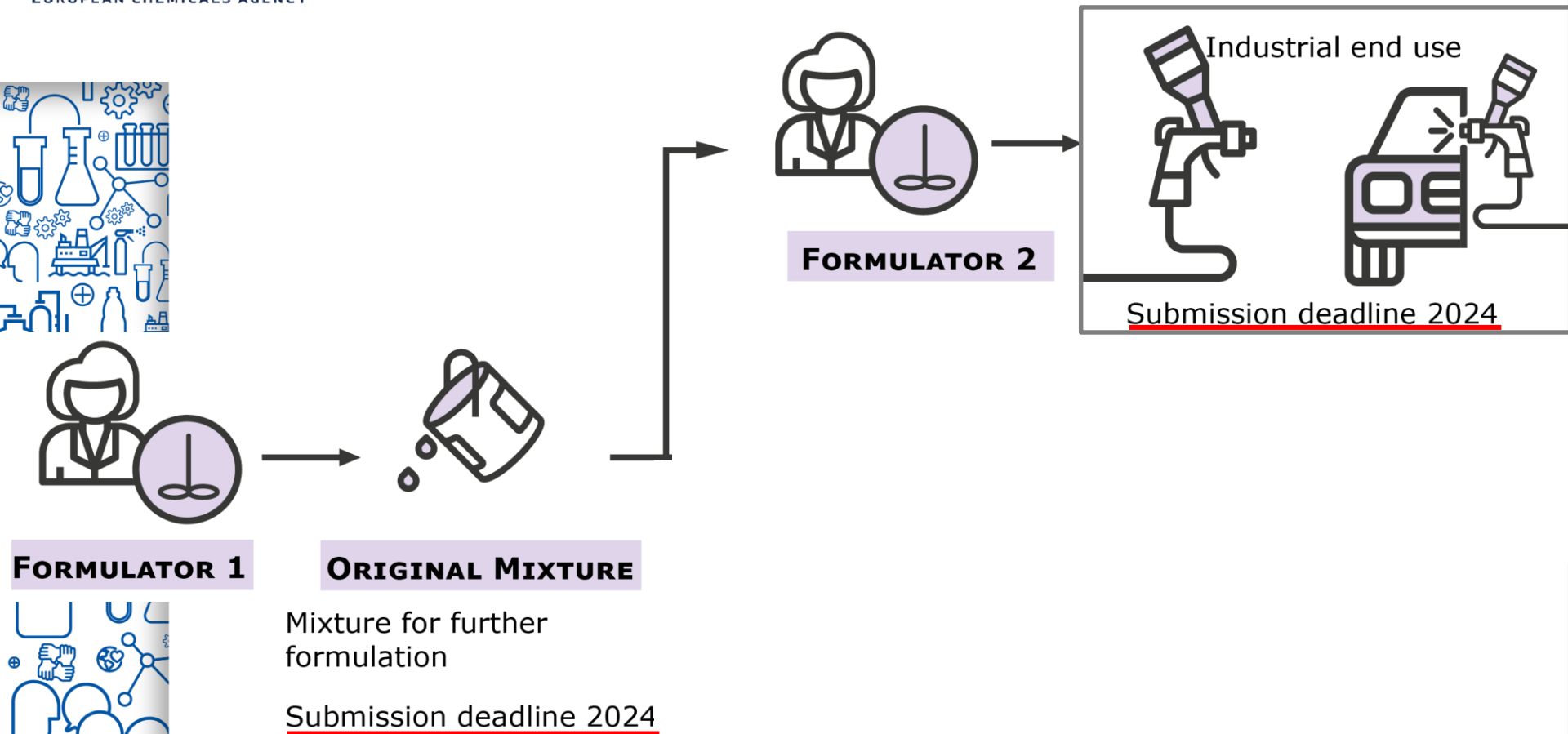


## Timelines for compliance

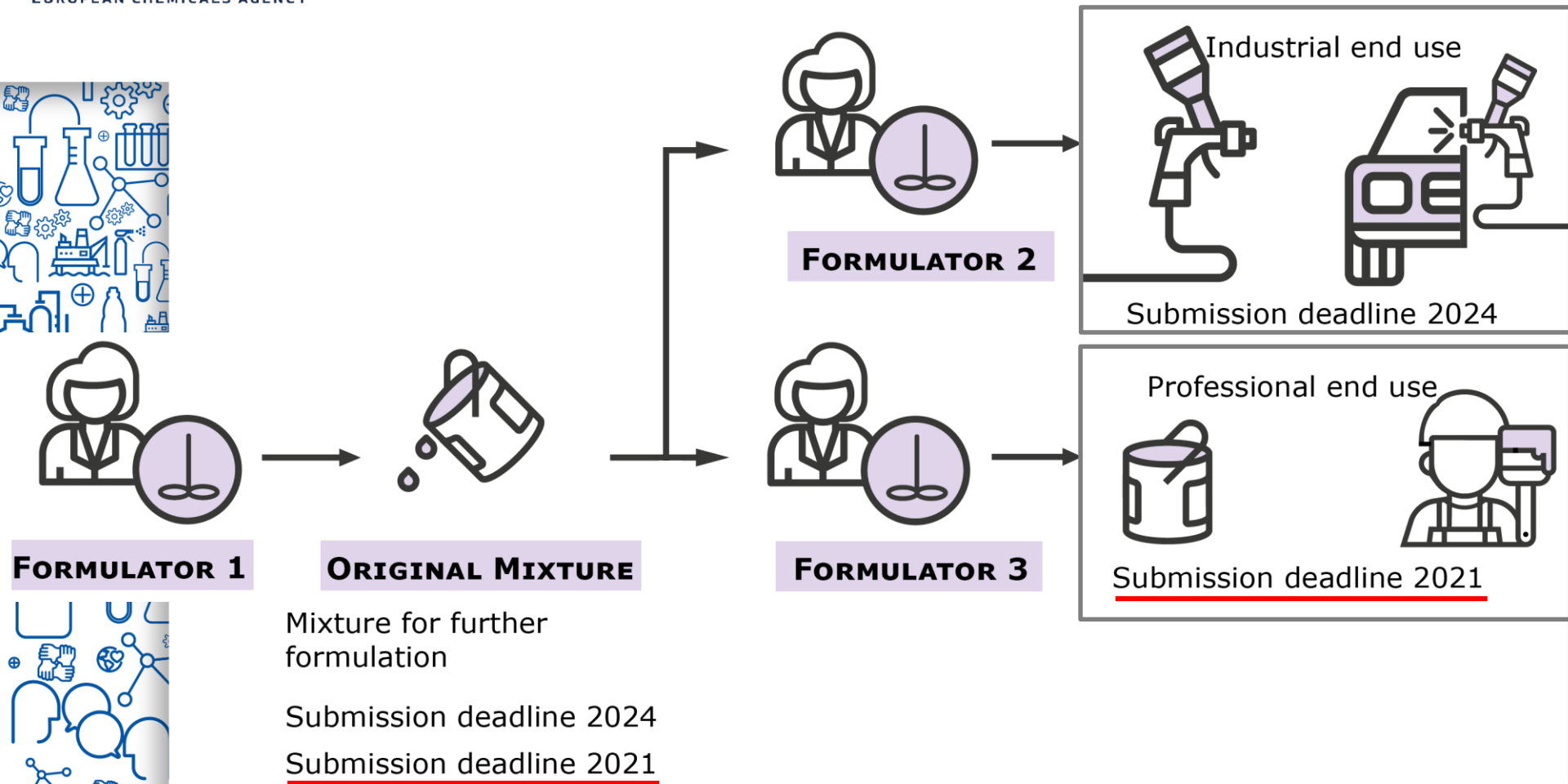
- Notifications must comply with the harmonised requirements according to the use type of the mixture
  - 1 January 2020: consumer uses
  - 1 January 2021: professional uses
  - 1 January 2024: industrial use only
- Transition period for existing products ends 1 January 2025
  - unless change made to existing notification between relevant deadline and end of transition period



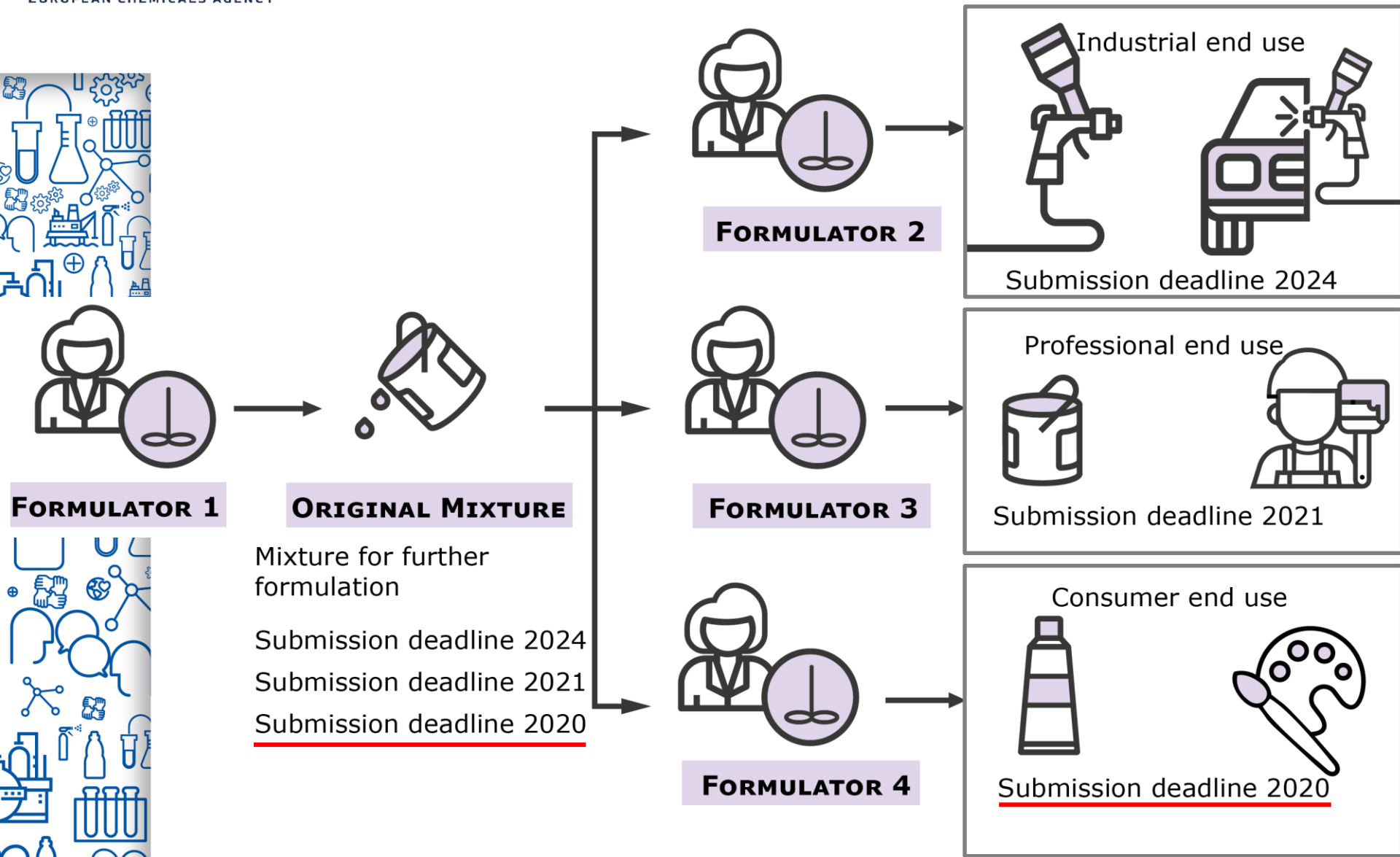
# Understanding the deadlines 1/3



# Understanding the deadlines 2/3



# Understanding the deadlines 3/3



# Information requirements – What?



# Harmonised requirements in brief



- **Submission format** – Poison Centre Notification (PCN) format, IUCLID compatible, structured fields for information
- **Submitter details** – name, address... - consistent with the label
- **Mixture information** - C&L, toxicological information, mixture composition, pH, physical state
- **Product information** - trade name, packaging, uses, colour
- **Unique formula identifier** – e.g. YV9K-3J9A-G209-C2T7

# Mixture vs. product

## Mixture

Mixture or solution containing chemical components having associated properties:

- Composition
- Toxicological properties
- Colour
- pH



## Product

Mixture in the form in which it is supplied to the user and defining the other aspects:

- Trade name
- Packaging
- Labelling
- Product category





# Mixture information

- hazard classification & label elements
- toxicological information
- pH
- physical state
- colour
- **full composition**

→ Substances

→ Mixture in mixture (MiM)



# Product information

- Packaging types
- Packaging sizes
- Use type
  - consumer
  - professional
  - industrial
- Product categorisation



# UFI – unique formula identifier

- Unique 16 character code
- Makes a link between a specific product on the market to the information submitted on the mixture
- Has to be included both:
  - on the label\*
  - in the notification
- One UFI can be assigned to only one mixture composition



\* unless not packaged or for industrial use only - SDS

# UFI – unique formula identifier

- High flexibility in its use and applicability:  
*Mixture/Product/Market/Language - centric approach*

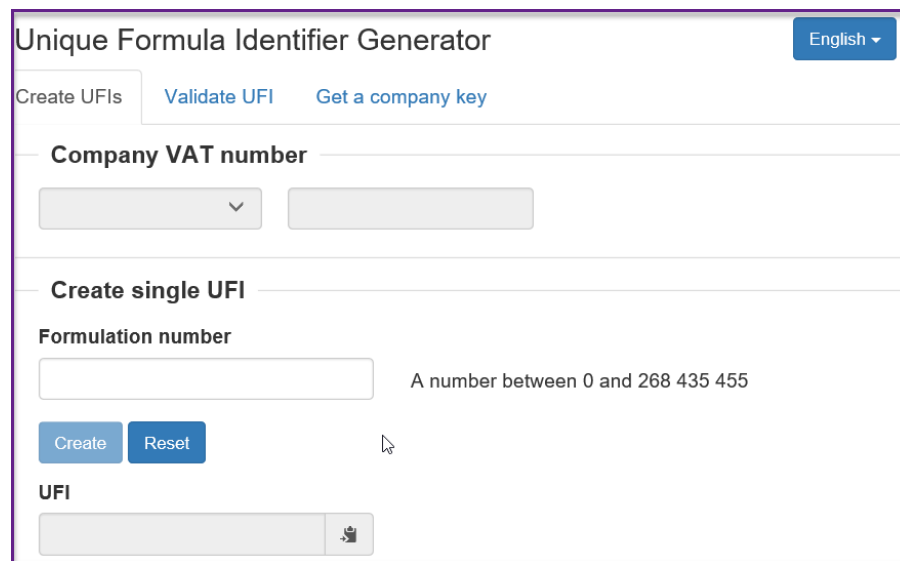
- It works to protect CBI (e.g. MiM)

UFI known to the relevant AB as part of a submission!

- Same UFI can be used along the supply chain as long as composition remains the same
- Not possible to retrieve information on the composition of the mixture
- New UFI (and new label) needed when:
  - adding, substituting or deleting a component
  - variation in concentration beyond the range specified
  - supplier changes UFI and it has impact on MiM

# UFI generation

- Can be generated at any time by any company
- VAT number of your company
- Formulation number
- UFI Generator tool <https://ufi.echa.europa.eu/#/create>



The screenshot shows the 'Unique Formula Identifier Generator' web interface. At the top right, there is a language dropdown menu set to 'English'. Below the title, there are three tabs: 'Create UFIs' (which is active), 'Validate UFI', and 'Get a company key'. The main section is titled 'Company VAT number' and contains a dropdown menu for selecting a country and a text input field for the VAT number. Below this is the 'Create single UFI' section, which includes a 'Formulation number' input field with a note: 'A number between 0 and 268 435 455'. There are 'Create' and 'Reset' buttons below the input field. At the bottom, there is a 'UFI' output field with a copy icon.

# Action points – Key messages



## Get ready now

- Understand your obligations
  - Role in the supply chain (e.g. formulator? rebrander?)
  - Product placed on the market (e.g. mixture exempted?)
  - End-use of the mixture (i.e. date of application)
  - Portfolio (e.g. market areas and possible application of transitional period)
- Invest in communication
  - with customers: use of the mixture, trade names, countries
  - With suppliers: composition, toxicological/hazard information

## Know the information requirements

- Possibly more detailed than before
- Provision (e.g. attachment) of SDS does **not** replace the need to provide Annex VIII info
- Composition  $\approx$  100%
  - Non-hazardous components
  - Low concentration components
  - Exact concentrations or ranges defined in Annex VIII
- Toxicological information (from Section 11 of SDS) to be potentially reviewed: check quality and avoid cross-references

# Plan the relabelling of your products

- Generate and assign UFI
- No rules on placement - redesign of label to incorporate this new element
- Printing of UFIs on the label should be planned to coincide with the submission of information







Thank you!

[daniele.ape@echa.europa.eu](mailto:daniele.ape@echa.europa.eu)  
[poisoncentres@echa.europa.eu](mailto:poisoncentres@echa.europa.eu)

Tools, support material and latest news at

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

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# Preparing and submitting using ECHA tools

Safer chemicals – ECHA conference

21 May 2019

Claudia Rimondo

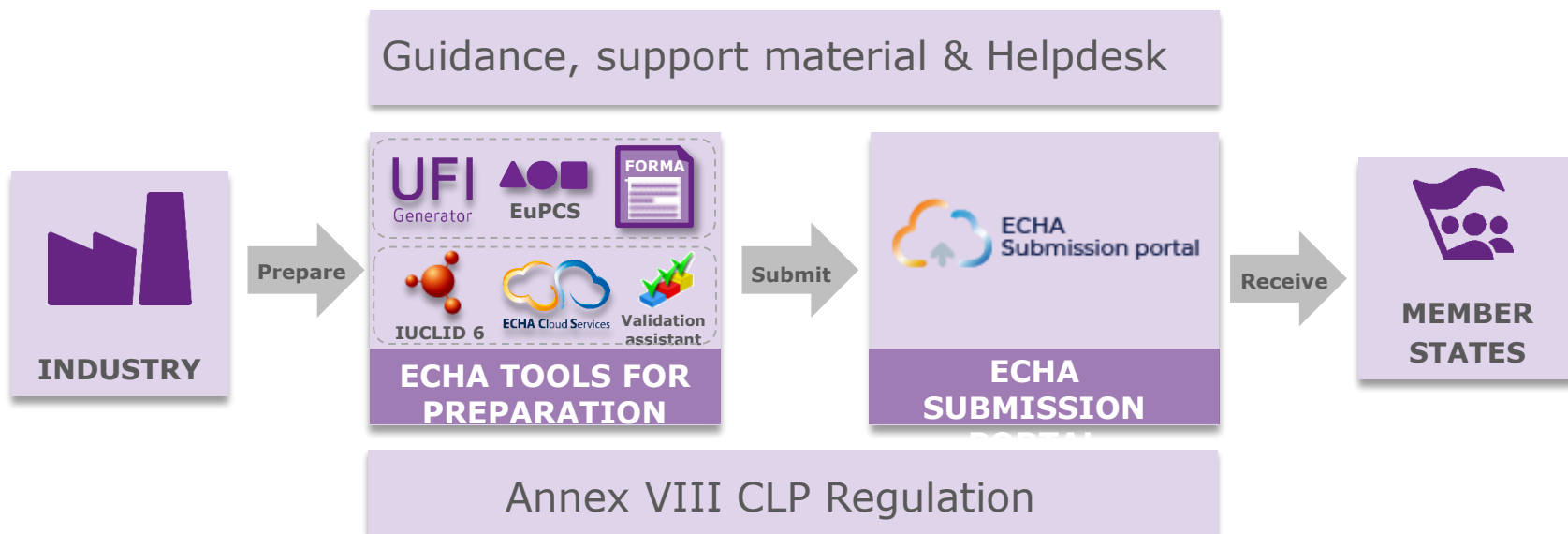
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# Table of content

- ECHA tools – Dossier preparation
- ECHA tools – Dossier submission
- Information material



# ECHA tools for preparation & submission



# ECHA tools – Dossier preparation



# UFI generator



Unique Formula Identifier Generator English

[Create UFIs](#) [Validate UFI](#) [Get a company key](#)

**Company VAT number**

The company does not have a VAT number.

By ticking this box, I declare that the company does not have a VAT number.

**Create single UFI**

Formulation number  A number between 0 and 268 435 455

UFI

**Create multiple UFIs**

From sequential formulation numbers

First formulation number  A number between 0 and 268 435 455

Count of formulation numbers  A number between 1 and 10 000

From a CSV file (of up to 10 000 formulation numbers)

<https://ufi.echa.europa.eu/#/create>

- UFI Developers Manual
- Available in official languages
- Webinar on the UFI

# EU Product Categorisation System

- To describe 'the intended use of a mixture' for which a submission has to be made (industry)
- To facilitate reporting and monitoring of poisoning incidents at EU level (Appointed Bodies/Poison Centres)
- Maintained by ECHA and subject to change
- Available in the EU official languages in the future



# PCN Format

- Annex VIII: harmonised format (.xml - IUCLID) to provide information
- PCN format version 1 published in April 2018
- Update PCN format (version 1.1) and related documentation published in April 2019
- Example dossier (with corresponding preview)
- Poison Centres Notification format  
<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>



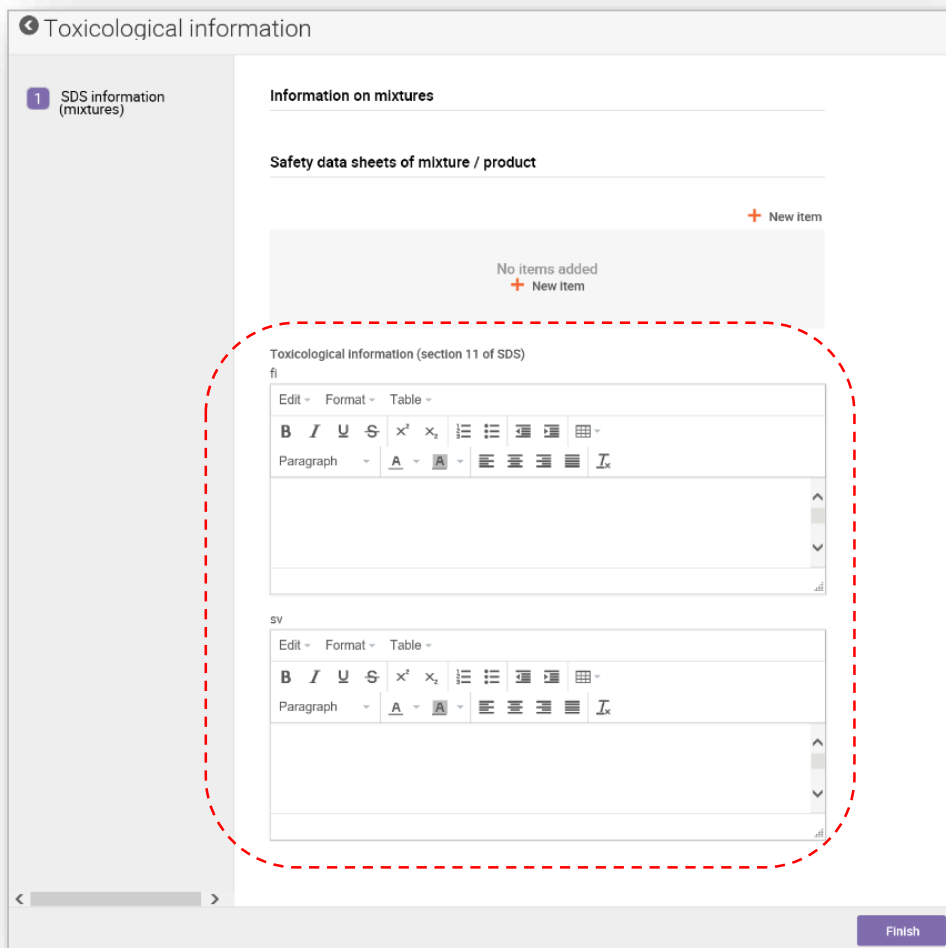
# How to prepare a PCN dossier

- **Online in the ECHA Submission portal:**
  - IUCLID Cloud
  - Guided dossier preparation tool
  - Information stored in the ECHA Cloud
- **Offline in IUCLID 6:**
  - Specific PCN interface
  - Local installations of IUCLID
  - Desktop and server versions on the IUCLID 6 website
- **Using the PCN format in company's own system:**
  - IUCLID compatible PCN format

# Information in multiple languages

- Annex VIII: submission in the official language(s) of the Member State(s) where the mixture is placed on the market [...]
- IUCLID Cloud: User Interface in EN but free text fields requiring input in multiple languages
- Selection from the header section of your submission
- Country/language: table available on the PCN website

# Information in multiple languages



The screenshot displays the 'Toxicological information' section of an SDS editor. It features a sidebar with 'SDS information (mixtures)' and a main content area. The main area includes 'Information on mixtures' and 'Safety data sheets of mixture / product' sections. A red dashed box highlights two text editors for different languages: 'fi' (Finnish) and 'sv' (Swedish). Each editor has a rich text toolbar with options for bold, italic, underline, strikethrough, bulleted list, numbered list, link, and unlink. A 'Finish' button is located at the bottom right of the editor area.




- Toxicological information (mandatory)
- Classification information (where relevant)
  - Specific effect;
  - Specific target organ toxicity – single;
  - specific target organ toxicity – repeated
- Labelling information (where relevant)
  - certain Hazard and Precautionary statements



# Validation assistant

- Before submission (only IUCLID Cloud and standalone)
- Upon submission (S2S transfer, additional checks)
- Types of checks for dossier content:
  - Presence of information (No empty fields)
  - Consistency of information
  - Accuracy/quality of information

# Validation report

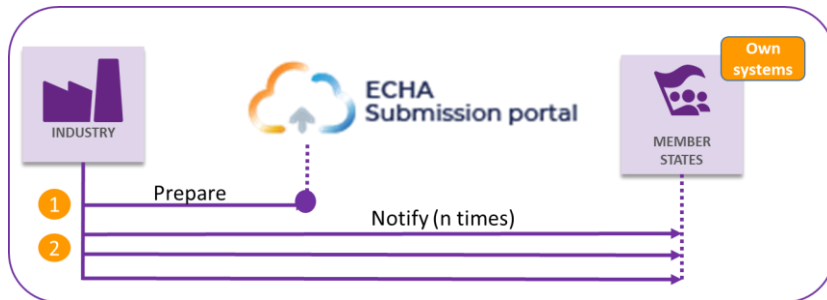
- **Pass** 
  - Successful submission
  - Available to Member States
- **Pass with warnings** 
  - As valid as 'pass'
  - Report with potential deficiencies
  - Report to Member State for their consideration
- **Fail** 
  - Report with deficiencies

# ECHA tools – Dossier submission

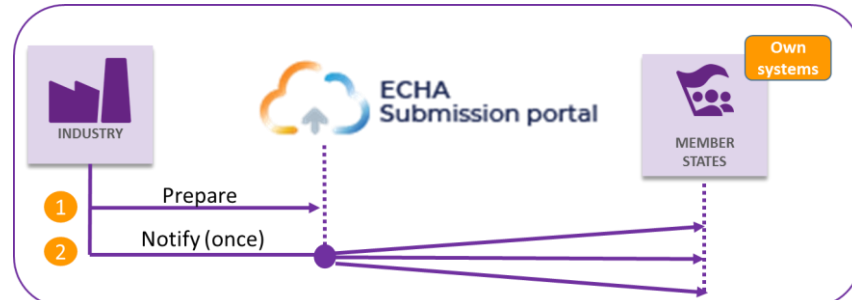


# Dossier submission options: MS or ECHA?

## Local systems of MS



## Central system of ECHA



Dossier preparation always using ECHA tools and harmonised format  
(no Member States specific requirements)

- *n* dossiers submitted for *n* Member States submitted *n* times
- submission modalities determined by Member State

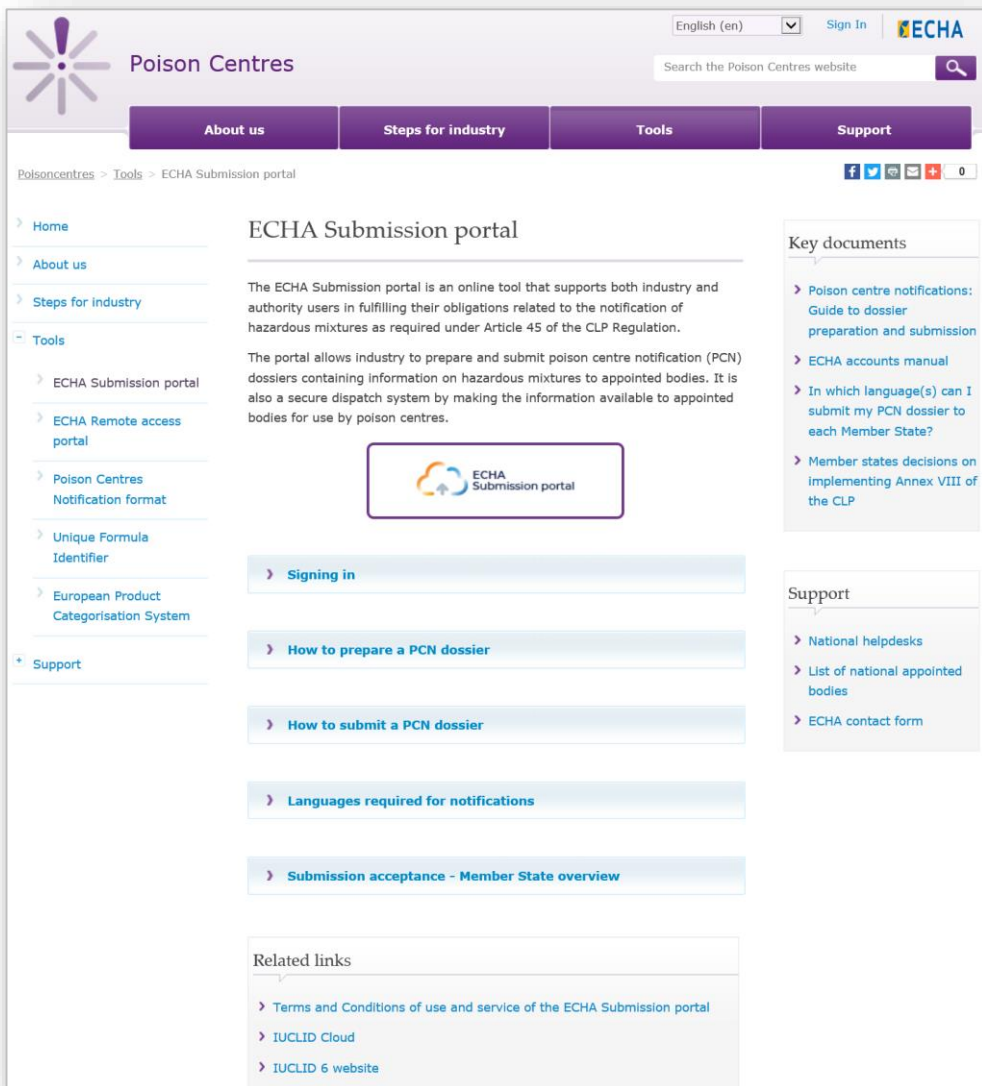
- *one* dossier for *n* Member States submitted *once* to ECHA
- ECHA makes data available to Member States

# PCN dossier submission using ECHA tools

- **Online through the ECHA Submission portal:**
  - dossier made available to all Member States indicated in the notification
- **Through a system-to-system (S2S) transfer from the company's own system to the ECHA Submission portal:**
  - Dossiers forwarded from the portal to all the relevant Member States
  - Functionality available in the second half of 2019



# ECHA Submission portal



The screenshot shows the ECHA Submission portal website. The page title is "Poison Centres". The navigation menu includes "About us", "Steps for industry", "Tools", and "Support". The main content area is titled "ECHA Submission portal" and contains the following text:

The ECHA Submission portal is an online tool that supports both industry and authority users in fulfilling their obligations related to the notification of hazardous mixtures as required under Article 45 of the CLP Regulation.

The portal allows industry to prepare and submit poison centre notification (PCN) dossiers containing information on hazardous mixtures to appointed bodies. It is also a secure dispatch system by making the information available to appointed bodies for use by poison centres.

The page features a central image of the ECHA Submission portal logo, a list of key documents, and a support section. The key documents section includes:

- Poison centre notifications: Guide to dossier preparation and submission
- ECHA accounts manual
- In which language(s) can I submit my PCN dossier to each Member State?
- Member states decisions on implementing Annex VIII of the CLP

The support section includes:

- National helpdesks
- List of national appointed bodies
- ECHA contact form

Related links include:

- Terms and Conditions of use and service of the ECHA Submission portal
- IUCLID Cloud
- IUCLID 6 website

Available from the ECHA Poison Centre website:

<https://poisoncentres.echa.europa.eu/echa-submission-portal>

## Version 1.0 features - Industry

- Guided dossier preparation tool / IUCLID Cloud
  - Validation assistant
  - Support to enter multilingual text
  - PDF preview
  - On-line help
- Dossier upload and submission
- Submission report
- Validation report
- Advanced search functionality

# Version 1.0 features – Member States



- ECHA Remote access portal:
  - Dispatching of the PCN dossier via a country specific secure folder (SSL VPN)
- Downloading dossier
- Validation report
- Login manual to ECHA's IT tools for authority users

# Information material



# Material to prepare and submit PCN notifications

- Guide to dossier preparation and submission
- Steps for industry to fulfil their new obligations
- In which language can I submit my PCN dossier to each Member State?
- Member states decisions on implementing Annex VIII of the CLP (translated)
- ECHA accounts manual



**Website**  
Poison Centres

## Other information

- Promotional animation “Notifying hazardous mixtures to poison centres”



- Q&A section
- Publications
- [IUCLID Website](#)
- [ECHA Cloud services](#)



Thank you!

[poisoncentres@echa.europa.eu](mailto:poisoncentres@echa.europa.eu)

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[#SAFERCHEMICALS](https://www.instagram.com/saferchemicals)



# Foreseen changes – what to expect?

Safer chemicals – ECHA conference

21 May 2019

Daniel Sompolski

#SAFERCHEMICALS



# Table of contents

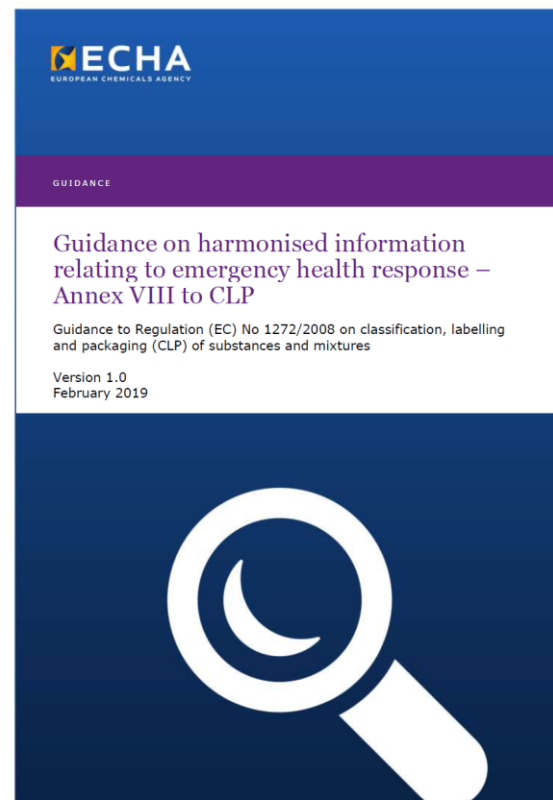
- Regulatory matters
- ECHA submission portal development
- Interactions between industry, ECHA and Member States during dossier submission
- Helpdesk

# Regulatory matters



# Regulatory guidance

- Version 1.0 published in February 2019
- Version 1.1 expected in summer 2019
  - Clarifications regarding the role of distributors
- Translations shortly after v1.1 publication



## Amendment of Annex VIII to CLP

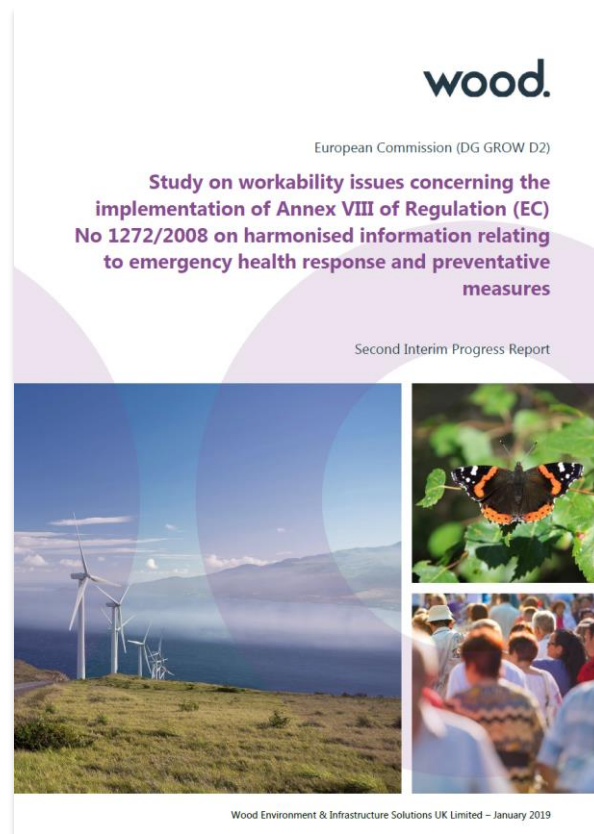
- Editorial changes (terminology)
- Non-editorial changes
  - Simplified rules for group submission
  - Reporting of MiM components
- No solutions for workability issues
- Amendment may be adopted in autumn 2019
- Proposal to add postponement of the first applicability date
  - Consumer use products to be notified from 2021 onwards
- ECHA advises to continue preparations according to existing deadlines

# Workability issues\*

- Draft final report in consultations with stakeholders until 3/06
- Final report expected in summer 2019
- The European Commission may propose further amendments to Annex VIII

\*sectors affected: petroleum, construction, gases, paints, perfumes, soaps & detergents;

\*issues: mixtures in mixtures and use type, high variability of the composition, multiple suppliers of 'same' ingredient (functional sameness vs chemical sameness), limited usability of generic product identifiers and group submission;



# ECHA Submission portal development



# Portal features for industry

	Now	July '19	November '19
Submission portal	Live!	Enhanced user interface	
Online dossier preparation tool / IUCLID Cloud	Prepare, create, save and preview	Navigation improvements	Group submission
Dossier validation assistant	Initial set of rules	Enhanced set of rules	
Submission process	Save, upload and submit	<ul style="list-style-type: none"> <li>- Submit online</li> <li>- System-to-system approach for automated submission</li> </ul>	

# Portal features for Member States

	Now	July '19	November '19
Data availability to Member States	Member States may download dossiers via secure folder (SSL VPN)	Automatic dossier transfer to Member States (eDelivery service)	ECHA database: Basic query functionality to access notifications



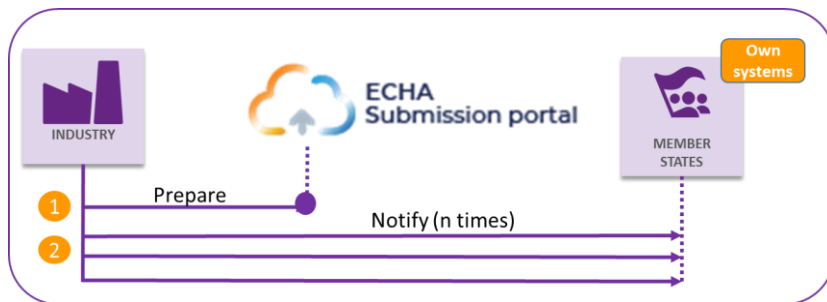
# Dossier submission process

Interactions between  
industry, ECHA and  
Member States

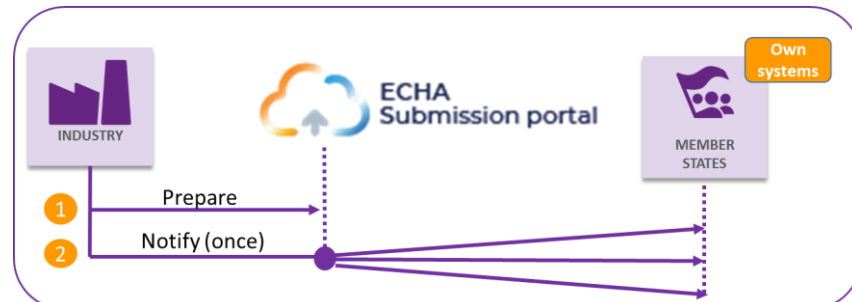


# Dossier submission options: MS or ECHA?

## Local systems of MS



## Central system of ECHA



Dossier preparation always using ECHA tools and harmonised format (no Member States specific requirements)

- $n$  dossiers submitted for  $n$  Member States submitted  $n$  times
- submission modalities determined by Member State

- *one* dossier for  $n$  Member States submitted *once* to ECHA
- ECHA makes data available to Member States:
  - dispatches to Member State
  - or
  - provides database at ECHA

# Member States decisions on submission portal



- 19 Member States will accept notifications only via ECHA submission portal (HR, CY, DK, EE, FI, EL, HU, IE, IT, LV, LT, MT, NL, NO, PL, SK, SL, ES, SE)
- 3 Member States will accept notifications via ECHA submission portal or their national submission system (AT, DE, PT)
- Awaiting decision of Member State (BE, BG, CZ, FR, IS, LI, LUX, RO, UK)

# Other decisions of Member States

- Language(s)
- Fees
- Acceptance of dossiers
- When will the portal be used?

**Overview of Member States decisions in relation to implementation of Annex VIII to the CLP Regulation (Poison Centre Notification) - version 1.0 (24.04.2019)**

Disclaimer: The information is based on input from Member States. The declarations of Member States are indicative and subject to changes. ECHA aims at updating this document to reflect the latest status. For further information, please contact national CLP helpdesk: <https://echa.europa.eu/support/helpdesk/>

Member State	Submission portal	Notification language	Fees for notifications	Placing on the market mixtures notified via ECHA submission system	Intentions of Member States regarding timelines for acceptance of notifications via ECHA submission system	Readiness of Member State to accept notifications via ECHA submission system
	Member State accepts notifications only via ECHA submission system	Duty holder may choose notification language between official language(s) of the Member State or English (includes Member States where English is official language)	No fees	Duty holder can start placing mixture on the market immediately after confirmation of successful submission by the ECHA submission system (without awaiting approval from Member State)	Member State intends to accept notifications from the moment of being connected to ECHA submission system (intended start time between 24 April 2019 and 31 December 2019)	Member State already connected to ECHA submission system and duty holders can start notifying their mixtures
	Member State accepts notifications via national submission system or ECHA submission system (duty holder has discretion of choice)	Duty holder must notify in one official language of the Member State (other than English)	Fees levied by Member State appointed body	Duty holder can start placing mixture on the market only after the Member State appointed body has determined the notification (information visible to duty holder in the submission report of ECHA system)	Member State intends to accept notifications via ECHA submission system from 1 January 2020	Member State not yet connected to ECHA submission system and duty holders must await further information
		Duty holder must notify in multiple official language(s) of the Member State (other than English)	Fees under consideration		Only Member State awaits the national legislation, requirements of that national legislation continue apply to duty holders	Member State already connected to ECHA submission system but duty holders must await until 1 January 2020 with notifications (national legislation in force)
	No information available		No information available	No information available	No information available	
Austria		German				
Belgium		Dutch or Dutch or German or English				
Bulgaria		Bulgarian				
Croatia		Croatian or English				
Cyprus		Greek or English				
Czech Republic		Czech				
Denmark		Danish				
Estonia		Estonian or English				
Finland		Finnish and Swedish				
France		French				
Germany		German or English				
Greece		Greek				
Hungary		Hungarian				
Iceland		Icelandic				
Ireland		English				
Italy		Italian or English				
Latvia		Latvian or English				
Lithuania		German				
Lithuania		Lithuanian or English				
Luxembourg		French or German or English				
Malta		Maltese or English				
Netherlands		Dutch				
Norway		Norwegian				
Poland		Polish				
Portugal		Portuguese				
Romania		Romanian				
Slovakia		Slovak				
Slovenia		Slovenian				
Spain		Spanish or English				
Sweden		Swedish or English				
United Kingdom		English				

[https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd\\_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009](https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009)

# Helpdesk













# National Helpdesks

National Helpdesks within the European Union (EU) and the European Economic Area (EEA)

 Austria  
 Croatia  
 Denmark  
 France  
 Hungary  
 Italy  
 Lithuania  
 Netherlands  
 Portugal  
 Slovenia  
 United Kingdom

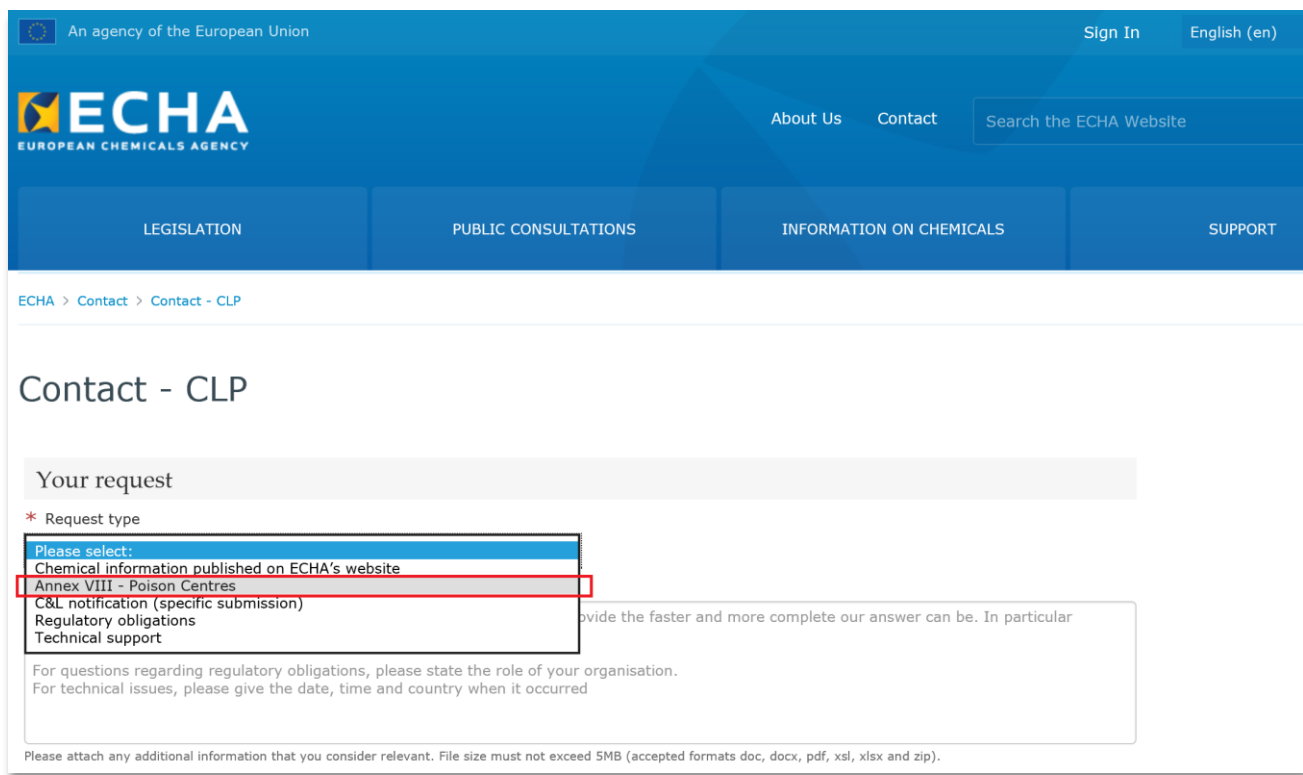
 Belgium  
 Cyprus  
 Estonia  
 Germany  
 Iceland  
 Latvia  
 Luxembourg  
 Norway  
 Romania  
 Spain

 Bulgaria  
 Czech Republic  
 Finland  
 Greece  
 Ireland  
 Liechtenstein  
 Malta  
 Poland  
 Slovakia  
 Sweden

<https://echa.europa.eu/support/helpdesks>

# How to contact ECHA?

<https://echa.europa.eu/contact/clp>



An agency of the European Union Sign In English (en)

**ECHA**  
EUROPEAN CHEMICALS AGENCY

About Us Contact

LEGISLATION PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

ECHA > Contact > Contact - CLP

## Contact - CLP

Your request

\* Request type

- Please select:
- Chemical information published on ECHA's website
- Annex VIII - Poison Centres**
- C&L notification (specific submission)
- Regulatory obligations
- Technical support

provide the faster and more complete our answer can be. In particular

For questions regarding regulatory obligations, please state the role of your organisation.  
For technical issues, please give the date, time and country when it occurred

Please attach any additional information that you consider relevant. File size must not exceed 5MB (accepted formats doc, docx, pdf, xls,xlsx and zip).



**Thank you!**  
[daniel.sompolski@echa.europa.eu](mailto:daniel.sompolski@echa.europa.eu)

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**#SAFERCHEMICALS**



~10 minutes



#SAFERCHEMICALS

We will be back in 20 minutes





# ECHA Submission portal: Introduction to the training

Safer chemicals – ECHA conference

21 May 2019

Vasileios Tsifoutis

#SAFERCHEMICALS



# Introduction

- The overall aim of today's training exercise is to get familiar with the ECHA tools to prepare and submit a dossier for a poison centre notification.
- Additionally, we want to improve our service and IT systems so we kindly ask for your feedback! Go to <https://app2.sli.do> (access code is **poisoncentre**). Poll closes 31<sup>st</sup> May 12.00 Helsinki time.

# Accessing ECHA's IT tools

- To create an ECHA account you will need:
  - First/last name
  - Email
  - User name
  - Establish password

**ECHA**  
EUROPEAN CHEMICALS AGENCY

Username

Password  
Enter password...  
**LOGIN**

Help

- > Create an ECHA account
- > Forgot your password?
- > Forgot your username?
- > Change password
- > ECHA accounts Q&A
- > ECHA accounts information

<https://idp-industry.echa.europa.eu/idp/>

# Legal entity

- Upon verification of the email you encode your legal entity
- A legal entity can also be created for non EU/EEA countries, BUT there will not be access rights to submit to the portal

Create Legal Entity

**Account security**

\* Security Question

\* Security Answer

**General details**

\* Legal Entity name

D-U-N-S

VAT number

**General Contact information**

\* Phone

\* Email  Example: name@domain.com

Website

Fax

**Address Information**

\* Street

Street 2

\* Postal code

\* City

\* Country

Note: you will not be able to modify "Country" after pressing the "Save" button.

**Billing Address**

Same information as per Legal Entity's name and address

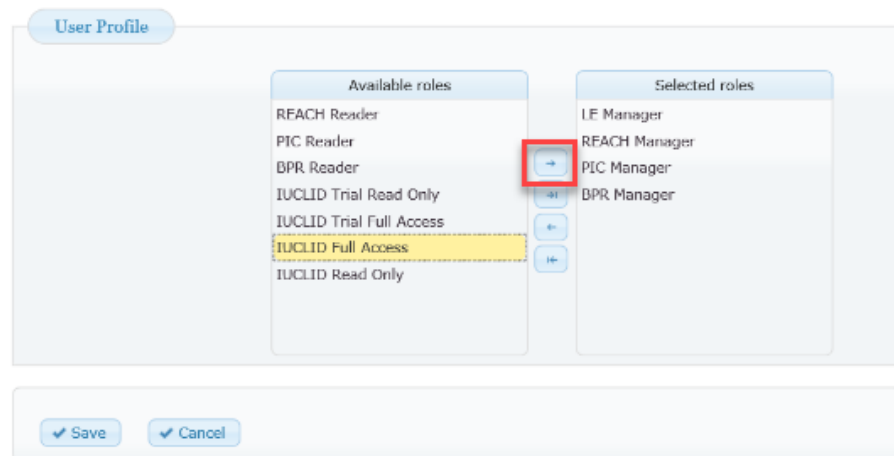
Not the same

Billing Address

Language

# Explaining user roles

- User roles control what the user can read or access.
- Go to the 'User' tab and check the user roles assigned to a user
- Edit roles if needed:
  - REACH Manager – allows access to ECHA portal
  - IUCLID Full Access – allows access to IUCLID cloud



# Adding a foreign user

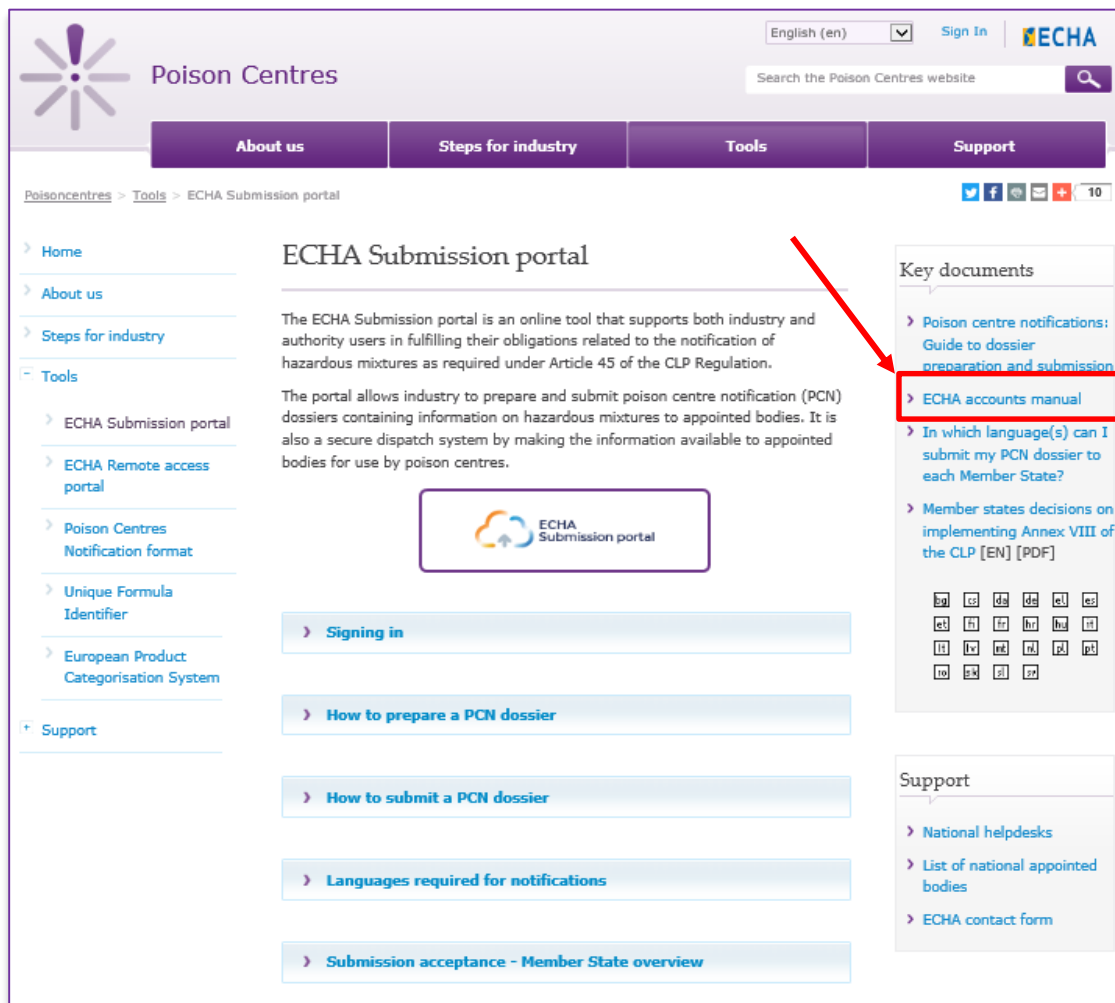
- A foreign user allows a third party e.g. a consultant to work on your behalf
- You can add a foreign user from the 'Users' tab by entering their legal entity information

The screenshot displays the 'Legal Entity profile' for 'Kangaroo chemicals' in the 'Users' tab. A dropdown menu is open under the 'Add' button, showing two options: 'A foreign user' (highlighted with a red box and a mouse cursor) and 'A personal account'. The table below shows one user: John Does, with email Kangaroo.Chemicals@elst, roles including LF Manager, REACH Manager, IUCLID Full Access, and IUCLID Trial Full Access, and an Active status.

Name	Email	User roles	Status	Actions
John Does	Kangaroo.Chemicals@elst	<ul style="list-style-type: none"><li>LF Manager</li><li>REACH Manager</li><li>IUCLID Full Access</li><li>IUCLID Trial Full Access</li></ul>	Active	



# Portal entry point

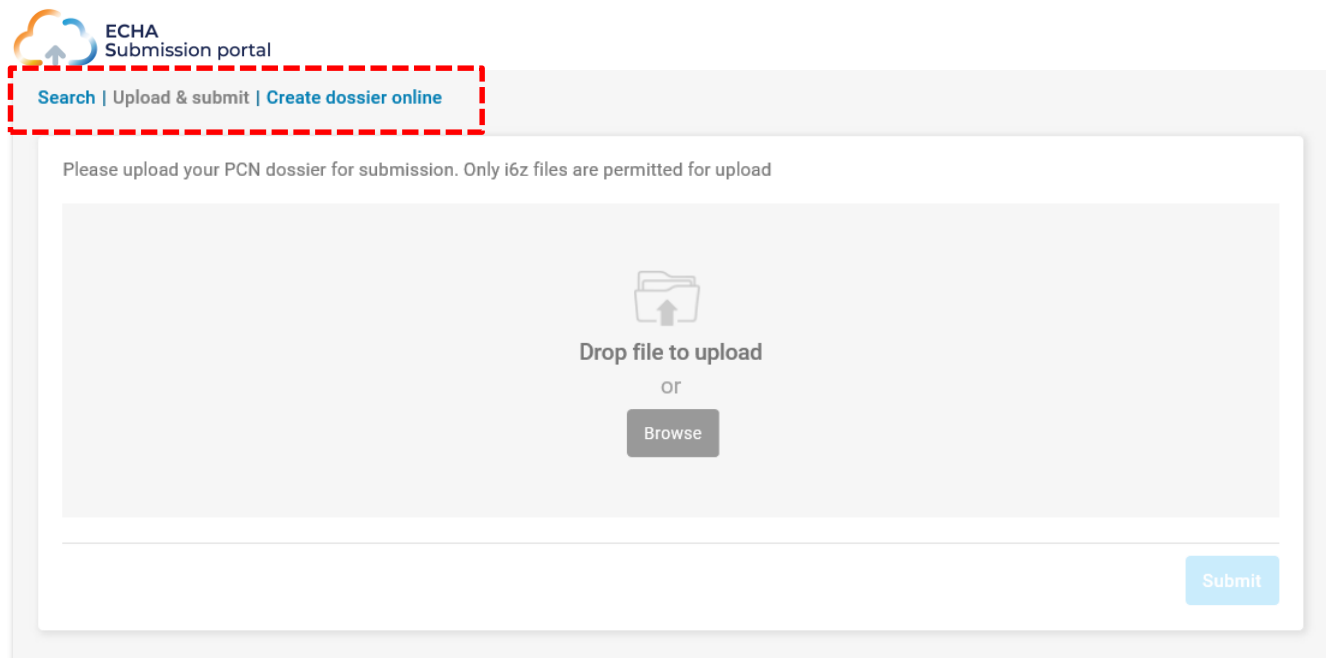


The screenshot shows the ECHA Submission portal website. The main navigation bar includes 'About us', 'Steps for industry', 'Tools', and 'Support'. The 'Tools' section is expanded, showing a list of tools including 'ECHA Submission portal', 'ECHA Remote access portal', 'Poison Centres Notification format', 'Unique Formula Identifier', and 'European Product Categorisation System'. The 'ECHA Submission portal' tool is highlighted with a red box and a red arrow pointing to it. The 'Key documents' section on the right lists several documents, with 'ECHA accounts manual' highlighted by a red box. The 'Support' section on the right lists 'National helpdesks', 'List of national appointed bodies', and 'ECHA contact form'. The main content area features a heading 'ECHA Submission portal' and a description: 'The ECHA Submission portal is an online tool that supports both industry and authority users in fulfilling their obligations related to the notification of hazardous mixtures as required under Article 45 of the CLP Regulation. The portal allows industry to prepare and submit poison centre notification (PCN) dossiers containing information on hazardous mixtures to appointed bodies. It is also a secure dispatch system by making the information available to appointed bodies for use by poison centres.' Below the description is a logo for the 'ECHA Submission portal' and a list of links: 'Signing in', 'How to prepare a PCN dossier', 'How to submit a PCN dossier', 'Languages required for notifications', and 'Submission acceptance - Member State overview'.


<https://poisoncentres.echa.europa.eu/echa-submission-portal>

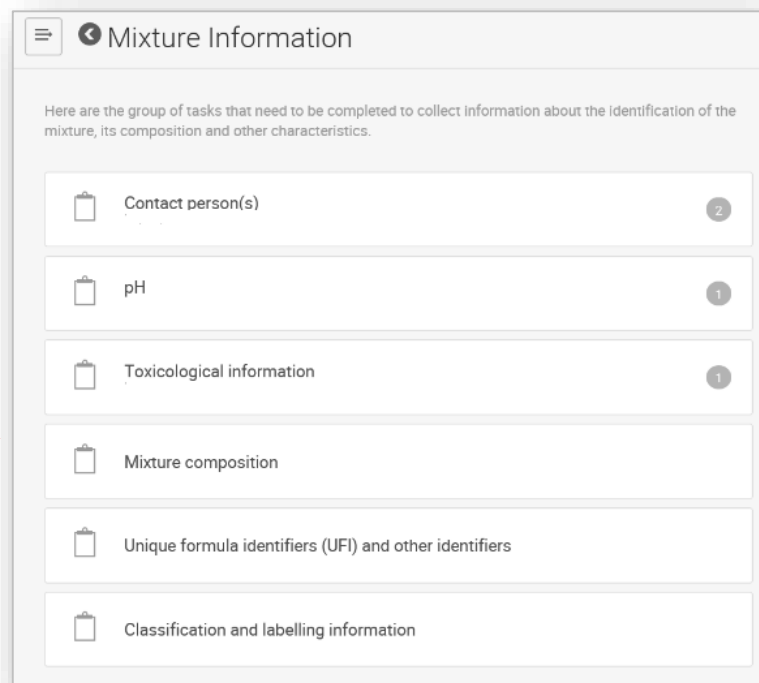
## From the portal navigation bar...

- Search submission page
- Upload and submit
- IUCLID Cloud for online creation of a dossier



# Structure of guided preparation / IUCLID Cloud

- Information is required in two main **task groups** - the mixture and the product.
- Each task group has a series of **tasks**. 
- **Records** are created for each task in which information can be entered.



Mixture Information

Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other characteristics.

- Contact person(s) 2
- pH 1
- Toxicological information 1
- Mixture composition
- Unique formula identifiers (UFI) and other identifiers
- Classification and labelling information

## To assist you...

- Desktop set up with shortcuts:
  - to ECHA's poison centre website
  - UFI generator
  - IUCLID 6
  - ECHA Submission portal (testing environment)
- Google drive with files containing the information needed to prepare the dossier plus today's presentations - [bit.ly/echaconference](https://bit.ly/echaconference)
- Raise your hand and ask one of our experts!




**Thank you!**  
[vasileios.tsifoutis@echa.europa.eu](mailto:vasileios.tsifoutis@echa.europa.eu)

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**#SAFERCHEMICALS**



# Poison Centre Notifications: hands on training exercise - Prepare and submit online

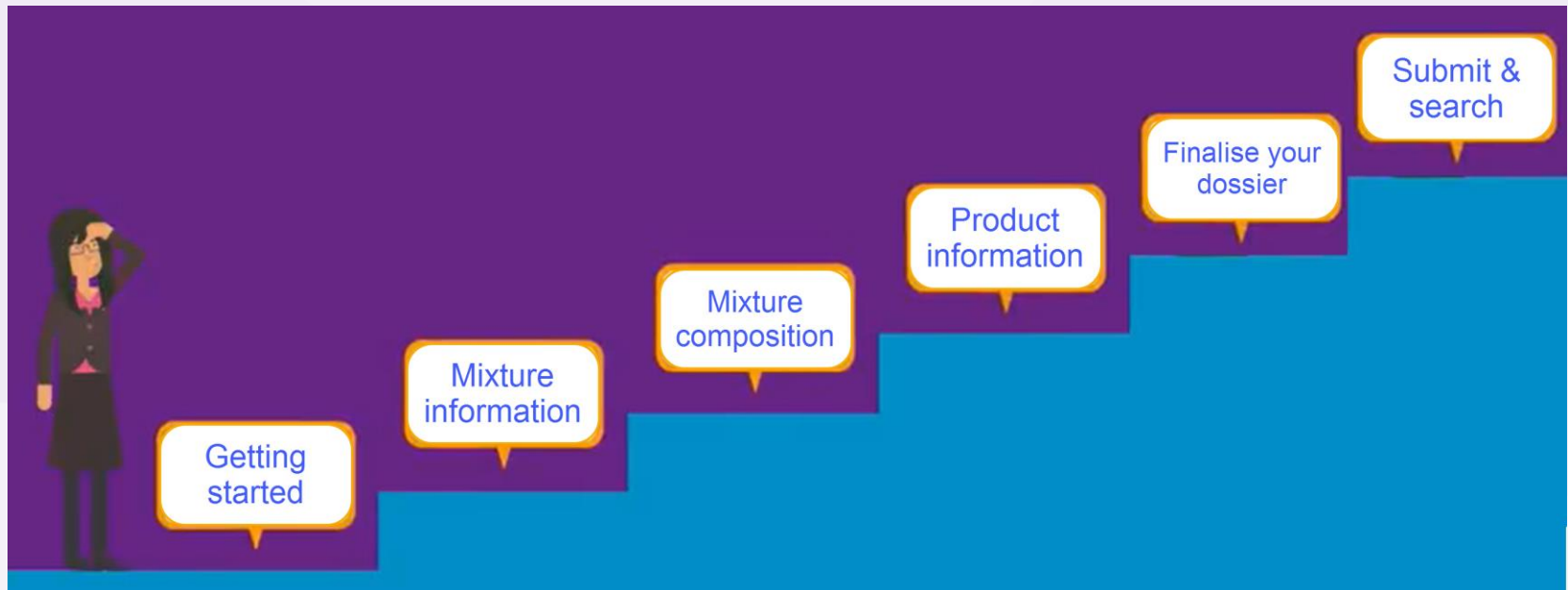
ECHA Conference 'Safer chemicals'

21 May 2019

Heidi Rasikari

# Modules for today's training

- Today's training exercise consists of a number of modules.
- Each will be first introduced to you then you will have some time to work independently.
- A demonstration of how to complete the task will be provided.



## Setting the scene

- Your task is to prepare and submit a poison centre notification for a mixture using the available ECHA tools.
- The mixture is a new formulation of dish washing liquid and comes in different package types, trade names and UFI's, and is placed on the market in Finland and in Sweden.
- You have been provided with an example data sheet with all the data you need.



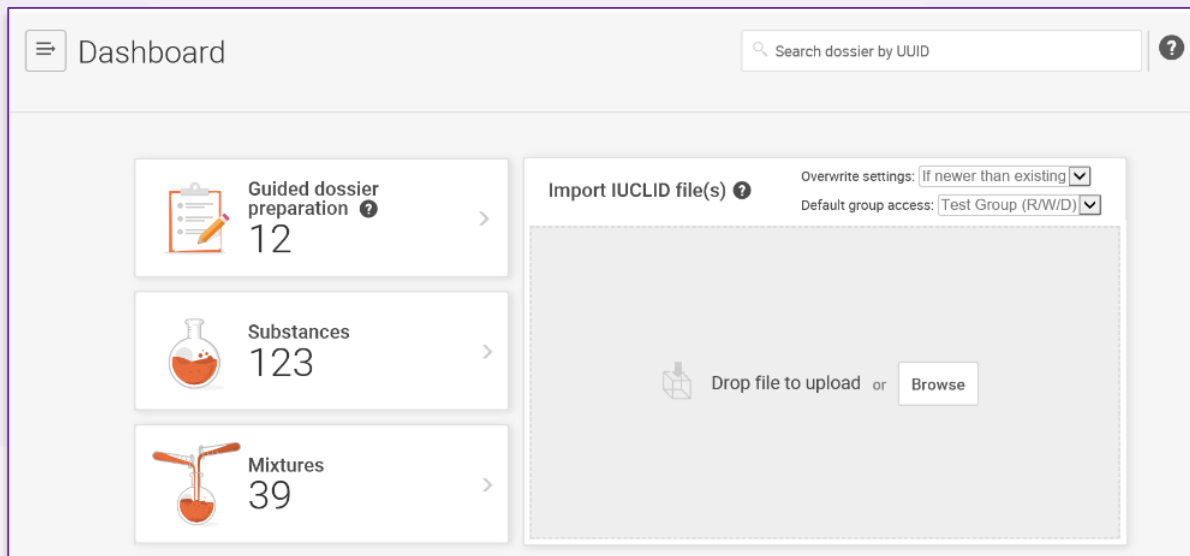


## **Module 1. Getting started**

Aim: to gather the information you need to initiate a guided dossier preparation, how it defines the scope of the submission in the dossier header.

## Let's begin!

- Login to the dossier preparation tool
- Landing page is the dashboard
- To start, select guided dossier preparation, then select new PCN submission
- Got everything ready? Google drive [bit.ly/echaconference](https://bit.ly/echaconference)



The screenshot shows a dashboard interface with the following elements:

- Dashboard** header with a search bar for "Search dossier by UUID" and a help icon.
- Guided dossier preparation** card: 12 items, with a help icon.
- Substances** card: 123 items.
- Mixtures** card: 39 items.
- Import IUCLID file(s)** section: Includes "Overwrite settings: If newer than existing" and "Default group access: Test Group (R/W/D)" dropdowns. A large dashed box contains the text "Drop file to upload or Browse" with a file icon.

## Before you begin the dossier header

- You need to build the framework for the dossier by completing the dossier header.
- Dossier header is like the 'cover note' to the dossier and information must be provided to:
  - define the scope of the submission (e.g. single or multi-market)
  - create the necessary fields in the dossier (e.g. multilingual fields)
  - allow the system to determine which rules need to be checked (e.g. updates vs initial submissions vs limited submissions).

**You are ready to GO!**


**Refer to your 'example data' and have fun!**



10 mins

# Outcome: Mixture navigation page

Dashboard > Guided dossier preparations > Dish washing liquid



 Dish washing liquid

Submission type: CLP Poison centres notification

**1 Provide dossier information**




Welcome! Start preparing your dossier by providing information in the following main task groups. You will be guided through a series of smaller tasks to complete each of the main task groups below. Your work can be saved and you can come back to it later if you do not have all the information at hand.

**Information to be completed**

-  Mixture Information
-  Product information

**2 Finalize your dossier**

Finalise your guided dossier preparation by validating and reviewing the information before you create your dossier. Additionally, you can preview the provided information in PDF.

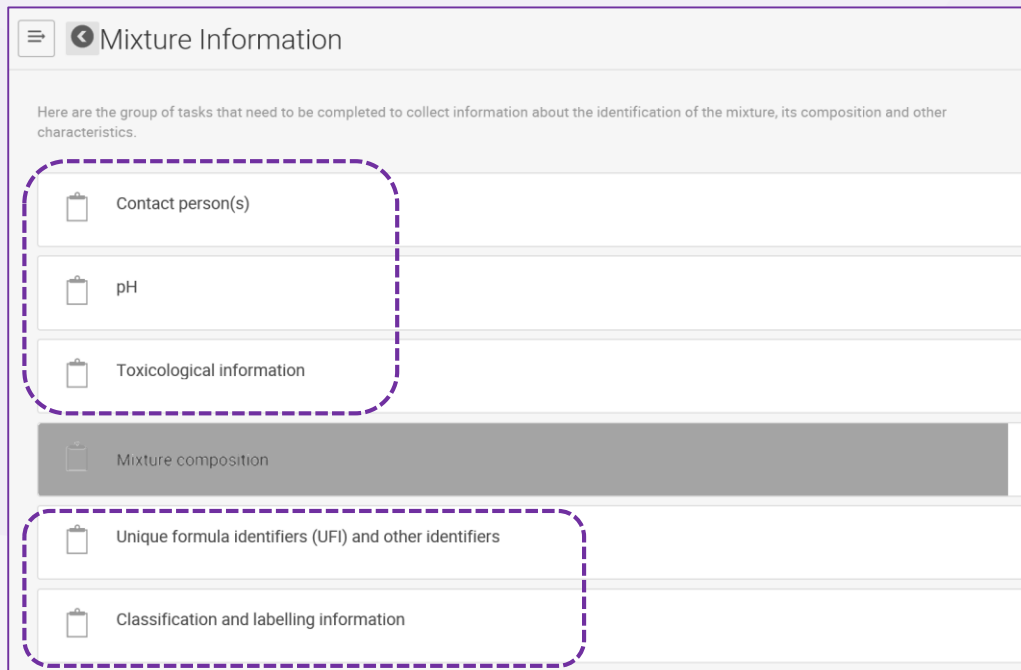
Task groups

## **Module 2. Mixture information**

Aim: To create records for each task and enter the required information for the mixture.

# Providing mixture information

- Six tasks have been created for the mixture information – no records exist yet.
- Composition task will be covered in the next module.



The screenshot shows a mobile application interface for 'Mixture Information'. At the top, there is a header with a menu icon, a back arrow, and the title 'Mixture Information'. Below the header, a light green box contains the text: 'Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other characteristics.' The main content area consists of a vertical list of six task items, each with a clipboard icon on the left and a text label on the right. The first three items are grouped together by a dashed purple rounded rectangle: 'Contact person(s)', 'pH', and 'Toxicological information'. The fourth item, 'Mixture composition', is highlighted with a grey background. The last two items are grouped together by another dashed purple rounded rectangle: 'Unique formula identifiers (UFI) and other identifiers' and 'Classification and labelling information'.

## Before you begin mixture information

- Remember for multimarket submissions, free text fields (in C&L and toxicological information) must be provided in all relevant languages.
- Consider the approach you take when entering UFIs in the UFI task, either:
  - One UFI code per UFI record (single assignment)
  - Multiple UFIs in a single record (grouped)
  - Or a combination of above.

Extra: Upload the SDS for the dishwashing liquid (non mandatory information) available in Google drive.







30 mins

# Outcome: Records created

Dashboard > Guided dossier preparations > Dish washing liquid > Mixture Information

☰ ◀ Mixture Information

Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other characteristics.

 <b>Contact person(s)</b> 17/05/2019 10:27	1
 <b>pH</b> 17/05/2019 10:13	1
 <b>Toxicological information</b> 17/05/2019 10:16	1
 <b>Mixture composition</b>	
 <b>Unique formula identifiers (UFI) and other identifiers</b> 17/05/2019 10:18	3
 <b>Classification and labelling information</b> 17/05/2019 10:27	1



## **Module 3. Mixture composition information**

Aim: Get familiar with the various subtasks for adding mixture components (i.e. mixture in mixtures and substances).

# Adding components

- Mixture composition tasks generates subtasks for:
  - mixture components (MiMs)
  - Substance components

☰ ◀ Mixture composition

---

**Mixture components** +Mixture component



---

No components have been added yet.

**Substance components** +Substance component

---

No components have been added yet.



☑ Function and concentration  
26/04/2019 14:50

---

☑ Unique formula identifiers (UFI)

---

☑ Mixture-in-mixture composition

---

☑ Classification and labelling information of the mixture-in-mixture

---

☑ Supplier

---

☑ Mixture safety data sheets

☑ Function and concentration  
26/04/2019 14:51

---

☑ Substance identification  
26/04/2019 14:51

---

☑ Classification and labelling information of the substance

## Before you begin mixture composition

- All components must be declared
- Function (except for GPI) and labelling information not mandatory
- All substance records created need to be linked to a reference substance.

Extra: Add an additional substance component (4.5% v/v)- non classified fragrance identified using the generic product identifier (GPI).

# Outcome: components listed

☰ ◀ Mixture composition

---

Mixture components + Mixture component

---

**Citrus fragrance mixture ( > 5 < 7 % (v/v) )** ✗  
17/05/2019 11:26

---

Substance components + Substance component

---

**Water solvent ( > 65 < 75 % (v/v) )** ✗  
17/05/2019 11:26

**FD&C green colourant** ✗  
17/05/2019 11:26

**Sodium dodecyl sulphate ( > 8.5 < 9.5 % (v/v) )** ✗  
17/05/2019 11:26

**GPI** ✗  
17/05/2019 11:26

## **Module 4. Product information**

Aim: to define your products in product records and link all UFI's created earlier.

# Product information

- All the product information is contained in a product record or records.
- Records can be defined flexibly– no right or wrong way
- Each product record contains:



# Defining product records (1/2)

- One record contain information on all products

Product details

1 Product identifiers

2 Market placement

3 Additional information

### Product identifiers

Trade names + New Item

Ultra	✎ ✕
Sitrus	✎ ✕
Citrus	✎ ✕
Citrus mini	✎ ✕

Other names + New Item

No items added  
+ New item

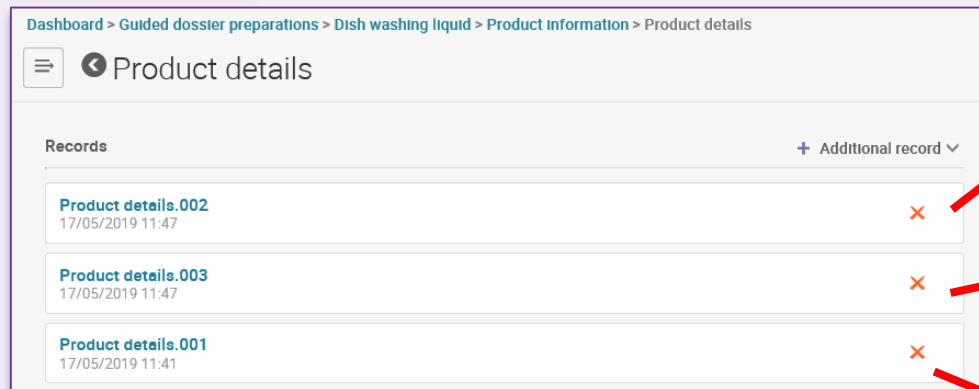
Unique Formula Identifiers (UFI)

Unique formula Identifiers (UFI) and other identifiers.003	✕
Unique formula Identifiers (UFI) and other identifiers.002	✕
Unique formula Identifiers (UFI) and other identifiers.001	✕

+ Select

## Defining product records (2/2)

- Or, multiple records can be created - each containing more specific product information.

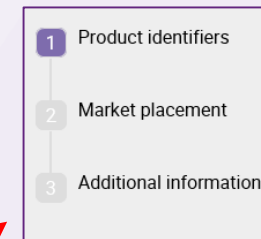


Dashboard > Guided dossier preparations > Dish washing liquid > Product information > Product details

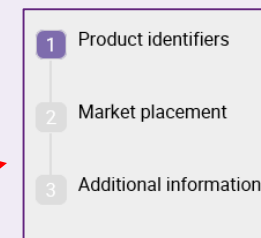
☰ Product details

Records + Additional record ▾

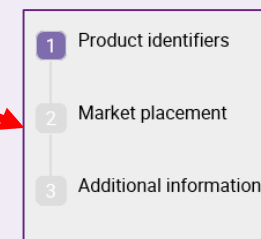
Product details.002 17/05/2019 11:47	✕
Product details.003 17/05/2019 11:47	✕
Product details.001 17/05/2019 11:41	✕



- 1 Product identifiers
- 2 Market placement
- 3 Additional information



- 1 Product identifiers
- 2 Market placement
- 3 Additional information



- 1 Product identifiers
- 2 Market placement
- 3 Additional information



## Before you begin

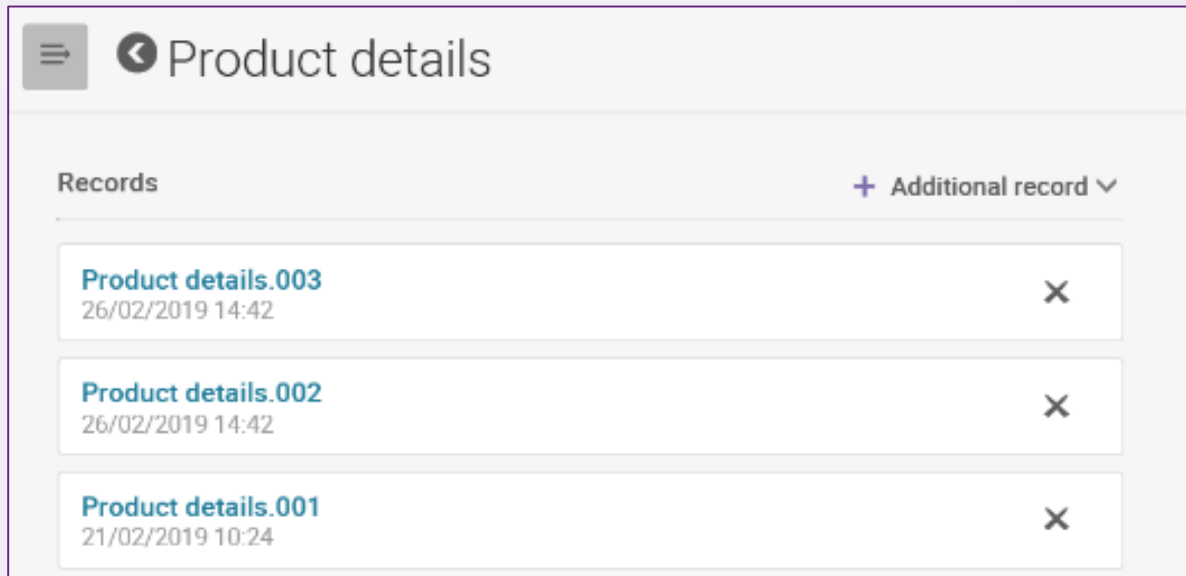
- Consider the approach you wish to take to define the product records.
- If you choose multiple record approach, you can reuse some of the existing information.

Extra: Try adding a new (4<sup>th</sup>) UFI for one of your products then go back to the UFI task and see if it is listed there.

30 mins

## Outcome: Product record(s) defined

- Your product records will be visibly listed, e.g.



The screenshot shows a mobile application interface for 'Product details'. At the top, there is a hamburger menu icon and a back arrow icon. Below the title, there is a section labeled 'Records' with a '+ Additional record' button and a dropdown arrow. The records are listed in a table-like format with three entries:

Record ID	Timestamp	Action
Product details.003	26/02/2019 14:42	×
Product details.002	26/02/2019 14:42	×
Product details.001	21/02/2019 10:24	×

## **Module 5. Finalise your dossier**

Aim: No pre-submission validation rules triggered, and a dossier is successfully created and saved to your desktop.

# Finalise your dossier


☰ Dish washing liquid


Submission type:CLP Poison centres notification

**1 Provide dossier information**

Welcome! Start preparing your dossier by providing information in the following main task groups. You will be guided through a series of smaller tasks to complete each of the main task groups below. Your work can be saved and you can come back to it later if you do not have all the information at hand.




**Information to be completed**

 Mixture Information

 Product information

**2 Finalize your dossier**

Finalise your guided dossier preparation by validating and reviewing the information before you create your dossier. Additionally, you can preview the provided information in PDF.

## Before you begin

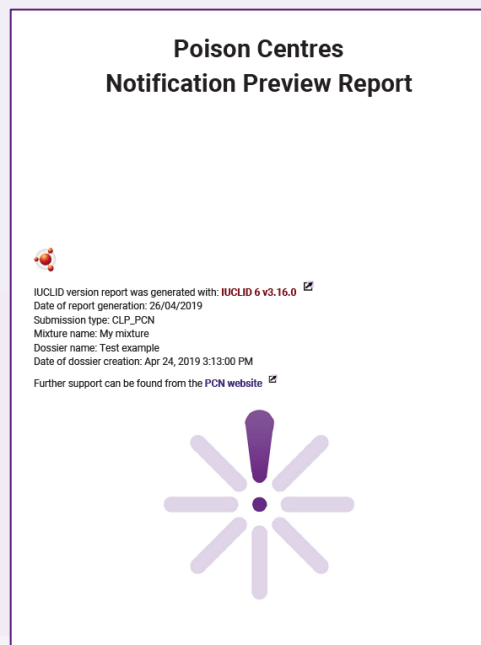
- If your information has triggered some validation rules, make any necessary changes, then revalidate.
- Once you create your dossier, open it, then export it to your desktop (see the overflow menu icon `...`)
- Save the .i6z file with a more meaningful name.
- Generate the preview report only after you create your dossier.

For users that passed the validation rules – CONGRATULATIONS! If you want see how the validation assistant works for failing dossiers, go back to one of the tasks and remove some information e.g. pH, and revalidate.

25 mins

# Outcome: Preview notification

- You can compare the outcome of the notification preview report with one we prepared earlier!



## **Module 6. Submit and search in the portal**

Aim: make a successful submission to the portal and check the submission status in the submission report.

## Before you begin

- Go to the ECHA Submission Portal tab (testing environment)
- To submit, you need to upload the dossier first
- Take note of your submission number and search for the submission report.




Thank you for your submission!  
Dossier\_leather cleaner.i6z is being processed.  
Your submission number is [RMH152233-30](#)

10 mins



# Outcome: Submission report


?

[Search](#) | [Upload & submit](#) | [Create dossier online](#)

**Submission status: Validation succeeded ✓**

<p>Dossier Type: CLP Poison centres notification</p> <p>Submission number: RMH031006-41</p>	<p>Submitted by: Jane Doe EcoChem ECHA-b307e804-ec85-400f-a30c-55b91c4643ca</p>
---------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------

**Dossier header**

---

Mixture name: My mixture  
Dossier name: Test example  
Dossier UUID: 19bda0fa-d365-483e-a6a4-8f4c314bfcbe  
Filename: AAA111.i6z  
Reason for submission: The submission is an initial notification  
Type of submission:  
PCN number: eab6f15a-6a48-4e7b-9b55-90083c91367

**Dossier information**

---

Use type: Consumer, Professional  
Name(s): name 1  
trade name 2  
trade 3  
Identifier(s): J200-U0CW-500A-Q4CG  
4500-C029-F00T-DFXR  
U800-UORP-S009-1THV  
C200-U0CW-500A-Q4EX

**Recipients (Member States - market placement)**

---

Finland  
Sweden

**Submission Events**

---

24/04/2019 15:14	Dossier submitted
24/04/2019 15:14	Dossier passed validation checks
24/04/2019 15:14	Dossier available to MS for download

## Congratulations!

- That concludes today's training on preparing and submitting a PCN dossier online!
- Don't forget to give your feedback! Go to <https://app2.sli.do> (access code is **poisoncentre**). Poll closes 31<sup>st</sup> May 17.00 Helsinki time.



Thank you!

[heidi.rasikari\(at\)echa.europa.eu](mailto:heidi.rasikari(at)echa.europa.eu)

## Want to go a step further?

Extra: Try creating and submitting a notification update by adding a new packaging type.