

Annex VIII to CLP: Harmonisation of information for emergency response

Daniele Ape

Processing and Dissemination Unit
European Chemicals Agency

Liptovsky Jan – 26 September 2019

ToC:

**1. Annex VIII to CLP:
background**

**2. Obligations: who, what,
when**

3. ECHA tools and solutions

4. *Take-home* messages



Article 45 and Annex VIII to CLP: Information for emergency response (Poison Centres)



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 [...]"

Who?

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 [...]"*

Who? ✓

What?

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 [...]"*

Who?



Why?

What?



Article 45 of CLP

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Who?



Why?



What?



Article 45 of CLP

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Who? ✓

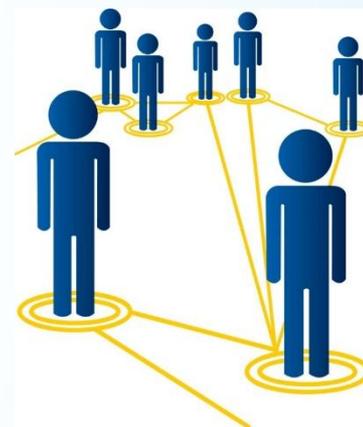
What? ✓

Why? ✓

How? ?

Result...

- Differences between national submission systems, formats, information requirements.
- Difficulties for industries in complying with the obligations from one MS to another.
- Information available to medical personnel/Poison centres inconsistent between MSs.
- Problems in the identification of poisoning agent and its chemical composition.



Annex VIII to CLP

- Published in March 2017.
- **Harmonisation of information related to health emergency response**

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2017/542
of 22 March 2017

amending Regulation (EU) No 2727/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, in Annex on harmonised information relating to emergency health response
(text with EEA relevance)

->How?

- .Same information requirements in all MSs
- .Harmonised format
- .Submission of data via central system (ECHA Submission portal) [Optional]
- .Official language (unless specified otherwise)

Note

Autumn 2019: Amendment of legal text!

Annex VIII and submission requirements: Who, when and what?



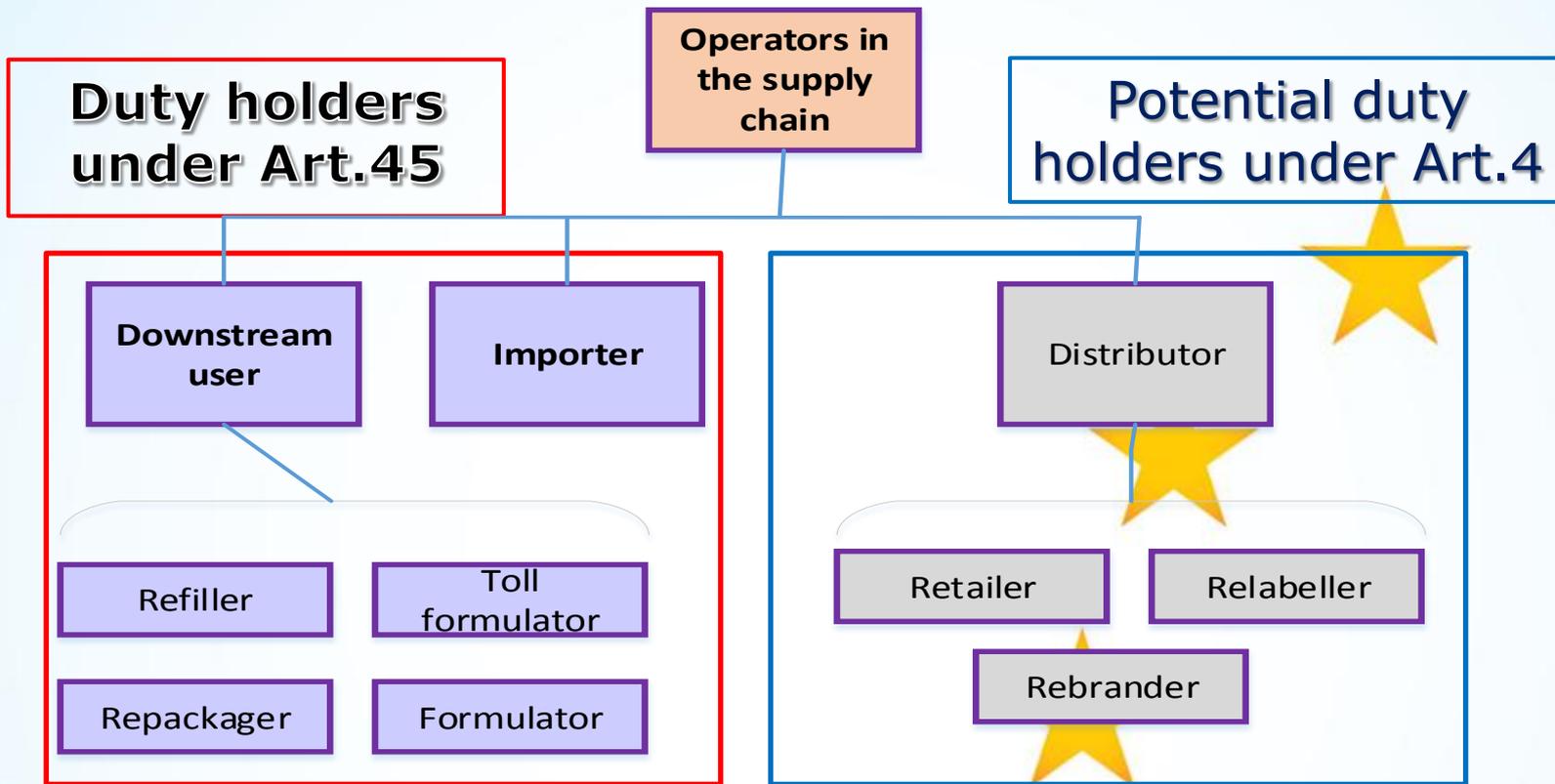
Who has notification obligations?

- 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?

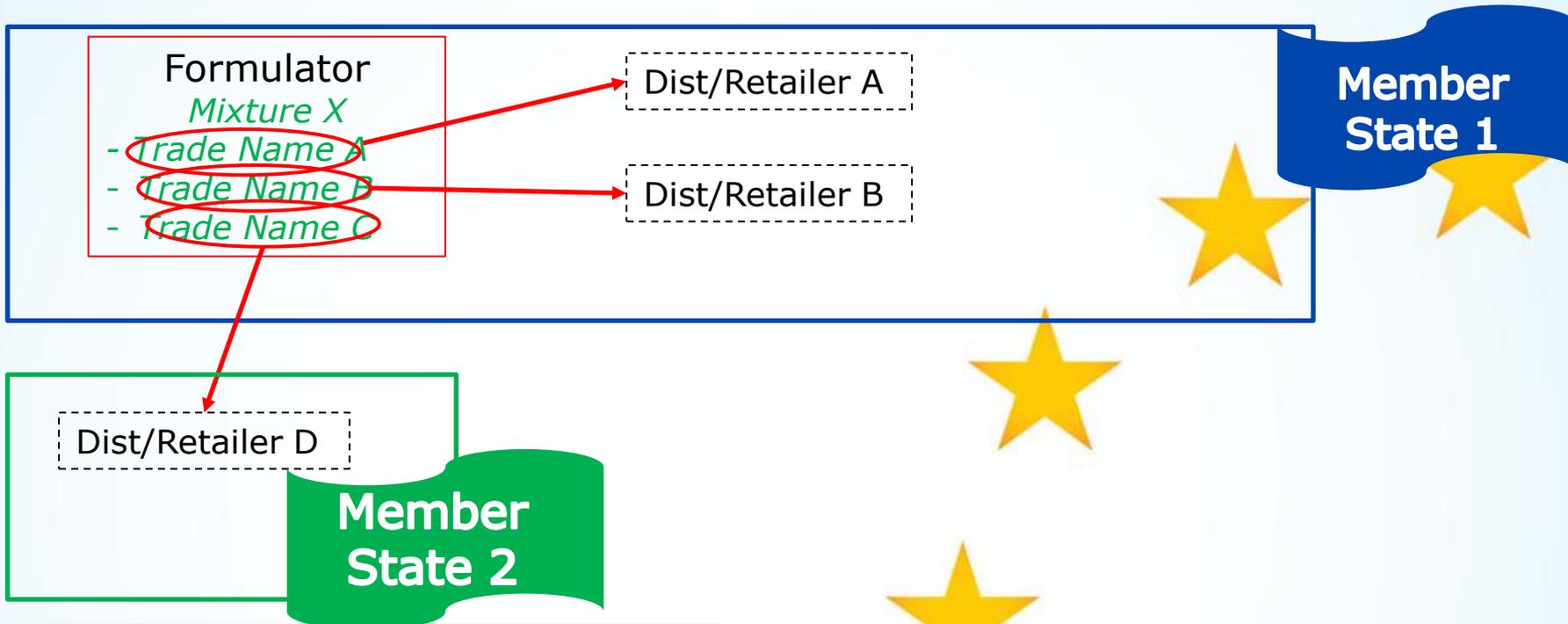


Article 45 - Direct obligations → Importers/Downstream user

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)

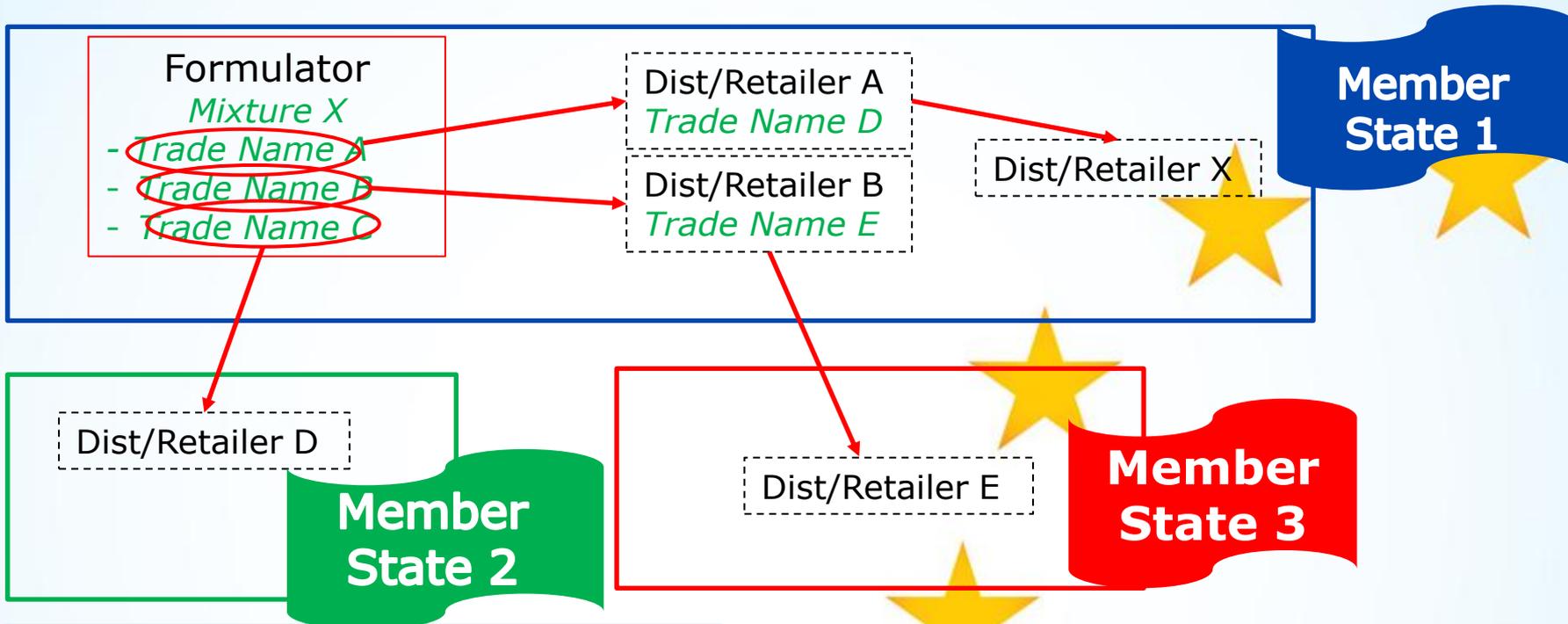
Who has to submit information?



(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?



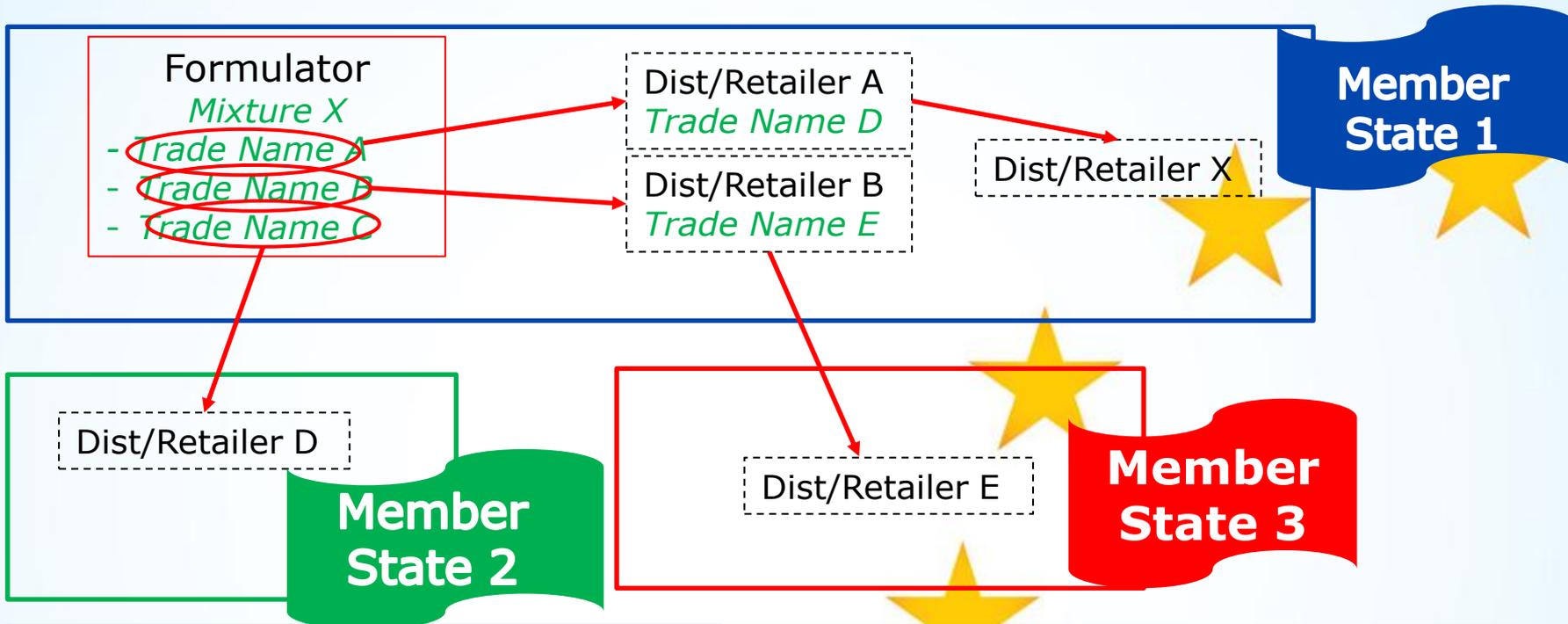
(Art.45) **Formulator** submits to appointed bodies in:

- 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

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)

(Alternatively)

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

Interpretation clarified
in version 2.0. of the
Guidance



Lack of agreement
among CAs

Dissenting view Note
attached to the Guidance

GUIDANCE

Guidance on harmonised information
relating to emergency health response –
Annex VIII to CLP

Guidance to Regulation (EC) No 1272/2008 on classification, labelling
and packaging (CLP) of substances and mixtures

Version 2.0
July

When reading this ECHA Guidance, the authorities of EU/EEA Member States should be aware of their duties of duty holders under Article 45. The text differs from the current Guidance where this concerns distributors, as distributors and not distributors.

Belgium
Germany
Greece
France

The authority of Sweden does not consider distributors in relation to Annex VIII a

The authorities of the following Member States

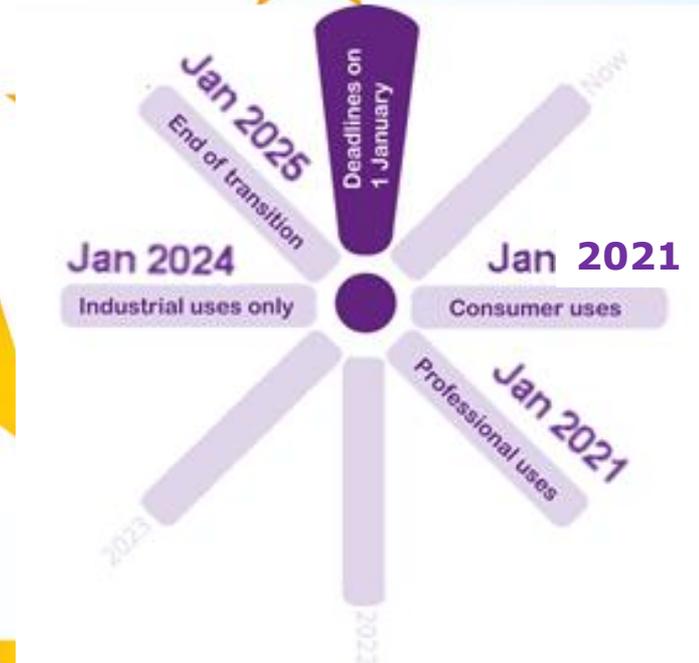
Denmark
Portugal

This is reflected in the CA/30/2019 do



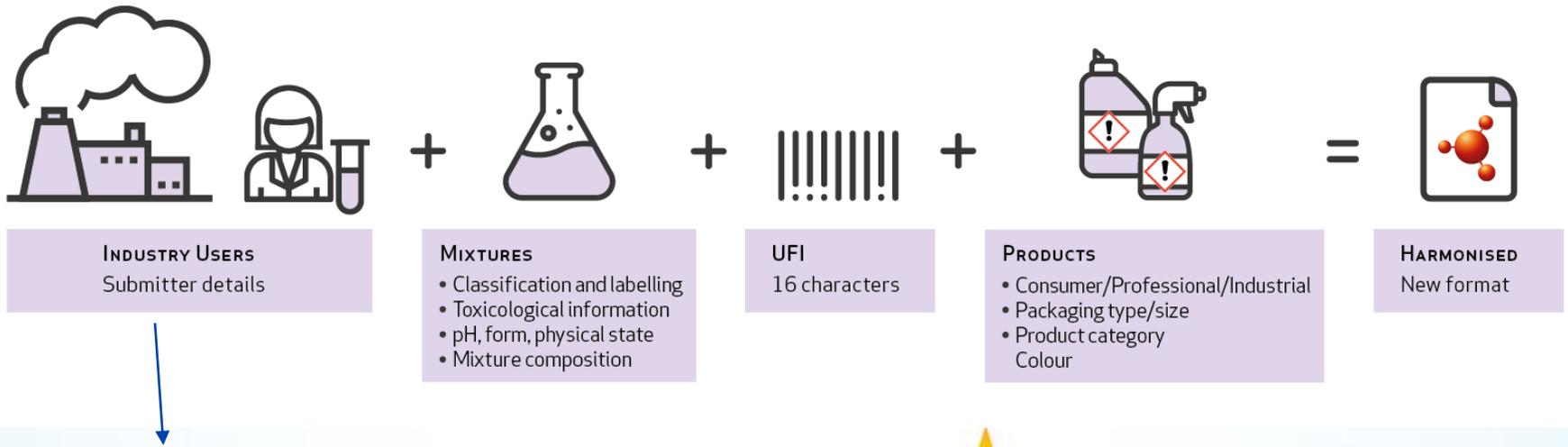
Timelines for compliance

- Notifications must comply with the harmonised requirements according to the use type of the mixture
 - 1 January **2021**: 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



Final use based on the ***end-use*** concept

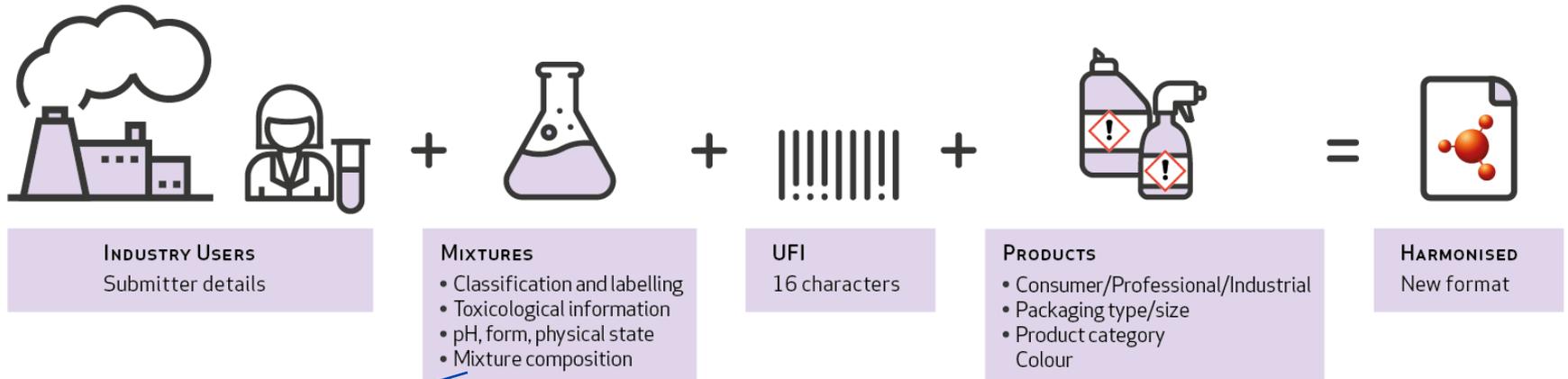
Harmonised information requirements



Submitter's details *[consistency with label information removed in the amended legal text]*

+ "Contact point" if person having further relevant information is other than the submitter

Harmonised information requirements

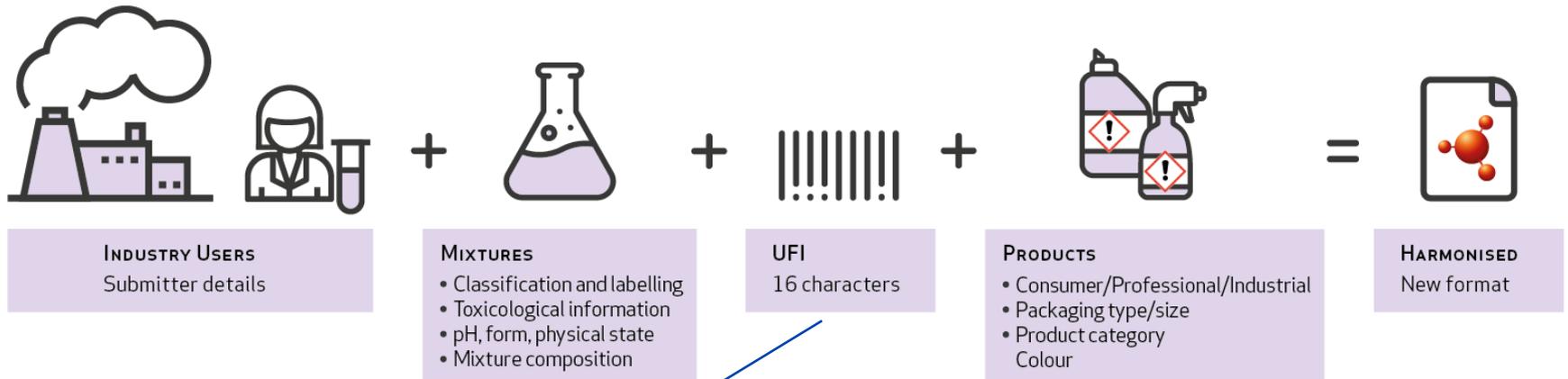


Complete composition, physico/chemical properties, toxicological information.

- Substances
- Mixture in mixture (MiM)
- *Generic Product Identifier (GPI)**

- **Subs and MiMs**: possible identification via GPI (**perfumes or colouring agents**)
- **MiMs**: identification via UFI or **known components** (SDS)

Harmonised information requirements

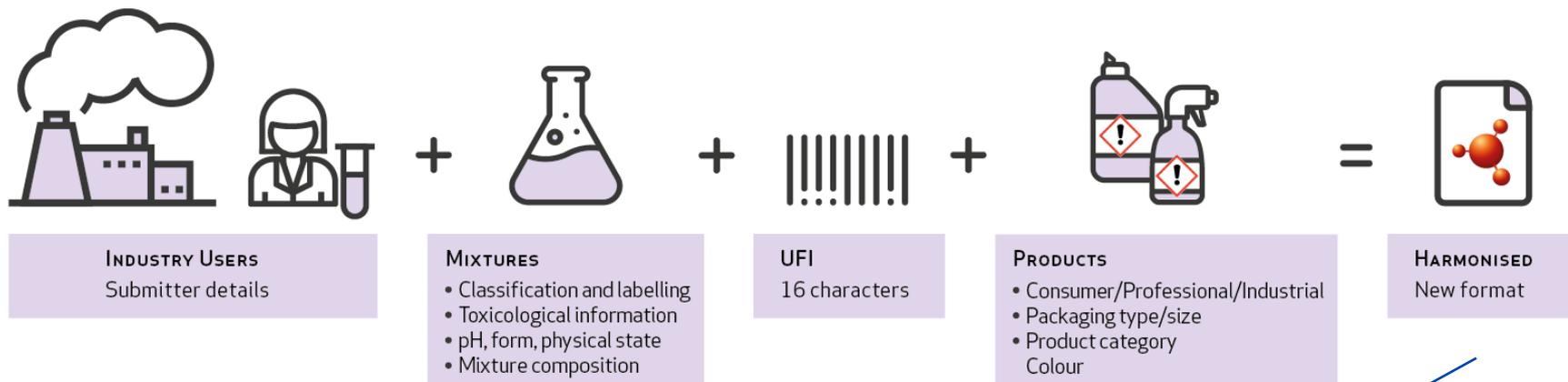


Unique Formula Identifier

Product(s) information:

- Trade name
- Packaging
- Colour
- Product categorisation according to the new *harmonised European product categorisation system* (EuPCS).

Harmonised information requirements



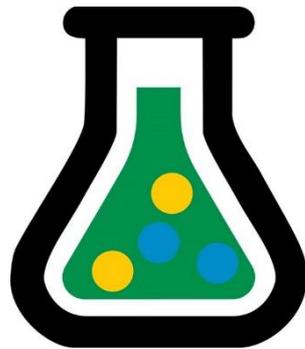
Harmonised format for the transmission of data (.xml).
Submitters can benefit from the international platform
IUCLID, already used for other processes and obligations.

Mixture vs. product

Mixture

Mixture or solution containing chemical components having associated properties:

- Composition
- Tox. 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



**Correct product
identification**

UFI



What is UFI?

Code with defined format (16 alpha-numerical characters)

Can be generated at any time by any company → "UFI generator" on the ECHA website

To what it is assigned?

General rule is that one UFI can be assigned to 1 (and only one) mixture/composition

How does it work?

UFI creates a unique link between product on the market and compositional information



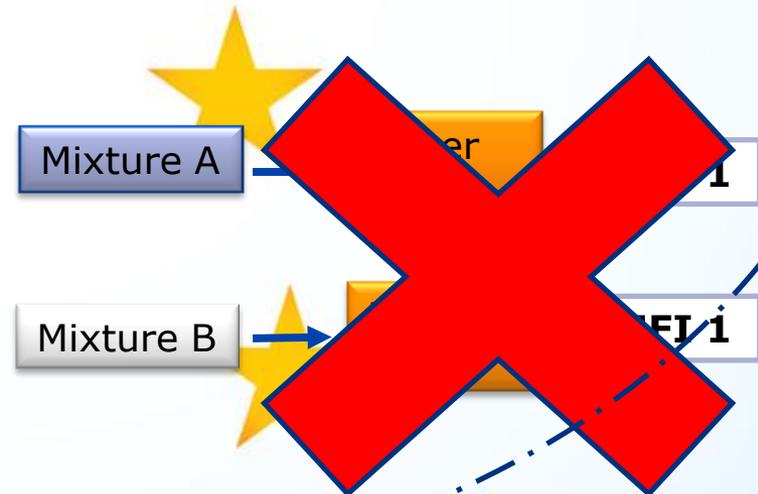
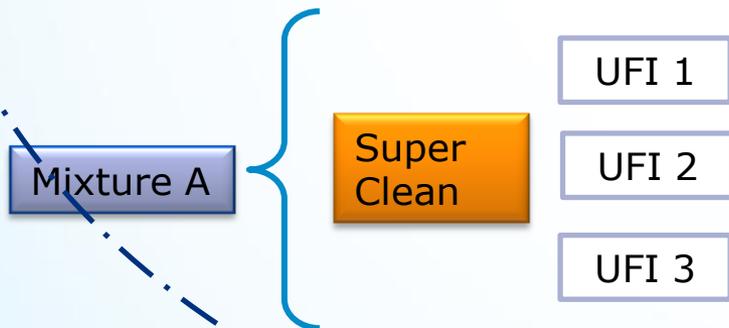
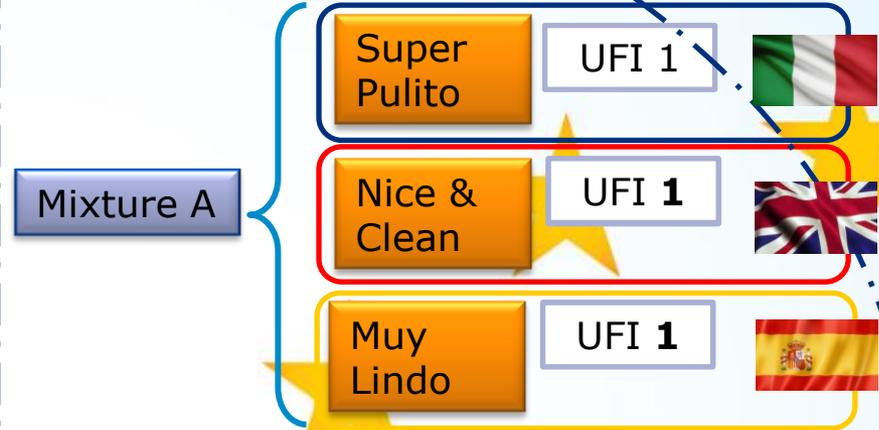
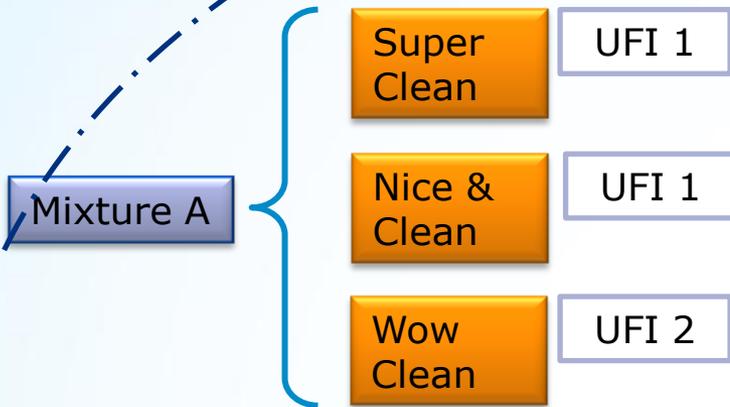
More on UFI...

- Has to be included both:
 - On the label*
 - In the notification
 - **Inner package**

*Exception in case of **industrial use** or unpackaged mixtures

- Same UFI can be used along the supply chain as long as composition remains the same
- It works to protect CBI (e.g. MiM) → **UFI known to the relevant AB as part of a submission**

UFI...

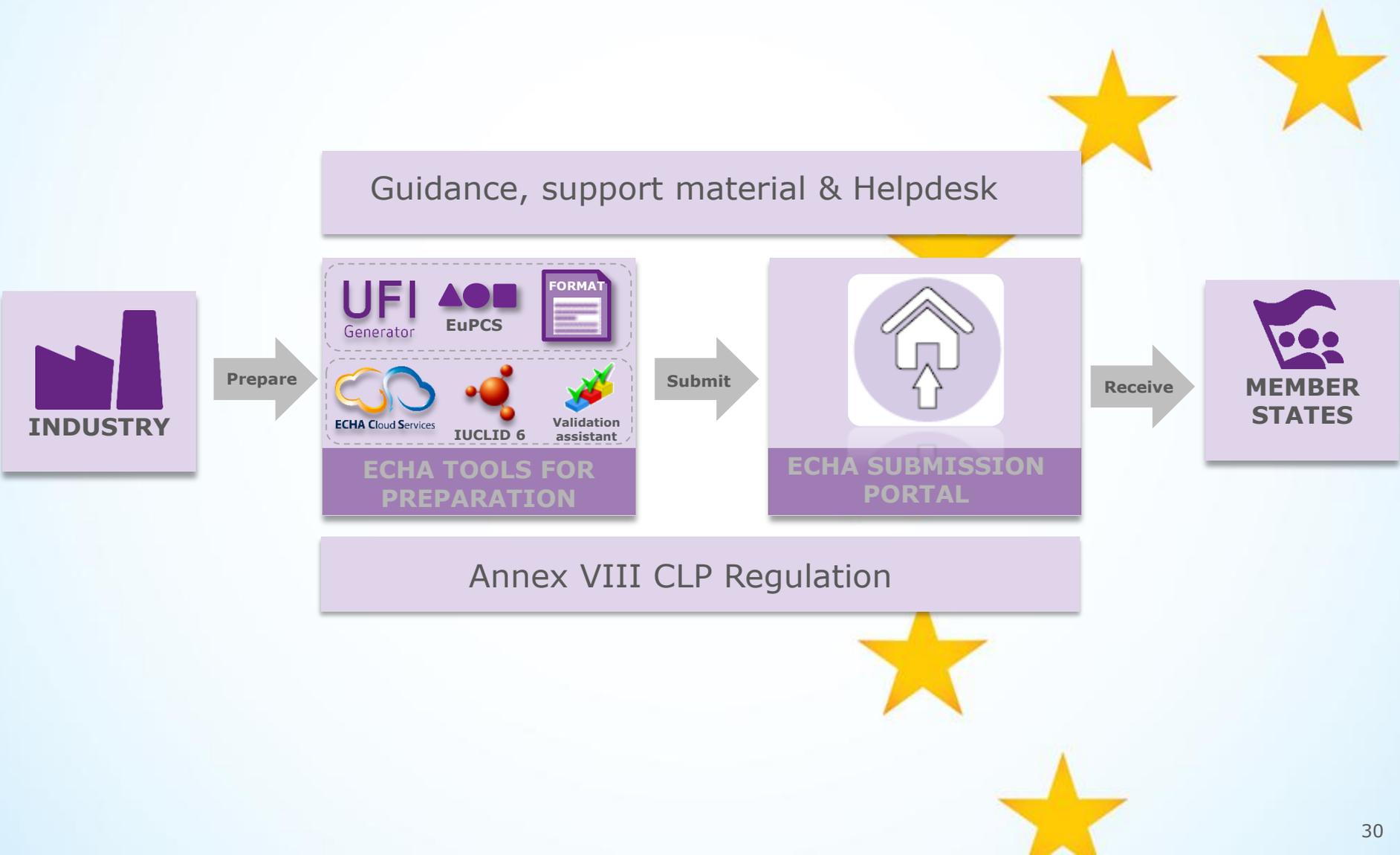


Amendment of Annex VIII to CLP

- Editorial changes (terminology)
- Non-editorial changes
 - Simplified rules for group submission
 - Reporting of MiM components
 - UFI on the inner packaging
- Postponement of the first applicability date
 - Consumer use products to be notified from 2021 onwards (=professional use)
- Amendment should be adopted in late autumn 2019
- No solutions for workability issues

In **red** in this presentation

ECHA tools for preparation & submission



Available tools

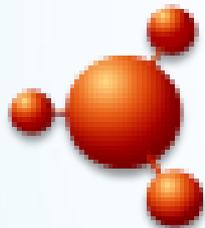
- **UFI generator:**
 - Freely available on the internet
 - UFI developer Manual
 - Available in all official languages
- **European Product Categorisation system:**
 - To describe the intended use of a mixture
 - To facilitate reporting and monitoring incidents
 - Maintained by ECHA
- **PCN format:**
 - Harmonised Annex VIII format
 - Freely available
 - Subject to updates

How to prepare a submission



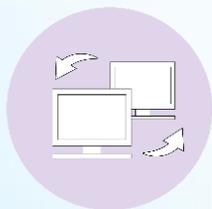
- **Online in the ECHA Submission portal:**

- IUCLID Cloud
- Guided dossier preparation functionality
- Information stored in the ECHA Cloud



- **Offline in IUCLID 6:**

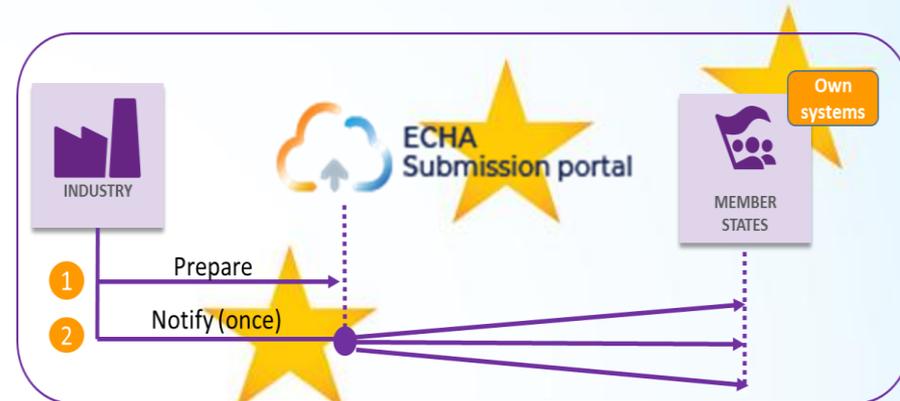
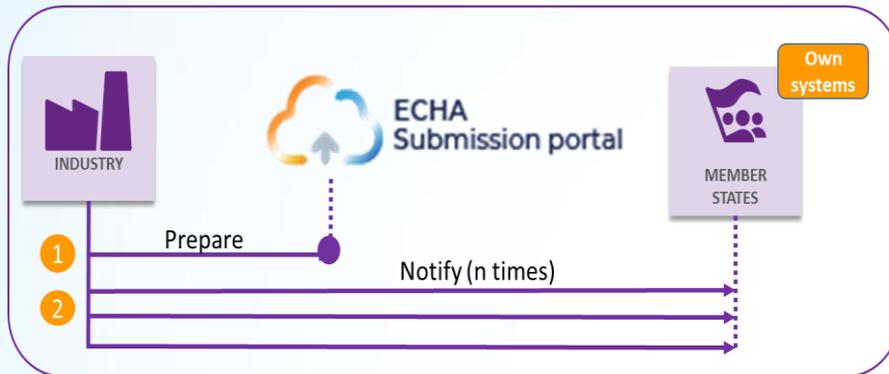
- Specific PCN interface
- Local installations of IUCLID
- Desktop and server versions on the IUCLID 6 website



- **Using the PCN format in company's own system:**

- IUCLID compatible PCN format

How to submit a PCN dossier



Dossier preparation always using ECHA tools and harmonised format

- 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 MS
 - provides database at ECHA

Ways to submit a PCN dossier

 ECHA
EUROPEAN CHEMICALS AGENCY



- **Online through the ECHA Submission portal:**

- dossier made available to all Member States indicated in the notification

 ECHA
EUROPEAN CHEMICALS AGENCY



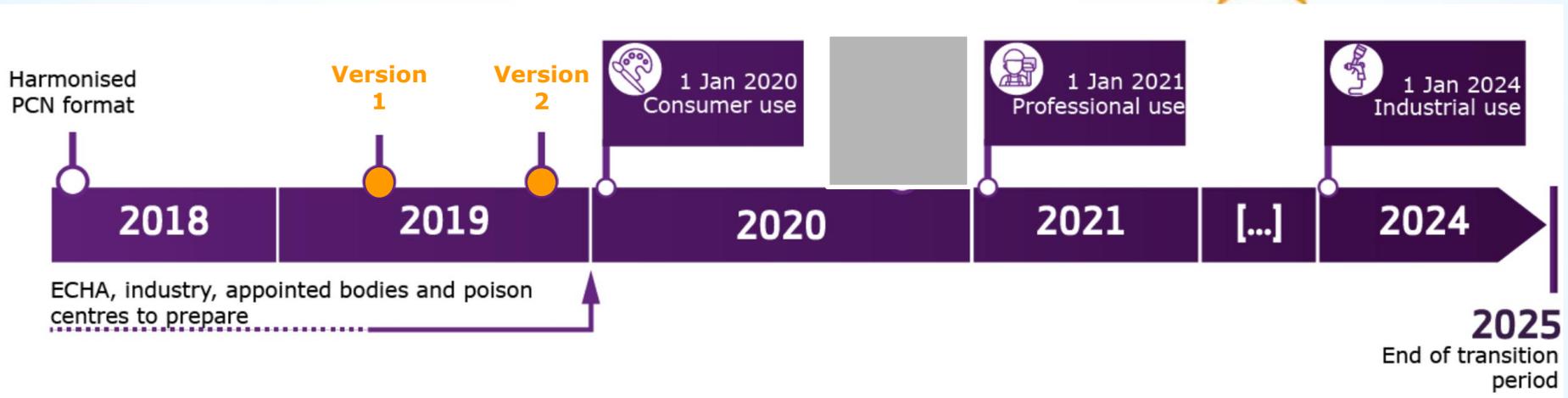
- **Through a system-to-system (S2S) transfer from the company's own system to the ECHA Submission portal:**

- Dossiers forwarded from the portal to all the relevant Member States
- Functionality available from October 2019



- **Via national submission system (if available)**

ECHA submission portal development



- Version 1 – 24th April 2019
- Version 1.1 – July 2019
- Version 2 – October 2019

ECHA Submission portal – Current version

Industry

Guided dossier preparation tool / IUCLID Cloud 

Validation assistant

Support to enter multilingual text

PDF preview

On-line help

Dossier upload and online submission

Submit online from IUCLID Cloud

Submission report

Validation report

Advanced search functionality

New way to indicate a GPI component

Navigation improvements

Additional non-GHS hazard statements



ECHA Submission portal – Current version

Member States

ECHA Remote access portal: dispatching of the PCN dossier via:

- a country specific secure folder (SSL VPN)
- eDelivery service

Downloading dossiers

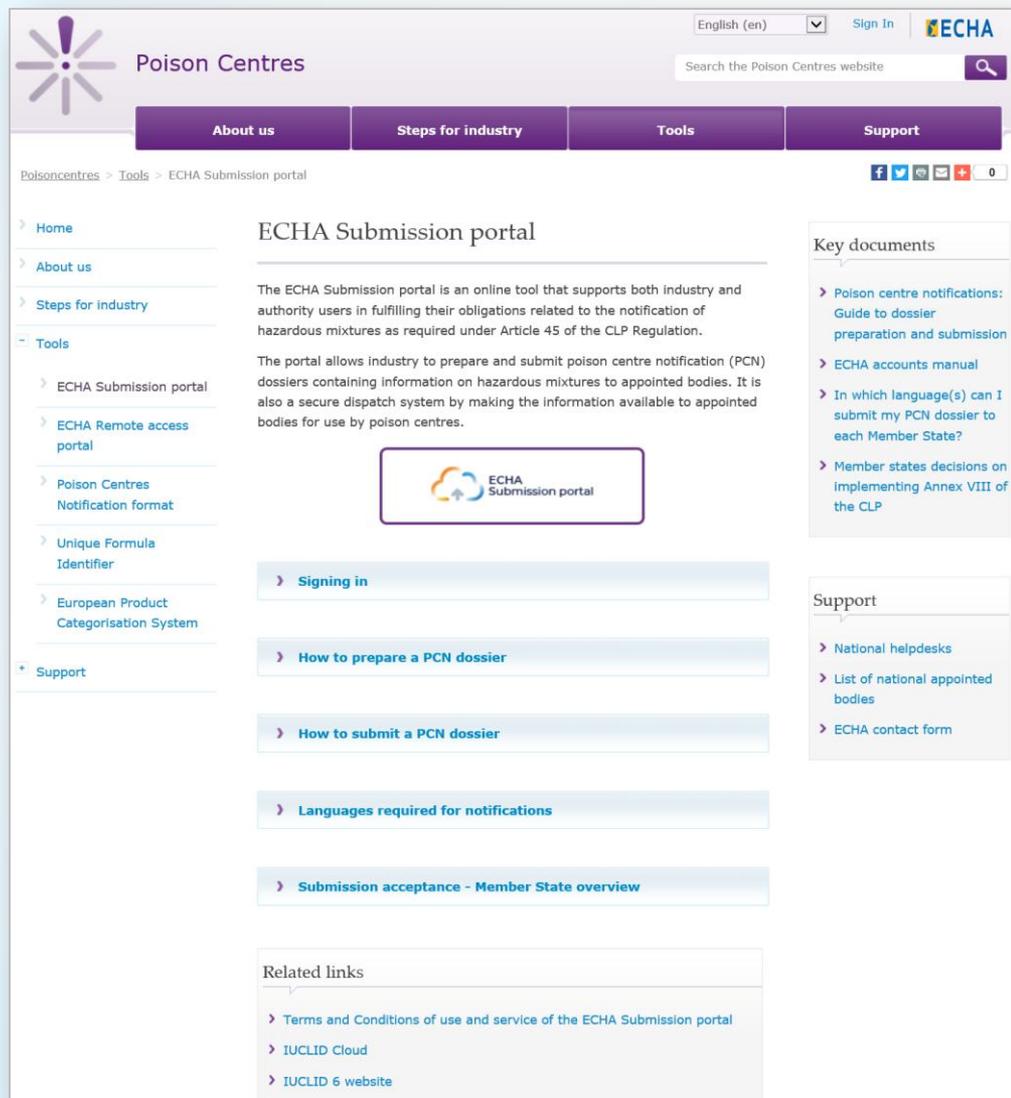
Validation report

Login manual to ECHA's IT tools for authority users

October 2019: kick off of the ***Consultation process***

November 2019: PCN database - basic query functionality to access notifications

ECHA Submission portal



English (en) Sign In ECHA

Poison Centres

Search the Poison Centres website

About us Steps for industry Tools Support

Poisoncentres > Tools > ECHA Submission portal

ECHA Submission portal

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.



- › [Signing in](#)
- › [How to prepare a PCN dossier](#)
- › [How to submit a PCN dossier](#)
- › [Languages required for notifications](#)
- › [Submission acceptance - Member State overview](#)

Key documents

- › [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](#)

Support

- › [National helpdesks](#)
- › [List of national appointed bodies](#)
- › [ECHA contact form](#)

Related links

- › [Terms and Conditions of use and service of the ECHA Submission portal](#)
- › [IUCLID Cloud](#)
- › [IUCLID 6 website](#)

The ECHA Submission portal webpage is available from the ECHA Poison Centre website:

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

Initiating a guided dossier preparation

The screenshot shows the IUCLID 6 dashboard. At the top, there is a search bar labeled "Search dossier by UUID". Below it, three summary cards are visible: "Guided dossier preparation" with a count of 0, "Substances" with a count of 9, and "Mixtures" with a count of 2. To the right, there is a section for "Import IUCLID file(s)" with an "Overwrite settings" dropdown set to "If newer than existing" and a "Drop file to upload or Browse" button. A red arrow points from the user profile area at the top right of the dashboard to the user menu.

- ECHA Cloud
- ECHA Submission portal
- Manage account
- Switch legal entity >
- Logout



The screenshot shows the "Guided dossier preparations" page. It features a search bar and a "2 results found" indicator. A table lists the following submissions:

Submission Name	Legal Entity	Submission type	Dossier Name	Update submission	Created
Hazardous mixture 1	EcoChem	CLP Poison centres notification		PCN	04/03/2019 07:34
zinc oxide / 215-222-5 / oxozinc / 1314-13-2	Placeholder substance LE	REACH Registration member of a joint submission - general case		REACH	21/02/2019 08:05

A "+ New" button is located at the top right, with a dropdown menu showing "REACH submission" and "PCN submission".



Establishing the dossier context for a new mixture

Guided dossier preparation for your Poison Centres Notification

- 1 Specify your mixture
- 2 Dossier information

Specify the mixture name of your Poison Centres Notification

Select an existing mixture
+ Select

OR

Create a new mixture

Mixture test



Guided dossier preparation for your Poison Centres Notification

The information you provide in this step will determine what fields will be visible during the preparation of your dossier.

Specify your mixture

Dossier information

Check the submitter information

Submitter Information

Undefined Company Name

Define the dossier information

PCN number* 0/255

PCN number field is mandatory.

Country (market placement)

Language

Limited submission (industrial use only)

Non hazardous mixture

The submission is an initial notification

The submission is a new notification after a significant change of composition

The submission is an update

Reason for updating

Justification + New item

No items added
+ New item

Previous Finish

Define the dossier by:

- Indicating the countries/languages
- Flagging alternatives to the standard information requirements e.g. limited
- Verifying the submission type e.g. initial
- Declaring, when relevant, the reason for updating

Guided dossier preparation 'navigation page'

Dashboard > Guided dossier preparations > Hazardous mixture 1

Hazardous mixture 1 Delete

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.

Validate Create dossier Preview notification

Useful information

- Targeted support - Steps for industry
- ECHA's poison centre website
- National Helpdesks
- Contact ECHA
- Poison Centres questions and answers
- Guidance on harmonised information relating to emergency health response

Mixture information task page

1 Information to be completed

- Mixture Information
- Product 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.

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

- Some tasks can contain additional sub-tasks
- Create a new record
- Use existing information

The 'Mixture composition' task

 Mixture composition

Mixture components +Mixture component

No components have been added yet.

Substance components +Substance component

No components have been added yet.

Generic Product Identifier components +Generic Product Identifier component

No components have been added yet.



 Function and concentration
15/02/2019 16:00 1

 Substance identification
15/02/2019 16:00 1

 Classification and labelling information of the substance

 Function and concentration
15/02/2019 15:59 1

 Unique formula identifiers (UFI)

 Mixture-in-mixture composition

 Classification and labelling information of the mixture-in-mixture

 Supplier

 Generic product identifier information
05/09/2019 17:11 1

 Classification and Labelling information



The product information tasks

Hazardous mixture 1

Submission type: CLP Poison centres notification

1 Provide dossier information
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Information to be completed

- Mixture Information
- Product information

2 Finalize your dossier
Finalise your guided dossier preparation by validating and n

Validate Create dossier

Product information

Here is where you can enter the product details. You will need product identifiers and other product characteristics such as

Product details
21/02/2019 10:24

1 Product details

Product identifiers

Trade names
No items added
+ New item

Other names
No items added
+ New item

Unique Formula Identifiers (UFI)
+ Select

Additional information

Colour and physical state

Link to the information about colour and physical state
+ Select

Packaging

- **Product identifiers:**

- Trade name(s)
- Other name(s)
- UFI and other identifiers

- **Market placement**

- **Additional information:**

- Colour and physical state
- Packaging
- End-use
- Product use category

Validation assistant and validation report

Dashboard > Guided dossier preparations > Hazardous mixture 1

Hazardous mixture 1

Submission type: CLP Poison centres notification

- 1 Provide dossier information**
Welcome! Start preparing your dossier by providing a series of smaller tasks to complete each of the steps 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.
[Validate](#) [Create dossier](#) [Preview notification](#)

Validation assistant report

Validated entity: Hazardous mixture 1
Validation time: 28/02/2019 10:17
Validation scenario: SC0173 - Poison centres notification, standard, initial, not 'Limit...'

[Re-validate](#) [Edit dossier settings](#)

Submission checks 2 **Quality checks 0**

Business rules 2 **Completeness check rules 0** Total rules executed 47

- Initial submission**
Dossier header
Business rule (BR610)
Market placement (country) indicated in product information record is not mentioned in dossier header as market placement country. Please ensure that the countries indicated in Product information record(s) are also indicated in the dossier header.
- Product details.001**
Product information Trade names, (1)
Business rule (BR508)
Product information is incomplete. At least one 'Trade name' must be provided under Product details > Product identifiers.

Dashboard > Mixture / Products > Hazardous mixture 1 > Product details.001 > edit

Product details.001

Group submission

Product Identifiers >

Market placement

Safety data sheet (SDS)

Additional Information

Product information Trade names, (1) [Validation report](#)
Product information is incomplete. At least one 'Trade name' must be provided under Product details > Product identifiers.

Product identifiers

Trade names [+ New item](#)

Trade names 01 [✎](#) [✕](#)

[Save](#)



Preview, create and export the dossier

Dashboard > Guided dossier preparations > Hype

Hype

Submission type: CLP Poison centres notification

1 Provide dossier information
Welcome! Start preparing your dossier by providing information in the following main task groups below. Your work can be saved and you can come back to it later if you

Information to be completed

- Mixture Information
- Product information

2 Finalize your dossier
Finalise your guided dossier preparation by validating and reviewing the information

[Validate](#) [Create dossier](#) [Preview notification](#)

Create dossier

✓ Dossier creation was completed successfully.
Do you want to open the created dossier?

[Close](#) [Open](#)

Dashboard > Mixture / Products > Hazardous mixture 1

Initial submission
93a6c06a-9512-450b-a65e-49353d2c45b1

Table of contents

- Mixture information and product identity 4
- Classification of the mixture and label elements 1
- Mixture safety data sheets and toxicological information 1
- Additional information 9

Dossier information

[Validate](#)

Submission type: CLP Poison centres notification

Dossier name: Initial submission

Subject: Hazardous mixture 1

Submitting legal entity: EcoChem

Created on: 28/02/2019 11:13

[View complete information](#) →

- Created dossiers available in the Mixtures dataset (lock)
- Provided information can be previewed in PDF

Search – Upload&Submit

Search | Upload & submit | Create dossier online

Search criteria ▾

Page 1 of 44 results

Sort by

 RMH363521-24 	29/08/2019 12:35	
PCN number	4ff2d556-62e5-49d1-ae46-5076fac0777c	UFI(s) 2W10-30GC-K00J-7X65
Names	Hietaranta beach, Update logic exercise,	
 RMH374866-05 	29/08/2019 12:31	
PCN number	f056504f-0870-4668-a211-c806cd293908	UFI(s) 2W10-30GC-K00J-7X65
Names	Hietaranta beach, Update logic exercise,	
 RMH591785-03 	29/08/2019 09:42	
PCN number	bc46c37c-0fee-461a-8dd2-4de0028d5564	UFI(s) 7U6K-45GT-U00S-HSRF
Names	Trade Name 1, Test BR598,	
 RMH377203-20 	28/08/2019 15:59	
PCN number	cc3fbbf3-d5a6-4ae9-a0a6-3905bcd9c4a	UFI(s) 1S00-V0W2-M008-0YMR
Names	Product no name, TEST 3.22.0,	
 RMH420107-34 	28/08/2019 08:42	
PCN number	15855ded-d56e-4365-8473-86ded6253fa9	UFI(s) X5S7-CMDX-0107-0CYQ
Names	fjghsgfrj, Trade Name 2, Test BR620 bis,	
 RMH103129-30 	28/08/2019 08:39	
PCN number	4a7a2736-136e-4afd-b1b0-d93359041ccc	UFI(s) X5S7-CMDX-0107-0CYQ
Names	fjghsgfrj, Test BR620 bis,	

- Search submitted dossier
- View validation reports
- Submit new dossier/updates
- Check submission status

Support for industry

Material to prepare and submit PCN notifications:

- Guide to dossier preparation and submission
- Steps for industry to fulfil their new obligations
- Member states decisions on implementing Annex VIII of the CLP (translated)
- ECHA accounts manual

In addition...

- Regulatory guidance - <https://echa.europa.eu/guidance-documents/guidance-on-clp>
- PCN Website: <https://poisoncentres.echa.europa.eu/>
- Contact us: <https://echa.europa.eu/contact>

Take-home 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, tox/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's
- No rules on placement - redesign of label to incorporate this new element
- Printing of UFI's on the label should be planned to coincide with the submission of information



Kiitos!
Thank you!
Grazie!

Questions?

