

# Poison Centre Notifications - Best practices from start to market

March 2021  
Webinar

Poison Centres Team  
Submission and Processing Unit  
European Chemicals Agency

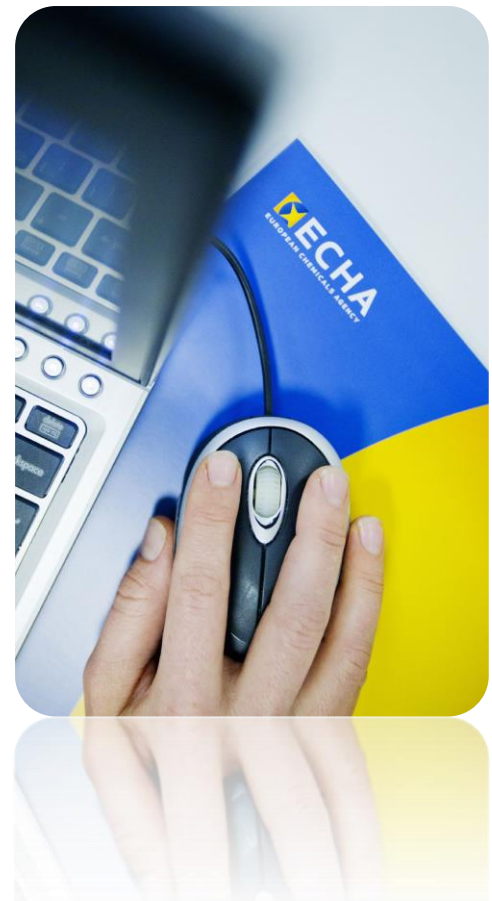
# Agenda



- 11:00     **Introduction** (webinar open for questions)  
          Heidi Rasikari
- 11:05     **Best practices for dossier preparation**  
          Heidi Rasikari
- 11:25     **Tips for most commonly failed validation rules**  
          Daniele Ape
- 11:45     **Guidelines for using the Portal**  
          Claudia Rimondo
- 12:05     **Concluding remarks**  
          Heidi Rasikari
- 12:10 - 13.00   Webinar remains open for questions

## What you can expect from today

- **New users** learn how to avoid and overcome common issues or misunderstandings
- **Tried users** accustomed to the PCN process but who may wish to update their notification to improve quality
- Ask your questions from our online panellists



# Questions

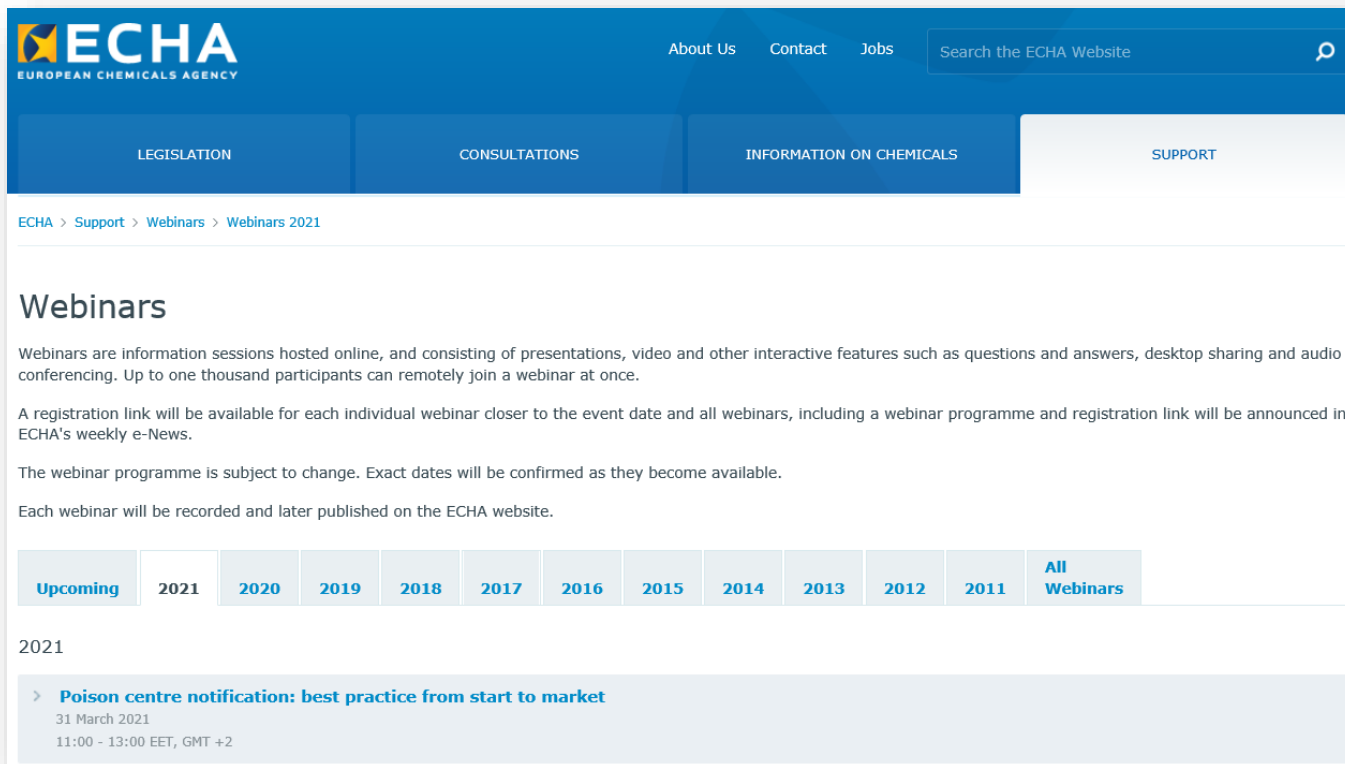
- Join Q&A at: [slido.com](https://www.slido.com)  
Event code: **#pcentre21**
- Send questions from **11:00 to 13:00 Helsinki time**
- Replies sent until 14:00
- Only questions within scope
- Question not answered?  
Contact us: [echa.europa.eu/contact](https://echa.europa.eu/contact)



# Material available

Video recording, presentations and Q&A:

[echa.europa.eu/support/training-material/webinars](https://echa.europa.eu/support/training-material/webinars)



The screenshot shows the ECHA website's 'Webinars' page. The header includes the ECHA logo, navigation links for 'About Us', 'Contact', and 'Jobs', and a search bar. A main navigation bar contains 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The breadcrumb trail is 'ECHA > Support > Webinars > Webinars 2021'. The page title is 'Webinars'. The main content area contains a description of webinars, a note about registration links, and a statement that the programme is subject to change. Below this is a horizontal navigation bar with tabs for years from 2021 to 2011, and an 'All Webinars' tab. The '2021' tab is selected. Underneath, a list of webinars is shown, with the first entry being 'Poison centre notification: best practice from start to market' on 31 March 2021, from 11:00 to 13:00 EET, GMT +2.

**ECHA**  
EUROPEAN CHEMICALS AGENCY

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ECHA > Support > Webinars > Webinars 2021

## Webinars

Webinars are information sessions hosted online, and consisting of presentations, video and other interactive features such as questions and answers, desktop sharing and audio conferencing. Up to one thousand participants can remotely join a webinar at once.

A registration link will be available for each individual webinar closer to the event date and all webinars, including a webinar programme and registration link will be announced in ECHA's weekly e-News.

The webinar programme is subject to change. Exact dates will be confirmed as they become available.

Each webinar will be recorded and later published on the ECHA website.

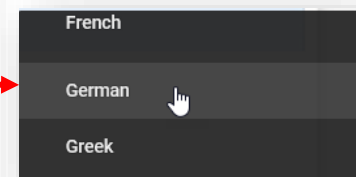
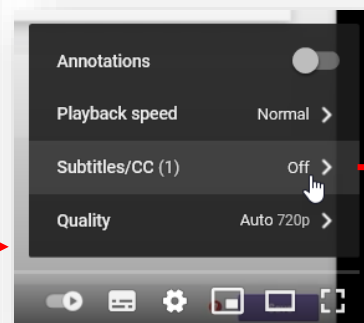
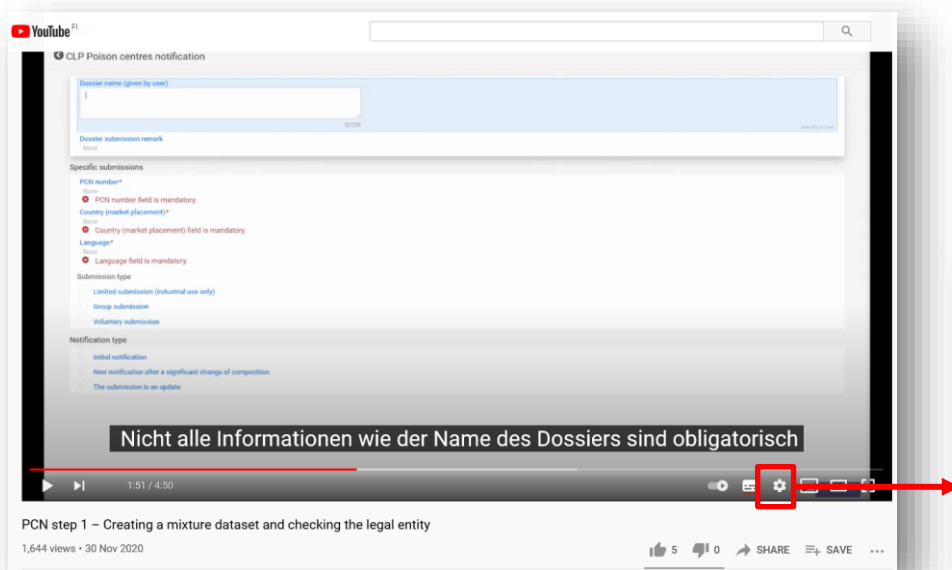
Upcoming 2021 2020 2019 2018 2017 2016 2015 2014 2013 2012 2011 All Webinars

2021

> **Poison centre notification: best practice from start to market**  
31 March 2021  
11:00 - 13:00 EET, GMT +2

# Poison Centre playlist

- Recorded material in YouTube - animations, tutorials...  
<https://www.youtube.com/playlist?list=PLOPGDACsD6qy-pVbXvKkxsIukZ3XAKOMy>
- Try the auto-translate functionality for subtitles – it may be helpful\*



# Best practices for dossier preparation

March 2021

Webinar PCN – best practices from start to market

Heidi RASIKARI

Poison Centres Team

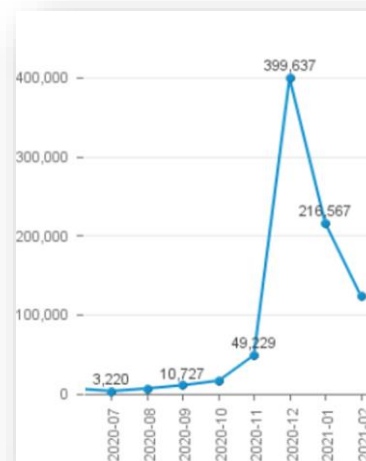
Submission and Processing Unit

European Chemicals Agency



# First compliance date has passed

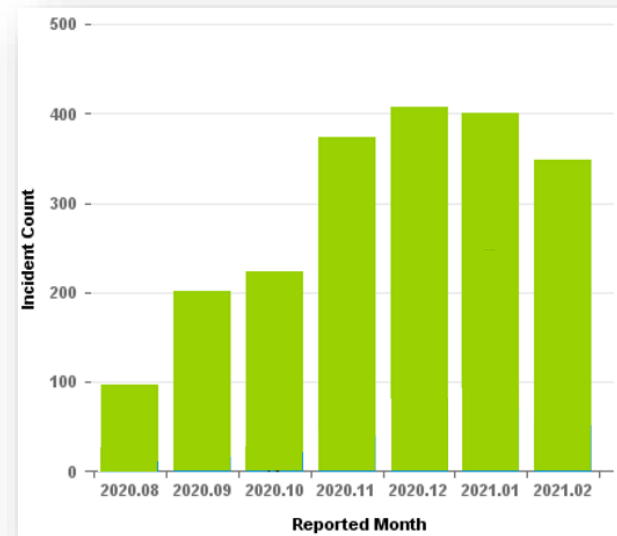
- Peak of total submissions in December
- Germany, Italy, France
- ~13% failure rate





## Our support efforts

- Helpdesk support and LinkedIn support channels received many 100s of questions
- Re-occurring concerns and mistakes
- These incidents form the basis of this presentation where:
  - Updates should be considered
  - Best practice should be employed
  - Mistakes can be avoided





## Keep information up to date!

- Certain changes require update before placing mixture on market (Annex VIII, Part B. 4.1) – *change product identifier, classification, new toxicological data, significant changes in composition*
- Notifying any change in existing information, include new or additional information important for work of poison centres
- Updates to include information that is not systematically checked by validation e.g.:
  - is required in the legal text
  - when mistakes are made
  - improve the quality of the notification
- **Appointed Bodies have the right to ask for further clarification and request an update.**

# Know your updates!

Notification type

The submission is an update

Reason for updating

Justification + New item

1 Justification ➔

Remarks  
None

Other update reason  
fi

- change in the mixture classification\*
- change in the product identifier\*
- correction of error
- correction/deletion of trade name
- expansion of market area
- new toxicological information available\*

- **Correction of error:** When you entered invalid information e.g. wrong phone number
- **Correction/deletion of trade name:** When you misspelled or entered wrong trade name
- **Expansion of market area:** Will always receive a warning
- **Remarks** 'free text' be used to provide further explanation
- More than one reason? Add **multiple** justifications
- **'Other'** reasons e.g. new packaging type - add free text!

# **Enhancing the quality of notifications- Free text considerations**





Language\*

- ✓ Dutch
- ✓ English
- ✓ French
- ✓ German

nl

en

fr

de

## Language requirements



- Free text fields generated for languages indicated in the dossier header
- Currently validation only checks '*Toxicological information*' free text section for each language specified in the header
- Other free text fields not checked
  - '*Additional text*'
  - '*Remarks*'
- Don't skip free text if relevant! If need to add free text, do it for all indicated languages

## Example 1 When the free text is not-mandatory to provide

Labelling **Calculate**

Signal word  
Warning

Hazard pictogram

GHS07: exclamation mark  
GHS08: health hazard

Hazard statements  
+ New item

1 Hazard statement  
H370: Causes damage to organs <or state all organs affected, if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Additional text  
None

Precautionary statements  
+ New item

1 Precautionary statement  
P264: Wash ... thoroughly after handling.

Additional text  
en

0/2000 press Esc to close


- Labelling section - Hazard & Precautionary statement 'codes' are referred to in Annex VIII.
- 'Additional text' fields available to complete some statements with free text and enhance quality e.g. <specific organs affected>.

## Example 2 additional text as a work-around

Labelling

Signal word  
Warning

Hazard pictogram



GHS07: exclamation mark

Hazard statements

1 Hazard statement  
None

Additional text  
en

SP03: After igniting the product, do not inhale smoke and leave the area immediately


84/255

- Where mandatory to provide obligatory supplemental label information under CLP (Article 25).
- 'Additional text' can be used to include certain "Safety Phrases" for plant protection products as required on the label.

## ***Example 3 Additional labelling requirements***

- 'Additional labelling' section available to indicate Hazard statements applied under different legislations
- Additional text used to complete statements for obligatory supplemental label information (e.g. EUH208 phrase naming the sensitising substance)

Additional labelling requirements

Additional non-GHS hazard statements + New item 

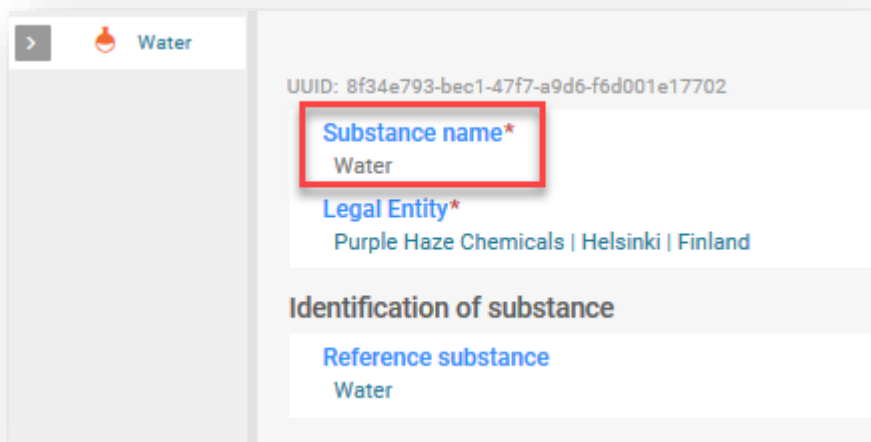
1 Additional non-GHS hazard statement  
EUH208: Contains <name of sensitising substance>. May produce an allergic reaction.

Additional text  
None



## Example 4 Substance and reference substance names

- Free text field but not language specific
- Language choice is at discretion of notifier – consider the language requirements of the recipients
- Additional languages can be included in the 'Synonyms' field of 'Reference substance'.



Water

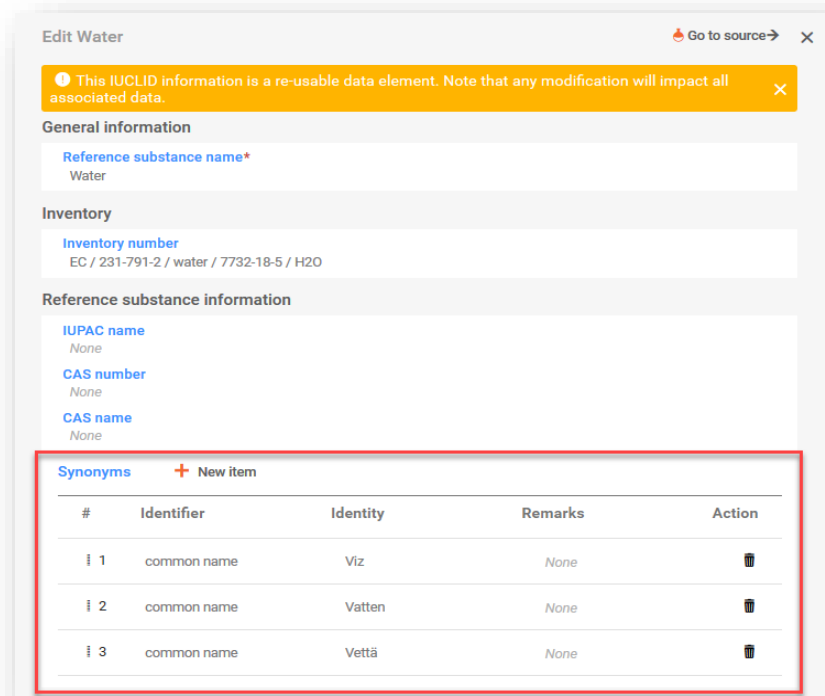
UUID: 8f34e793-bec1-47f7-a9d6-f6d001e17702

**Substance name\***  
Water

**Legal Entity\***  
Purple Haze Chemicals | Helsinki | Finland

**Identification of substance**

**Reference substance**  
Water



Edit Water Go to source → ×

**This IUCLID information is a re-usable data element. Note that any modification will impact all associated data.** ×

**General information**

**Reference substance name\***  
Water

**Inventory**

**Inventory number**  
EC / 231-791-2 / water / 7732-18-5 / H2O

**Reference substance information**

**IUPAC name**  
None

**CAS number**  
None

**CAS name**  
None

**Synonyms** + New item

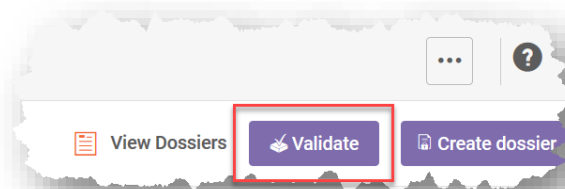
#	Identifier	Identity	Remarks	Action
1	common name	Viz	None	<span>🗑️</span>
2	common name	Vatten	None	<span>🗑️</span>
3	common name	Vettä	None	<span>🗑️</span>

**Mistakes are preventable**

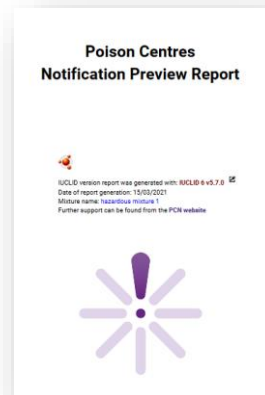


# Tools to help avoid mistakes

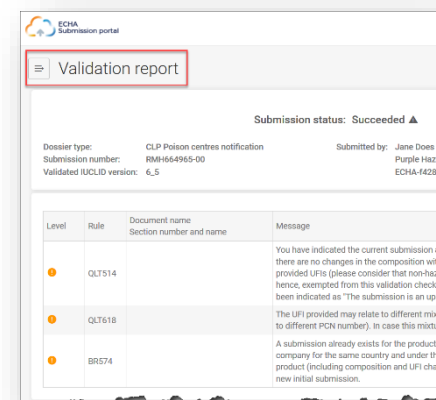
- Run the validation assistant any time



- Check before you submit - use the PCN preview report



- Check the validation report after you submit (Additional checks are run in the Portal)

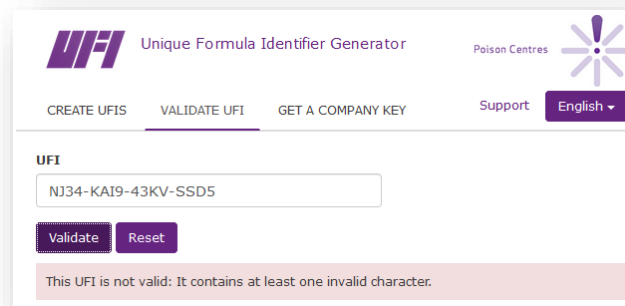


## Double check...

**Correct UFI** – assigned to the correct mixture composition



**UFI validity** - invalid UFI issue if already on the label as it cannot be accepted by the system. UFI generator 'Validate UFI'



UFI Unique Formula Identifier Generator

CREATE UFIS VALIDATE UFI GET A COMPANY KEY Support English

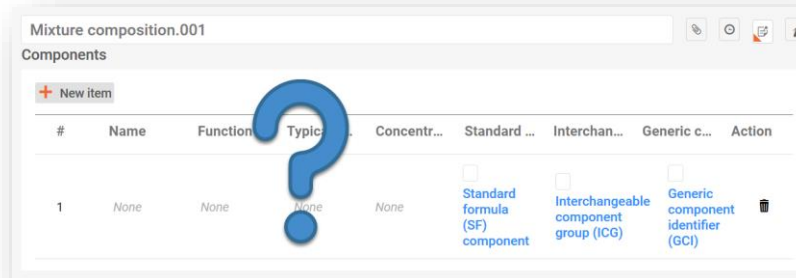
UFI

N134-KA19-43KV-SSD5

Validate Reset

This UFI is not valid: It contains at least one invalid character.

**Components** – concentration, identifiers, specific flags



Mixture composition.001

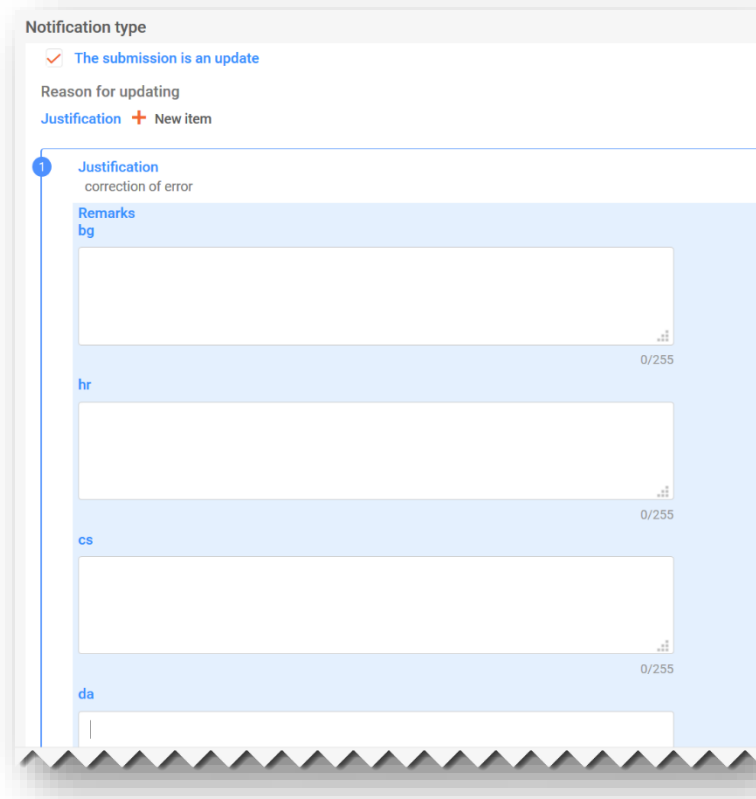
Components

+ New item

#	Name	Function	Type	Concentr...	Standard ...	Interchan...	Generic c...	Action
1	None	None	None	None	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	

# Update for 'Correction of error'

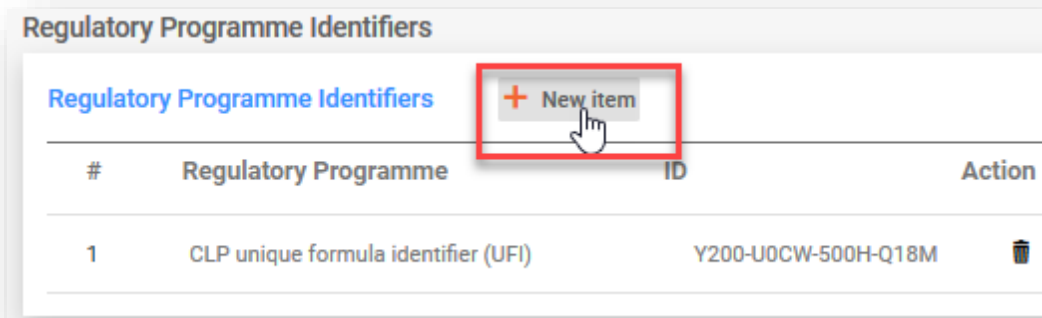
- Solution for when an error in an entry has been made
- Select the update reason '**Correction of error**'
- Important to provide the explanation of the error in the 'Remarks' field
- Include in every relevant language!
- Not possible to use for all errors e.g. change in concentration outside of allowed limits!
- IT solution coming




The screenshot shows a web form for updating a submission. At the top, it says 'Notification type' with a checked box for 'The submission is an update'. Below this, it asks for the 'Reason for updating' and shows 'Justification' selected with a plus sign next to 'New item'. A blue bar indicates the selected reason is 'Justification' with a sub-label 'correction of error'. The form then has a 'Remarks' field for each language: 'bg', 'hr', 'cs', and 'da'. Each field is currently empty and has a '0/255' character count indicator. The bottom of the form has a decorative, jagged border.

## Example - correcting wrong UFI

- Update for 'Correction of error' and add remarks
- In the notification add the correct UFI
  - The incorrect UFI needs to remain

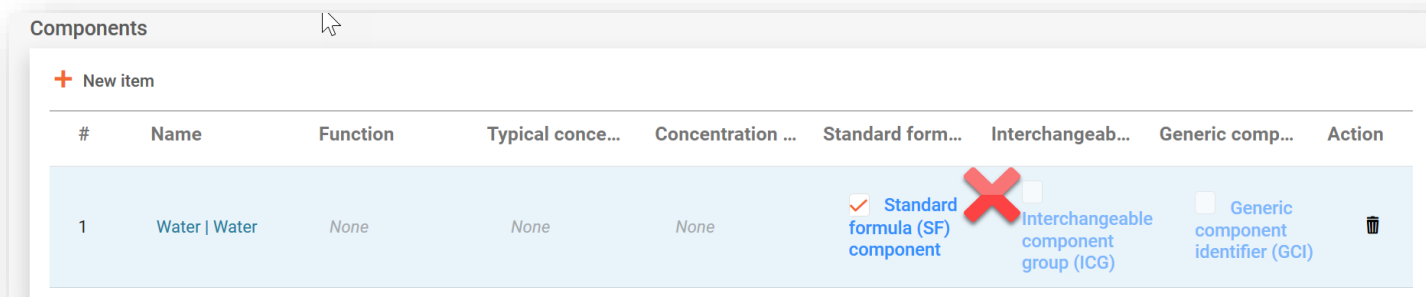


#	Regulatory Programme	ID	Action
1	CLP unique formula identifier (UFI)	Y200-U0CW-500H-Q18M	


**Practice good management with the correct VAT, re-typing**

## Example – incorrect use of standard formulas

- New component identifiers where specific criteria met
- **Standard formulas** used only to identify specific construction products and fuels listed in Annex VIII
- DO NOT select the Standard Formula box if not relevant
- Update for '**Correction of error**'
  - Deselect the tick-box



The screenshot shows a table titled 'Components' with a '+ New item' button. The table has columns for '#', 'Name', 'Function', 'Typical conce...', 'Concentration ...', 'Standard form...', 'Interchangeab...', 'Generic comp...', and 'Action'. A single row is visible for 'Water | Water' with 'None' in the other columns. In the 'Standard form...' column, the checkbox is checked. In the 'Interchangeab...' column, the checkbox is unchecked, but a large red 'X' is drawn over it, indicating that this selection is incorrect. The 'Generic comp...' column also has an unchecked checkbox.

#	Name	Function	Typical conce...	Concentration ...	Standard form...	Interchangeab...	Generic comp...	Action
1	Water   Water	None	None	None	<input checked="" type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	

# Mixture in mixtures – best practice














# Substance, MiMs, reference substances



Main mixture composition is made up of

- Substance components 
- Mixture components (MiM) 
- Dataset of each substance is linked to a reference substance  — 
- Dataset of each MiM consists of substances each linked to a reference substance  —  —   
 — 

# Identify components at the correct level

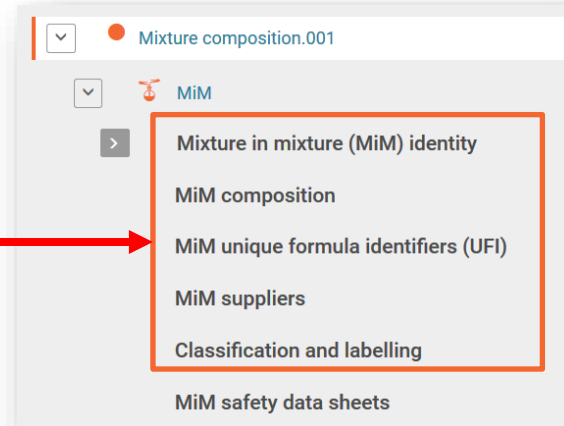
- If you know the full composition of the MiM
  - add all substance components to main mixture composition
- If you don't know the full MiM composition
  - add MiM component to main mixture composition and identify it with its name, and either the UFI/compositional information/supplier details

### 3.2.2. Mixture in mixture

When a mixture is used in the composition of a second mixture placed on the market, the first mixture is referred to as a mixture in mixture ("MIM").

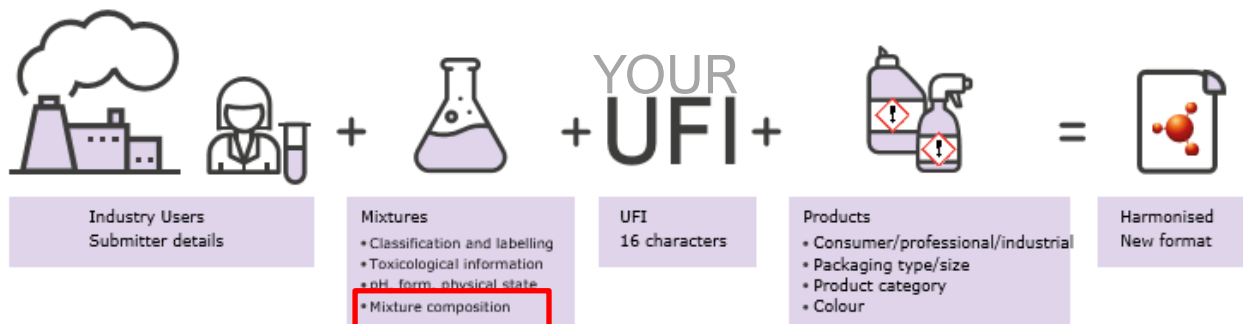
Information on the substances contained in a MIM shall be provided in accordance with the criteria of Section 3.2.1, unless the submitter does not have access to information on the full composition of the MIM. In the latter case,

- if a UFI has been created for the MIM and the appointed body has received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI;
- if a UFI has been created for the MIM, but the appointed body has not received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI and the compositional information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 of the MIM and any other known components, as well as the name, email address and telephone number of the MIM supplier;
- in absence of a UFI, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and the compositional information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 of the MIM and any other known components, as well as the name, email address and telephone number of the MIM supplier.



## Notifying 100% MiM

- Where a company identifies their 'mixture composition' using a UFI that has already been notified by their supplier
- When the notifier does not have access to the compositional information e.g. re-packager
- No procedure for notifying a 'UFI' - full notification according to harmonised format
  - Supplier's UFI indicated in the mixture composition (MiM UFI section)



# Indicating supplier contact details

- When identifying a MiM component ensure you use 'EU supplier' details
- Why? This is to assist Authorities in case of further follow up on composition
- If you are an EU importer of a mixture for further formulation i.e. not placed on the market per se:
  - need to notify the imported mixture (i.e. MiM) plus,
  - your own final product

Legal entity name\*  
MiM Supplier

Legal entity type  
None

Remarks  
None

Other names + New item

#	Flags
---	-------

Address None None

Address 1  
Street name and number

Address 2  
None

Postal code  
12345

Town  
Town

Region / State  
None

**Country**  
Spain

Phone  
+123456789

Fax  
None

Email  
name@domain.com

Web site  
None

# Avoiding mistakes - MiM UFI

## Practice good communication in the supply chain

- Supplier inform customer:
  - if UFI has been notified
  - through which system: ECHA or national system
  - on which markets
- If customer notifies MiM UFI not in the database

-> Warning for customer

Legitimate warning or need to update?

- Customer inform upstream industrial mixture supplier if the 'MiM' will have consumer or professional use
- If the upstream supplier only indicates 'Industrial use'

-> Failure for customer

Supplier update the notification to include other use types

# Conclusions

- Avoid mistakes & don't rush
  - use tools available
- If you need help with an issue
  - contact ECHA for advice
- Remember the importance of the information you provide
  - keep your notification up to date



# Tips for most commonly failed validation rules

March 2021

Webinar PCN – best practices from start to market

Daniele APE

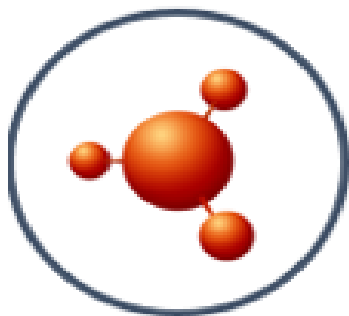
Poison Centres Team

Submission and Processing Unit

European Chemicals Agency



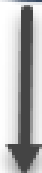
## Validation rules



### **IUCLIDs**

**BR** – **Failure** if information not provided

**QLT** – **Warning** if information not provided



### **Portal**

IMPORT – Wrong format leads to **failure**

**[BR]** **Failure** if information not provided

**[BR/QLT]** **Warning** if information not provided



## Validation rules – Tips (i)

### ***IUCLID validation rules***

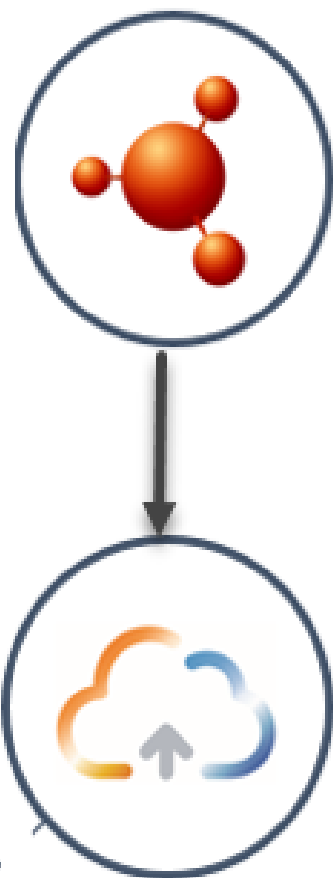
\* Can be checked before sending the notification to ECHA Submission Portal



***ECHA submission portal rules*** (‘contextual rules’)

\* Checked upon submission to Portal

# Field validation



**BR538** Toxicological information must be provided (at least 200 characters) in 'Toxicological information (section 11 of SDS)' field(s) in all relevant languages.

**QLT634** If 'IUPAC name/International chemical name' was provided, then it should be meaningful.

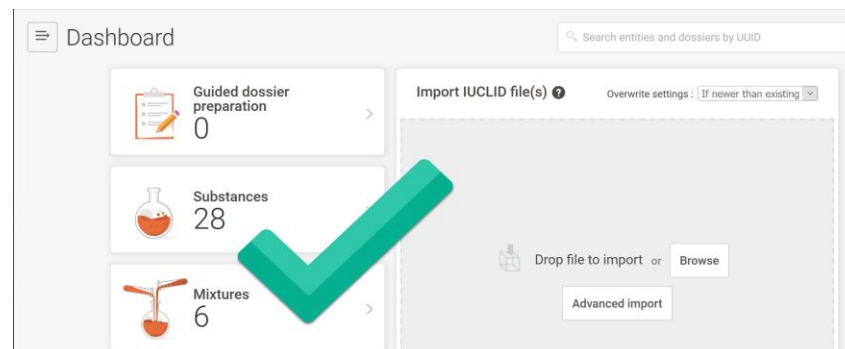
For instance '*not available*' or '*proprietary substance*' are not IUPAC names. If you do not have 'IUPAC name/International chemical name' for the substance, then leave the field empty.

**[BR564]** The exactly same dossier cannot be submitted again.




**[QLT516]** The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component) in the relevant market placement countries if the MiM was not 'identified with substances.' ('Identified with substances' means that MiM did include Supplier information and if it was hazardous component(s) were provided.).

## Validation rules – tips (ii)

- Use the latest version of IUCLID.
  - IUCLID Cloud automatically updated to latest version
  - IUCLID Standalone latest version released October 2020 (IUCLID6.5)
  - 'Classical' IUCLID interface does not have language specific fields



## Validation rules – tips (iii)

 <b>RMH377203-20</b> <b>Failed submission</b>	
PCN number	cc3fbbf3-d5a6-4ae9-a0a6-3905bcdf9c4a
Names	Product no name, TEST 3.22.0,
 <b>RMH420107-30</b> <b>Successful submission, but contains warnings</b>	
PCN number	15855ded-d56e-4365-8473-86ded6253fa9
Names	fgjhsgfrj, Trade Name 2, Test BR620 bis,
 <b>RMH103129-30</b> <b>Successful submission</b>	
PCN number	4a7a2736-136e-4afd-b1b0-d93359041ccc
Names	fgjhsgfrj, Test BR620 bis,

## Common issues (1#) *Inexplicable Update failures*

I fixed the errors and submitted an **update**.

Why now the submission **failed again**...?

The PCN number was the same...

Reason reported by the Portal:

**[BR568]**

An existing 'PCN number' should be used in updates notified by the same legal entity.



## Common issues (1#) - *Inexplicable Update failures*

What happened is that...

The first notification was rejected...

...no valid PCN is present in the Portal...

...no link to the updated notification.

**That is, send a new 'Initial notification' if you do not already have a valid initial notification for your mixture.**




Notification type

- Initial notification
- New notification after a significant change of composition
- The submission is an update

## Common issues (2#) *Missing dossier header*

I submitted my dossier and the Portal showed this error message:

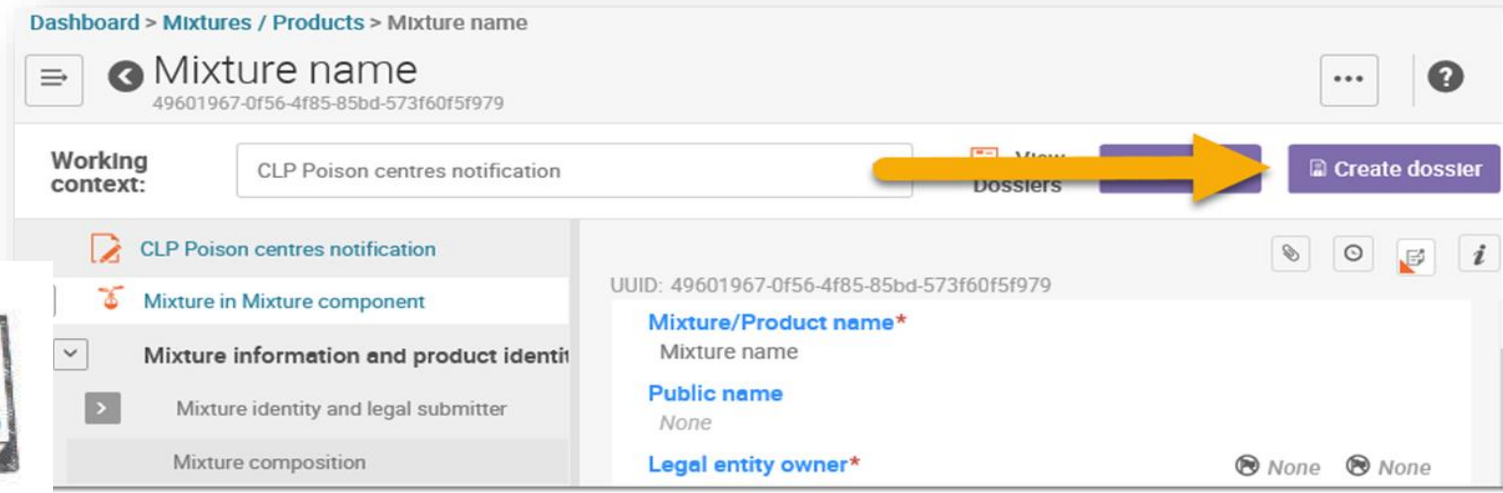
Level	Rule	Document name Section number and name	Message
	IMPORT		Missing dossier header

What is a '**Dossier header**' and how do I include it in my notification?



The 'Dossier header' is the dossier "main page"  
It contains necessary **administrative information** such as  
"PCN number" and submission type (e.g. Initial or update)

It can be added by selecting '**Create dossier**' from the top  
right corner of the finished mixture data set.



Dashboard > Mixtures / Products > Mixture name

Mixture name  
49601967-0f56-4f85-85bd-573f60f5f979

Working context: CLP Poison centres notification

View Dossiers

Create dossier

CLP Poison centres notification

Mixture in Mixture component

Mixture information and product identification

Mixture identity and legal submitter

Mixture composition

UUID: 49601967-0f56-4f85-85bd-573f60f5f979

Mixture/Product name\*  
Mixture name

Public name  
None

Legal entity owner\*  
None None





## Common issues (3#) *Warnings and submission*

It seems I made a mistake with  
**concentration value's decimals:**

**QLT505**

If the concentration value is 0.1-1 %, the recommended number of decimals is two.

If I don't edit that concentration value, will my dossier be rejected?



**Warnings (linked to *quality rules*) do not prevent a successful submissions**

Notifications that are '*Successful with warnings*' will be dispatched to the relevant appointed bodies.

However, consider the need for reviewing and possibly correct the information



## **Common issues (4#)** ***Inexplicable failure...***

The Validation Assistant shows **no errors** in my dossier.

However, when I submit it through the Portal, it was rejected.

**Is my Validation Assistant not working correctly?**



IUCLID Validation checks the information in the **individual dossier**

Following submission to Portal, information is also checked against **previously submitted information** from the same notifier and from other legal entities.

- IUCLID Standalone users: check that you have the latest IUCLID version!
- IUCLID Cloud users: the Validation Assistant automatically updated to the latest version.



## Common issues (5#) *Missing tox info*

An error message tells me that there are **no toxicological information...** but I did provide it!

Toxicological information must be provided (at least 200 characters) in 'Toxicological information (section 11 of SDS)' field(s) in all relevant languages.

What could be wrong?



## Common issues (5#) *Missing tox info*

'Toxicological information' must be provided **for each relevant language.**

Languages are indicated in the Dossier header and depend on market area selected.

**Each** language-specific field must be filled.



# Validation assistant report

Submission checks 1 Quality checks 0

Business rules 1 Completeness check rules 0

**Mixture safety data sheets and toxicological information 001**  
Mixture safety data sheets and toxicological information

Mixture information is incomplete. You must provide information (mixtures). This section must include information on toxicological information. At least 200 characters are expected to be provided. Note that attached documents must contain information on toxicological information (section 11 of SDS).

Information required for section 11 of the SDS is specified in Annex 17.

**Common issues (5#)**

### Information on mixtures

Name or trade name of mixture / product  
None

Safety data sheets of mixture / product

+ New item

#	Safety data sheet	Country	Language	Remarks	Action
---	-------------------	---------	----------	---------	--------

Toxicological information (section 11 of SDS)  
en

Edit Format Table

**B** *I* U ~~S~~ x<sup>2</sup> x<sub>2</sub> [List Icons] [Table Icon]

Paragraph [Color A] [Color A] [List Icons] [Table Icon]

de

Edit Format Table

**B** *I* U ~~S~~ x<sup>2</sup> x<sub>2</sub> [List Icons] [Table Icon]

Paragraph [Color A] [Color A] [List Icons] [Table Icon]

# Fixing errors – The validation assistant report

✖ **Mixture composition.001**

Mixture composition Components (2)

Mixture information is inconsistent. Ensure that for each component of you B.

Business rule (BR518)

^ Hide

✖ Mixture composition Components, (2)

Mixture information is inconsistent. Ensure that for each component of your Mixture composition that is classified as hazardous component of major concern, you have provided the concentration ranges in accordance with Annex VIII of the CLP Regulation: Table 1 of Part B.

## Components

+ New item

#	Name	Function	Typica...	Conce...	Standa...	Interch...	Generi...	Action
1	Calcium sulphate   Calcium sulfate	None	None	> 30 < 35 % (w/w)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	
2	Calcium dihydroxide   Calcium dihydroxide	None	None	> 20 < 35 % (w/w)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	
3	Water   Water   Water   7732-18-5	None	None	> 50 < 60 % (w/w)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	



## Coming up in April

Rule checking justification if pH not available changed from **QLT** (warning) to **BR** (failure)

Set of rules checking the selection of required language(s)

Allow use of same Generic Component Identifier multiple times

**N.B.:** Full list of validation rules available on the ECHA Poison Centre website at <https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

# Guidelines for using the Submission Portal

March 2021

Webinar PCN – best practices from  
start to market

Claudia RIMONDO

Poison Centres Team


Submission and Processing Unit

European Chemicals Agency



# Pick the right submission environment


## Submission services



ECHA  
Submission portal

The ECHA Submission Portal is an online tool for submitting SCIP, Poison Centres notifications and EFSA applications.

[Access service](#)



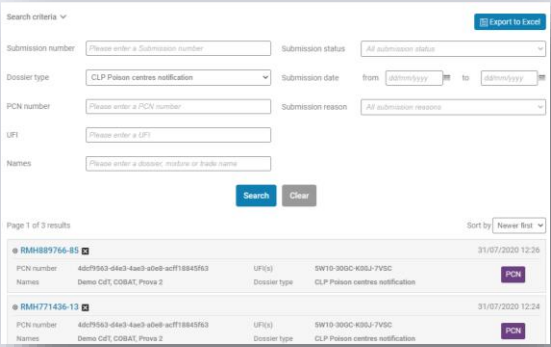
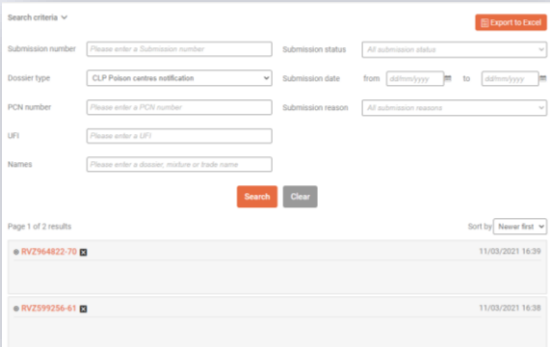


ECHA  
Submission portal  
Trial

Trial version to get familiar with the features. All submissions made in trial will not be treated as real data.

[Access service](#)

- Commonalities
  - Same functionalities (upload, submit, search, submission report, validation report)
  - Same validation rules

Item	ECHA Submission portal <b>PRODUCTION</b>	ECHA Submission portal <b>TRIAL</b>
Outcome	Dossiers <b>dispatched</b> to Appointed Bodies	Dossiers <b>NOT dispatched</b> to Appointed Bodies
URL	<a href="https://ecs.echa.europa.eu/cloud/submissions/home">https://ecs.echa.europa.eu/cloud/submissions/home</a>	<a href="https://test-env.ecs.echa.europa.eu/cloud/submissions/home">https://test-env.ecs.echa.europa.eu/cloud/submissions/home</a>
Logo		
Layout		
Disclaimer	None	<p><i>This is the ECHA Submission portal Trial version. You may use this ECHA Submission portal Trial version to get familiar with the functionalities. However, all submissions made in Trial will not be treated as real data to fulfil legal obligations. To meet your regulatory obligations, please use the ECHA Submission portal <u>Production</u> version.</i></p>

## Outcome of a submission

- **Submission number:** a unique identifier automatically assigned upon submission
- **Submission report:** it details the status and the context of the submission
- ECHA Submission portal does not send the user any notification after a submission has been made

# When is my notification received?

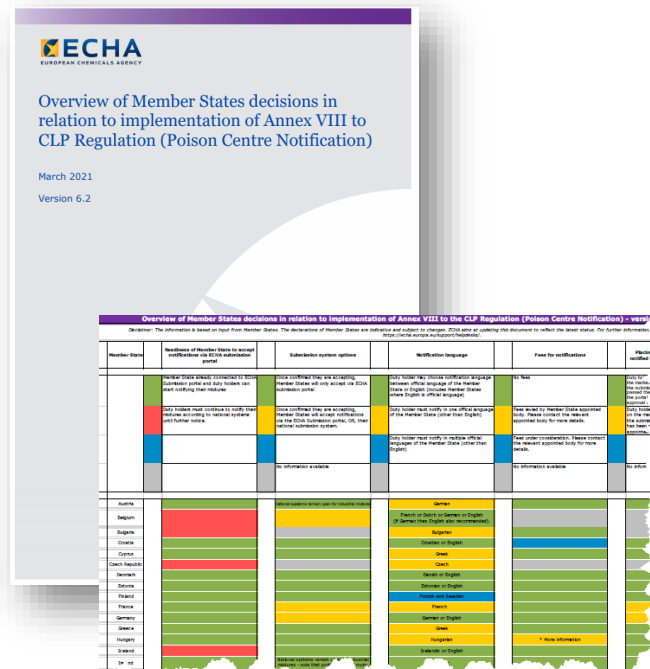
- Submission report shows “Submission events”
- Event “*Dossier received by [country code]*” is generated when dossier
  - has reached the Appointed Body (eDelivery)
  - is available for access to Appointed Body (PCN database)
- Receiving channels are different (eDelivery or PCN database)
  - Submission event may be generated in different moments
  - If Submission event does not appear for a longer period, please contact the [ECHA Helpdesk](#) for further investigation

## Submission events

19/02/2021 13:28	Dossier submitted
19/02/2021 13:28	Dossier passed validation checks
19/02/2021 13:28	Dossier received by CY
19/02/2021 13:28	Dossier received by AT
19/02/2021 13:28	Dossier received by GR
19/02/2021 13:28	Dossier received by SE
19/02/2021 13:28	Dossier received by ES
19/02/2021 13:28	Dossier received by FR
19/02/2021 13:28	Dossier received by HR
19/02/2021 13:28	Dossier received by LT
19/02/2021 13:28	Dossier received by NO
19/02/2021 13:28	Dossier received by EE
19/02/2021 13:28	Dossier received by IE
19/02/2021 13:28	Dossier received by IS
19/02/2021 13:28	Dossier received by IT
19/02/2021 13:28	Dossier received by DE
19/02/2021 13:28	Dossier received by FI
19/02/2021 13:28	Dossier received by HU
19/02/2021 13:28	Dossier received by SI
19/02/2021 13:28	Dossier received by PL

# Dossier received $\neq$ Dossiers accepted

- “Dossier received by [country code]”  $\neq$  Notification accepted
- $\neq$  You can place the product on the market
- Check the [Overview of MS decisions in relation to implementation of Annex VIII to CLP](#) to know when the Appointed Body considers your notification “accepted”
  1. Check the colour of the cell (e.g. green cell = accepting via portal)
  2. Check acceptance criteria for accepted



**Overview of Member States decisions in relation to implementation of Annex VIII to CLP Regulation (Poison Centre Notification) - v06.2**

Decision: The information is based on input from Member States. The decisions of Member States are indicative and subject to change. ECHA does not conduct the document to reflect the latest status. For further information, please contact [echa.ecs@ec.europa.eu](mailto:echa.ecs@ec.europa.eu)

March 2021  
Version 6.2

Member State	Requirements of Member States to accept notification via CLP notification portal	Submission system options	Notification language	Fees for notification	Funding source
Belgium	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State or English (except Member States where English is other language)	Not applicable	Not applicable
Bulgaria	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Denmark	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
France	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Germany	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Italy	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Netherlands	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Poland	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Portugal	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Spain	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Sweden	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
United Kingdom	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable
Other	Member States should be contacted by the business owner and only notify via portal pending further decision	Member States will only accept via CLP notification portal	Member States will accept the language of the Member State (other than English)	Not applicable	Not applicable

## What to do with “Pending” dossiers?

- “**Pending**” status means that the submission has not been processed yet
- If the “**Pending**” status is displayed for a longer period, **do not resubmit**
  - Try to refresh the submission report page
  - If the status does not change, please contact the [ECHA Helpdesk](#) for further investigation



## What if I submitted wrong information?

- More recurrent reasons:
  - Wrong UFI notified
  - Test dossier submitted in production environment
- Currently, dossiers submitted via the ECHA Submission portal cannot be deleted
  - Industry to inform the relevant Appointed Bodies about the wrong submission
- October 2021: technical solution to indicate that a submitted dossier is “annulled”
  - Dossier remains in the portal but it flagged as “annulled”, both in the portal and to Appointed Bodies
  - Submitted data treated as they were never submitted
  - More details on the solution close to the October release

# 2021 Main scope and schedule

## April 2021

- Multilingual “other” and “remarks” fields for picklist
- Guided Dossier discontinued
- Dossiers size increased in portal
- Quota limit in Cloud services

## October 2021

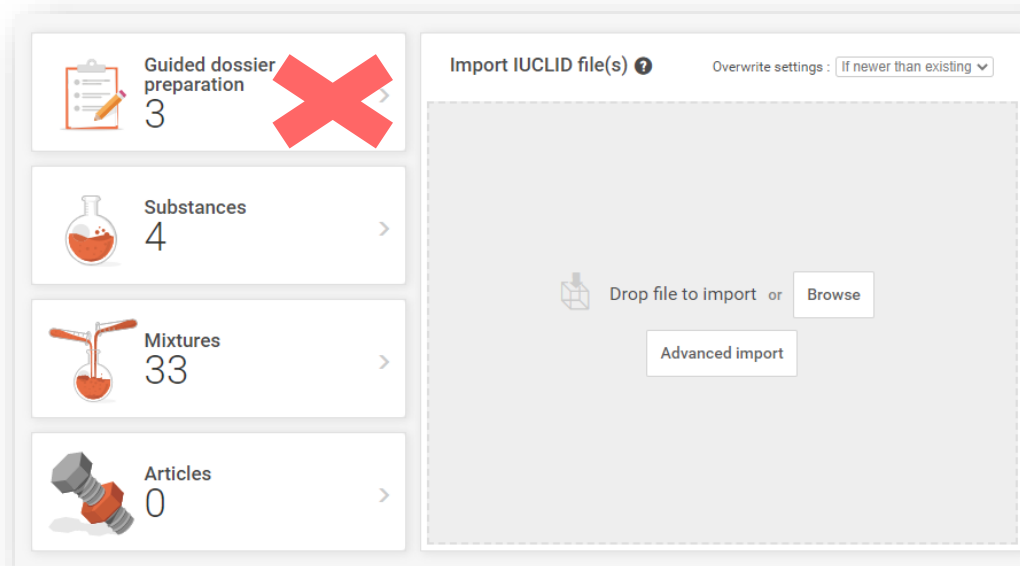
- PCN-IUCLID format changes
  - Group submission
  - Cease product from market
- ‘Annul’ submission



Follow our LinkedIn community for full updates on all improvements  
<https://www.linkedin.com/groups/12364138/>

## Guided dossier preparation *discontinued*

- Widget removed April release
- Data remains available in dataset view (substances and mixtures)
- Dossier header available in mixtures dataset



## Size of submitted files

- In ECHA Submission portal, currently it is possible to submit files:
  - $\leq 100$  MB
  - $< 1\ 200$  IUCLID documents
    - if files  $> 1\ 200$  documents, it remains in “pending status”
- April release:
  - Increase file size to 1 GB
  - Allow submission of dossier with  $>1\ 200$  IUCLID documents

## Changes in IUCLID Cloud capacity

- Current capacity 1 GB
- Feedback from users: need more space
  - Message inviting user to clean their instance
  - No limitations in terms of functionalities
- 26th March 2021:
  - Capacity increased to 5 GB (standard service)

## Engagement with S2S users

- In 2021, aim to create an S2S users community to:
  - Provide technical support
  - Communicate technical updates, downtime, information of common interest, etc.
  - Announce technical informative sessions
  - Publish FAQ and/or Q&A
  - Collect feedback
  - Enhance information exchange among users
  - News item and LinkedIn group announcement

# Closing remarks

March 2021

Webinar PCN – best practices from  
start to market

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European Chemicals Agency



# Check support material first

## The answer is probably there!

**Guidance** (v.4) available - translations on way

<https://echa.europa.eu/guidance-documents/guidance-on-clp>

**PCN Practical Guide**

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

**e-Learning page for video tutorials – try the auto translate!**

<https://poisoncentres.echa.europa.eu/training-material>



# Help is always available

- **If you have checked the support & still don't know, ask for help:**

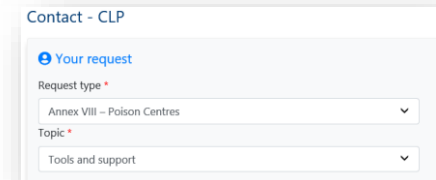
**National Helpdesks** first point of contact  
(regulatory advice)

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



**Contact ECHA**

[https://comments.echa.europa.eu/comments/cms/Contact\\_CLP.aspx](https://comments.echa.europa.eu/comments/cms/Contact_CLP.aspx)



**LinkedIn community** (over 1,700 members)

<https://www.linkedin.com/groups/12364138/>



## Take home messages

- Check important information before submitting
- Keep your information up to date
- Be informed of common validation pitfalls
- Don't ignore 'warnings' they help to improve the quality
- Know how the Portal works and how to work successfully in it

# Thank you!

poisoncentres@echa.europa.eu

- Webinar open until **13:00 Helsinki time** to answer questions
- If your question is not answered by the end of the webinar, send it via our contact form: [echa.europa.eu/contact](https://echa.europa.eu/contact)