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 commononly failed validation rules**
Daniele Ape

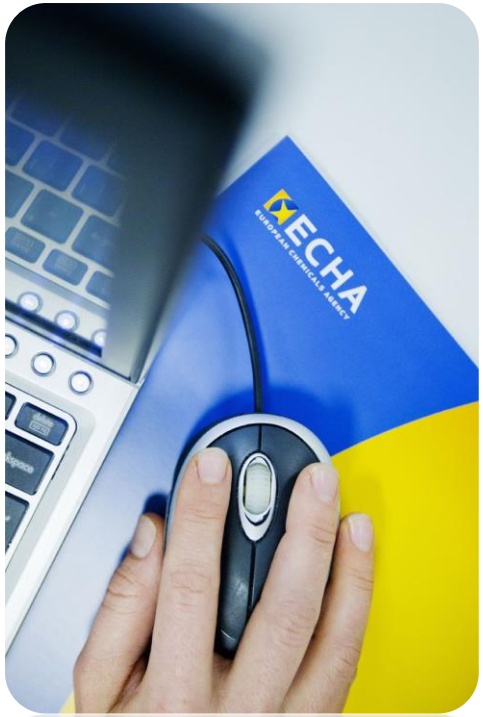
11:45 **Guidelines for using the Portal**
Claudia Rimondo

12:05 **Concluding remarks**
Heidi Rasikari

12:10 - 13.00 Webinar remains open for questions

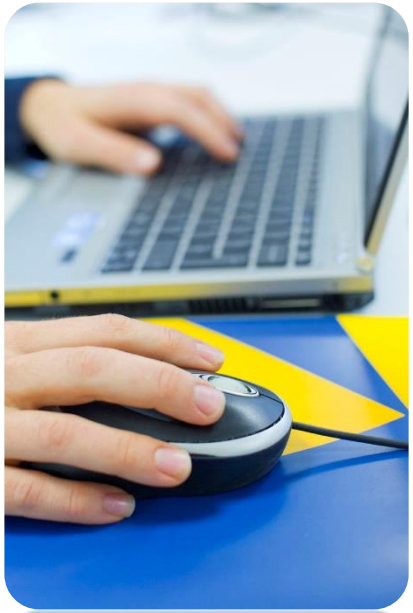
What you can expect from today

- **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



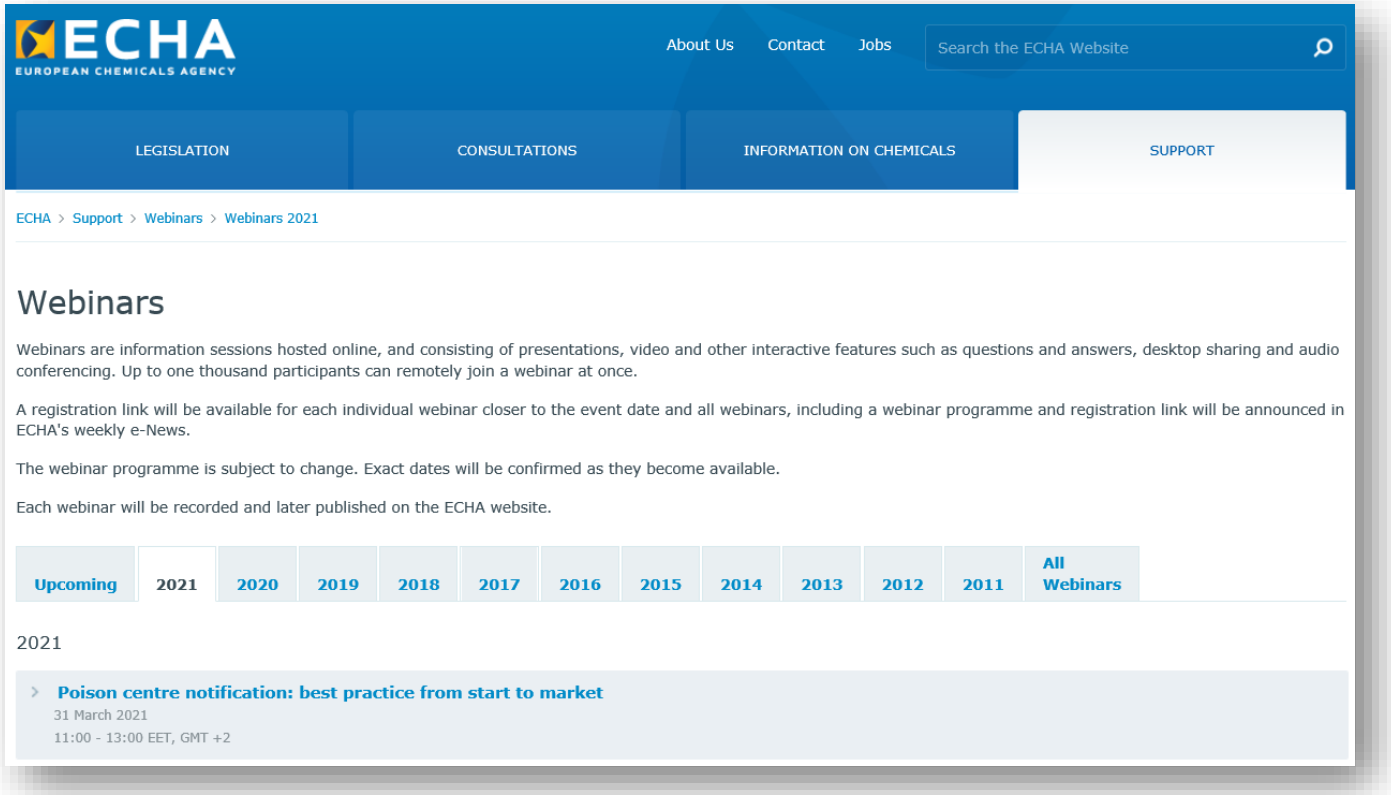
Questions

- Join Q&A at: slido.com
  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



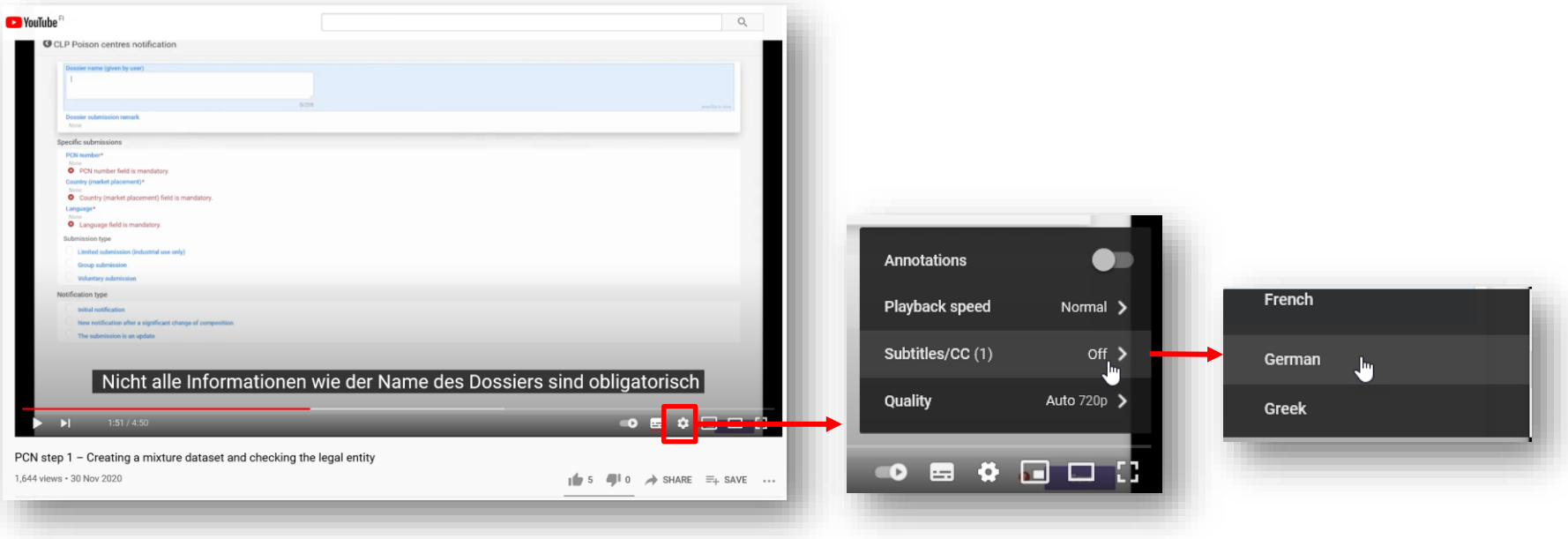
Material available

Video recording, presentations and Q&A:
echa.europa.eu/support/training-material/webinars



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*



* Translation not officially endorsed by ECHA

Best practices for dossier preparation

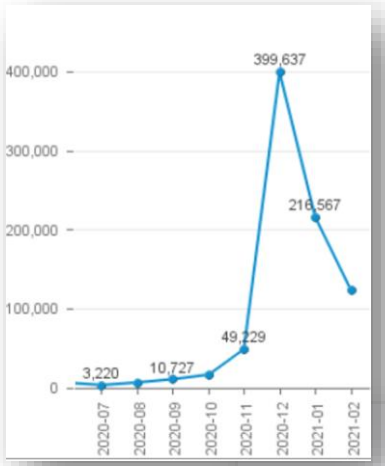
March 2021

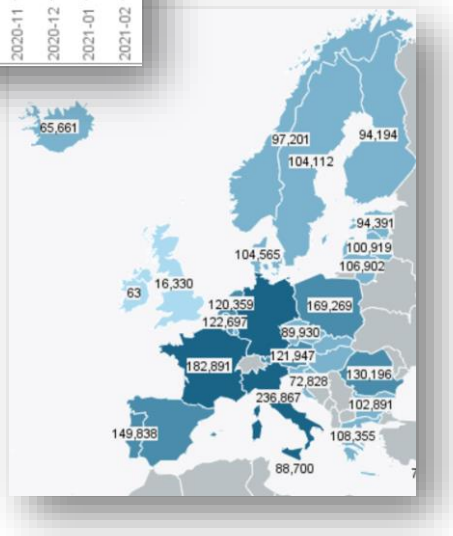
Webinar PCN – best practices from start to market

Heidi RASIKARI
Poison Centres Team
Submission and Processing Unit
European Chemicals Agency

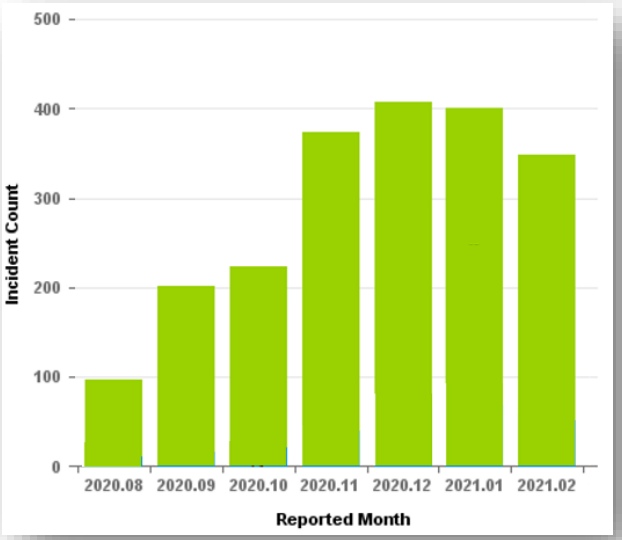
First compliance date has passed

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





Our support efforts

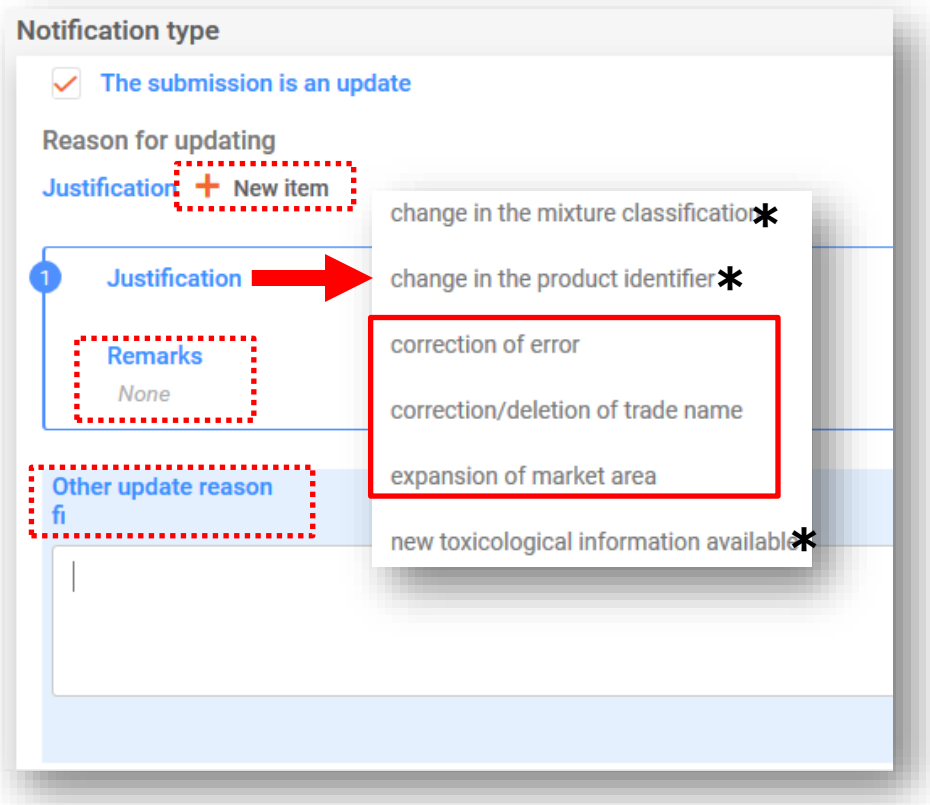


- Helpdesk support and LinkedIn support channels recieved many 100s of questions
- Re-occuring concerns and mistakes
- These incidents form the basis of this presentation where:
  - Updates should be considered
  - Best practice should be employed
  - Mistakes can be avoided

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.**

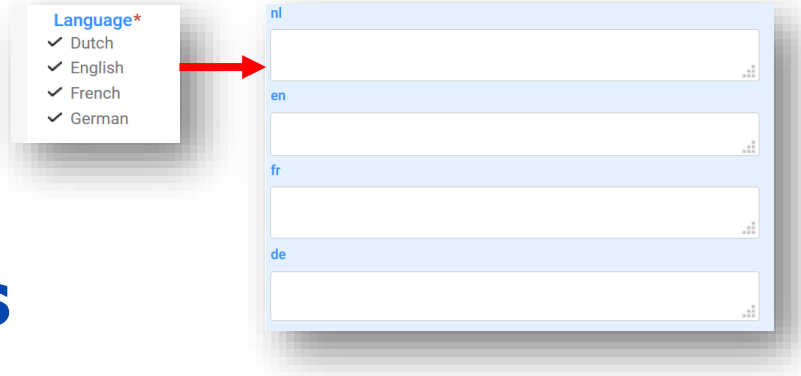
Know your updates!



- **Correction of error:** When you entered invalid information e.g. wrong phone number
- **Correction/deletion of trade name:** When you mispelled or entered wrong trade name
- **Expansion of market area:** Will always recieve 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!

* Listed in Annex VIII Part B, section 4.1

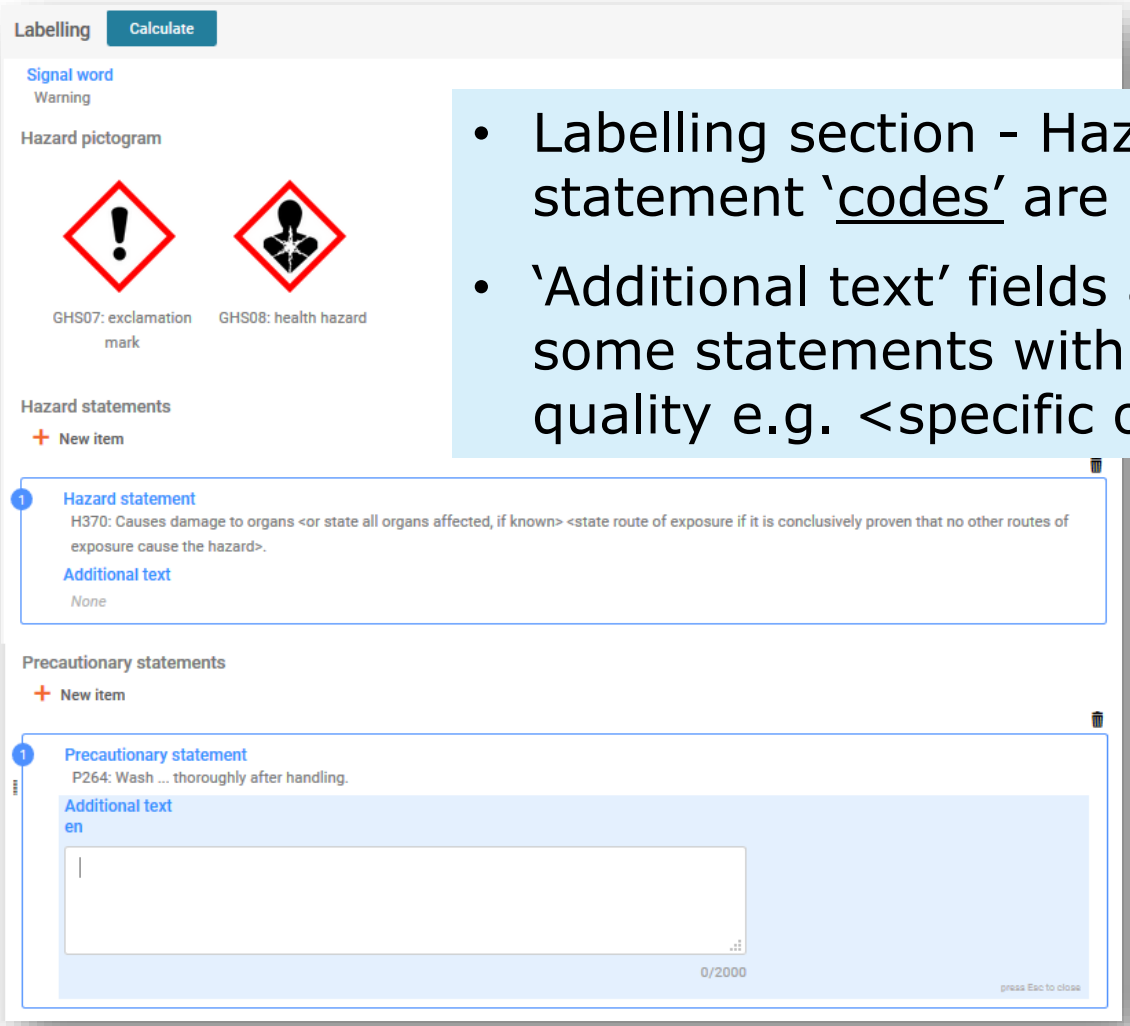
Enhancing the quality of notifications- Free text considerations



Language requirements

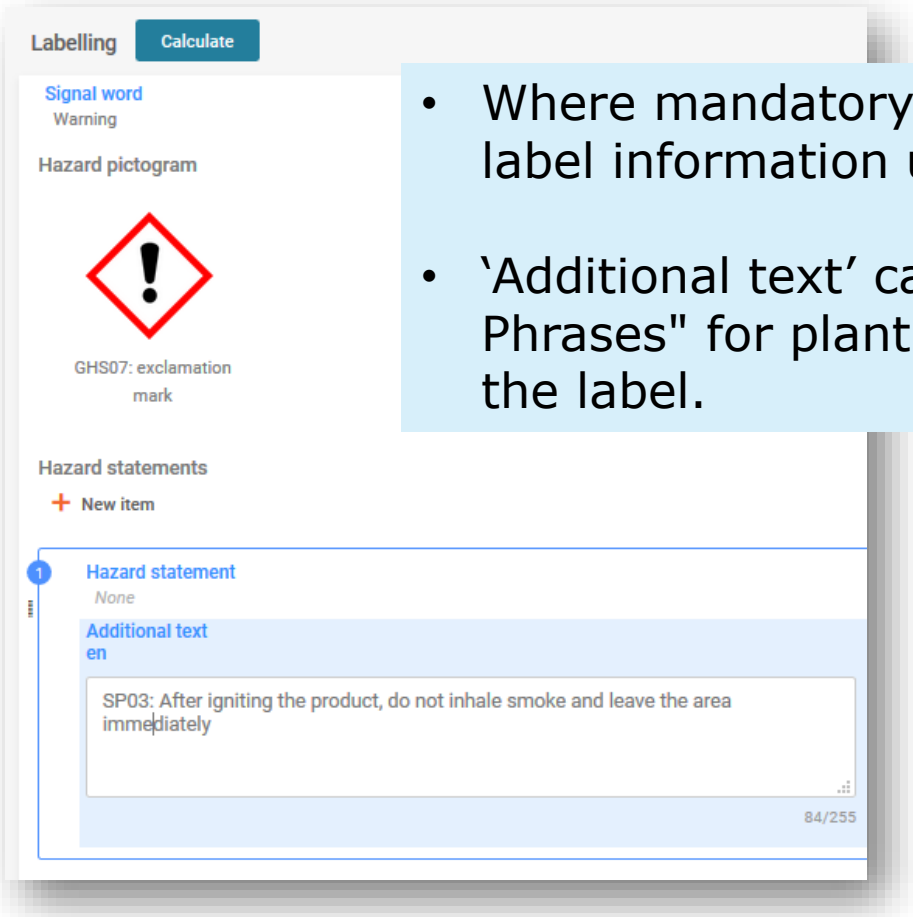
- Free text fields generated for languages indicated in the dossier header
- Currently validation only checks '*Toxicological information*' free text section for each language specified in the header
- Other free text fields not checked
  - '*Additional text*'
  - '*Remarks*'
- Don't skip free text if 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 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>.

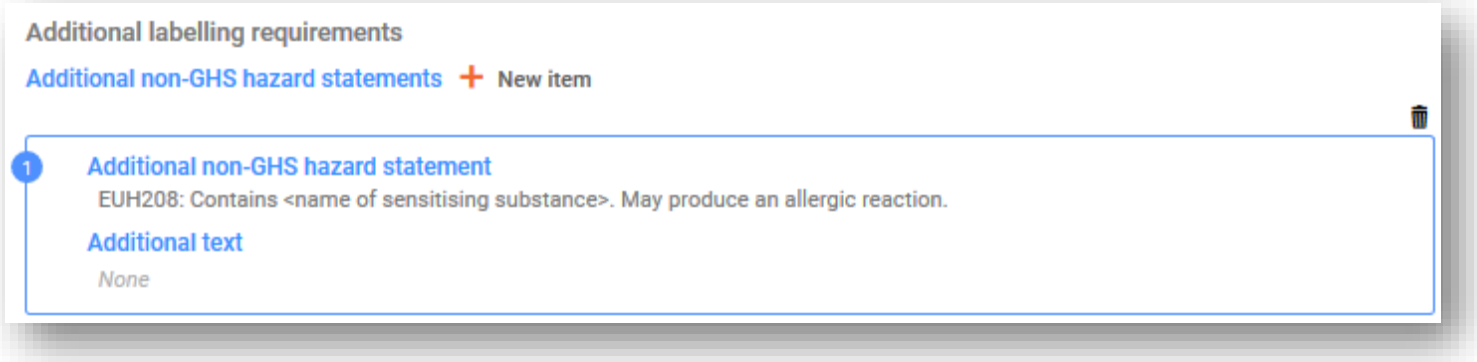
Example 2 additional text as a work-around



- 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

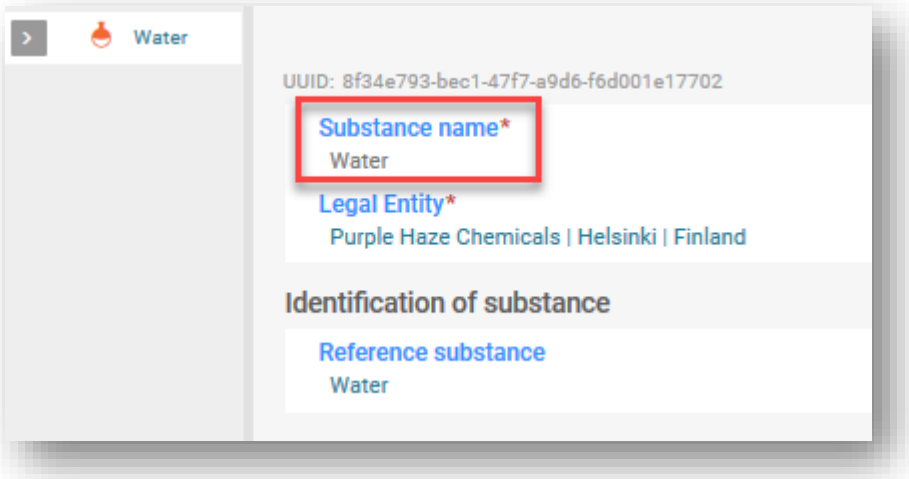
- 'Additional labelling' section available to indicate Hazard statements applied under different legislations
- Additional text used to complete statements for obligatory supplemental label information (e.g. EUH208 phrase naming the sensitising substance)

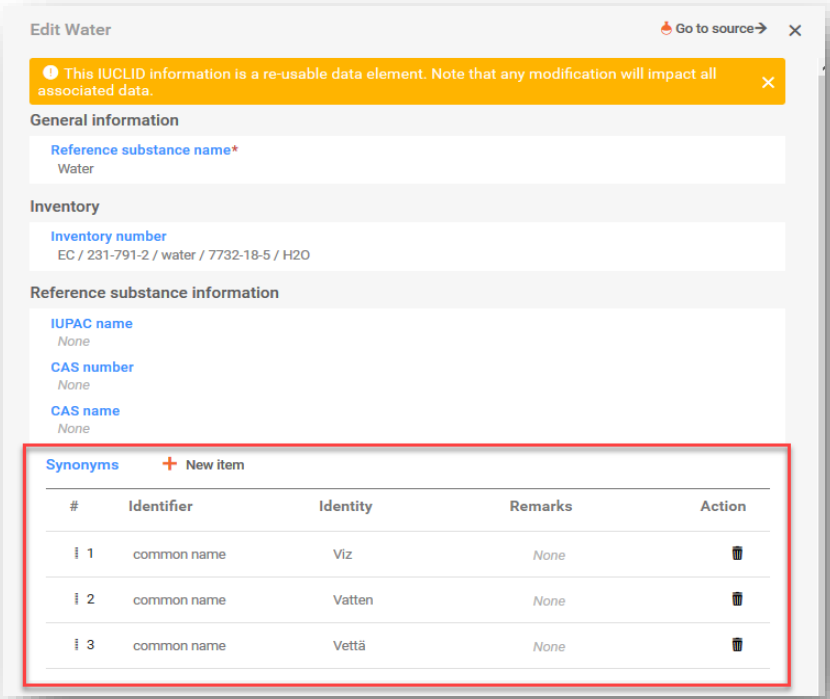


Example 4 Substance and reference substance names

- 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'.

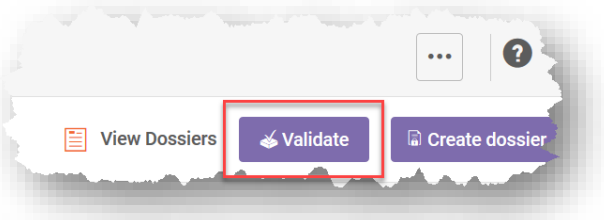




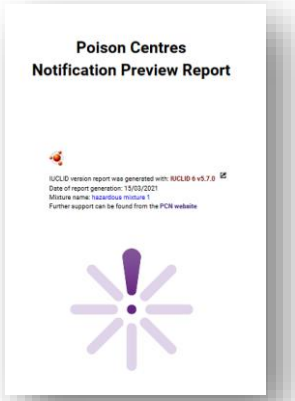
Mistakes are preventable

Tools to help avoid mistakes

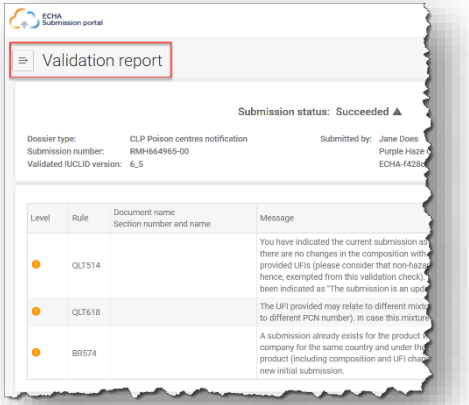
- Run the validation assistant any time



- Check before you submit - use the PCN preview report



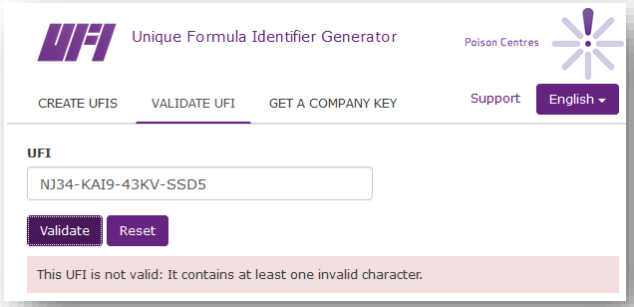
- Check the validation report after you submit (Additional checks are run in the Portal)



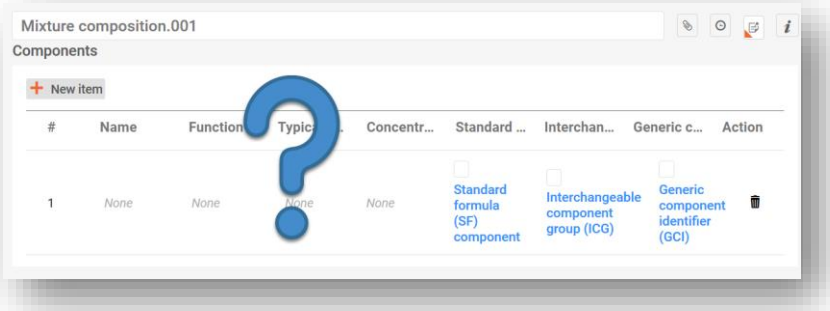
Double check…

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'

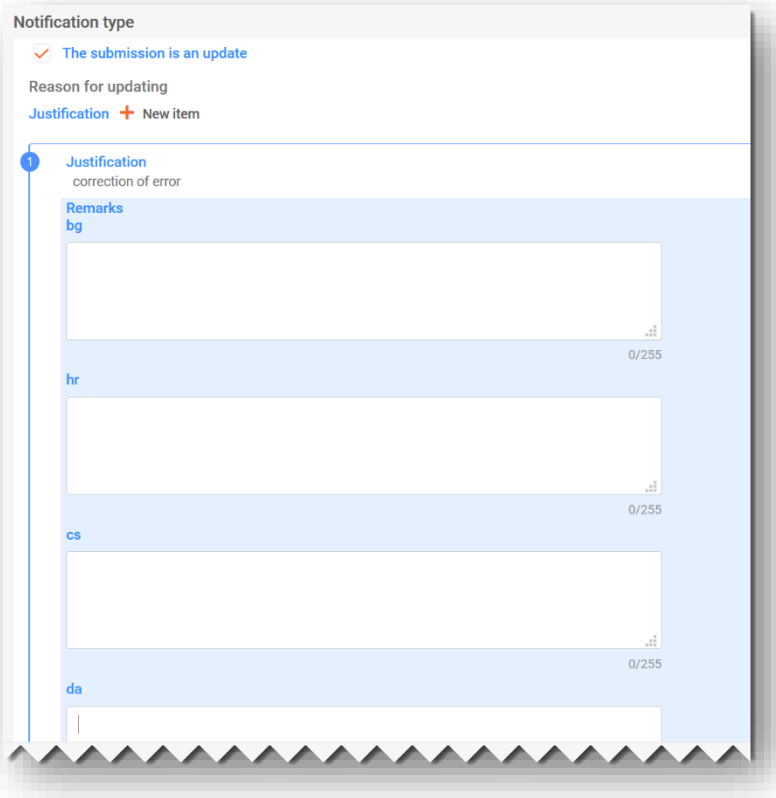


Components – concentration, identifiers, specific flags



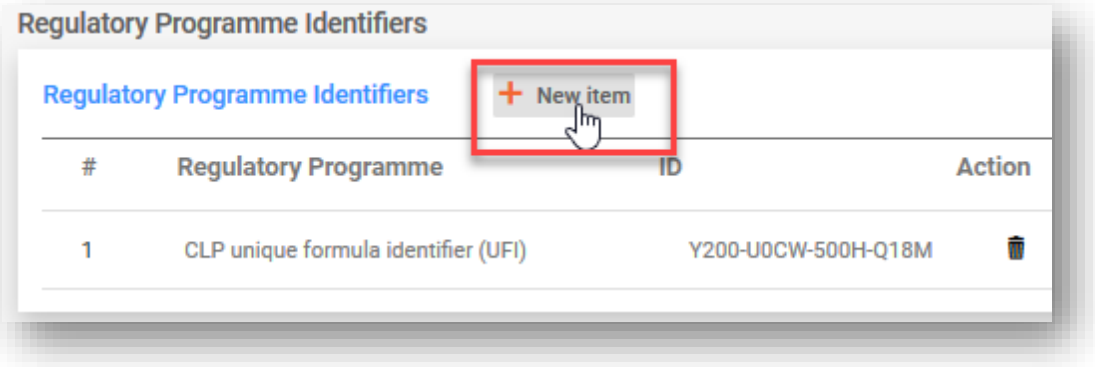
Update for ‘Correction of error’

- 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 <u>every</u> relevant language!
- Not possible to use for all errors e.g. change in concentration outside of allowed limits!
- IT solution coming



Example - correcting wrong UFI

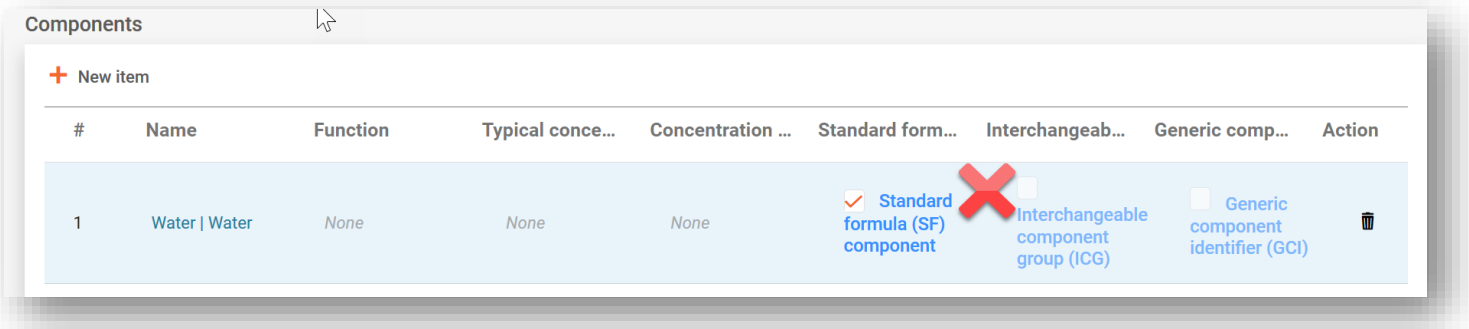
- Update for ’Correction of error’ and add remarks
- In the notification add the correct UFI
  - The incorrect UFI needs to remain



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



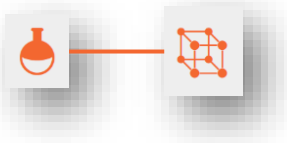
Mixture in mixtures – best practice

Substance, MiMs, reference substances

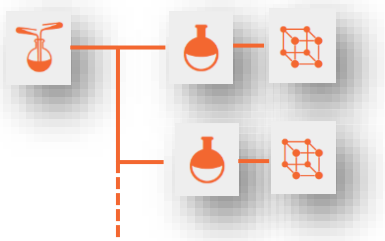
Main mixture composition is made up of

- 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



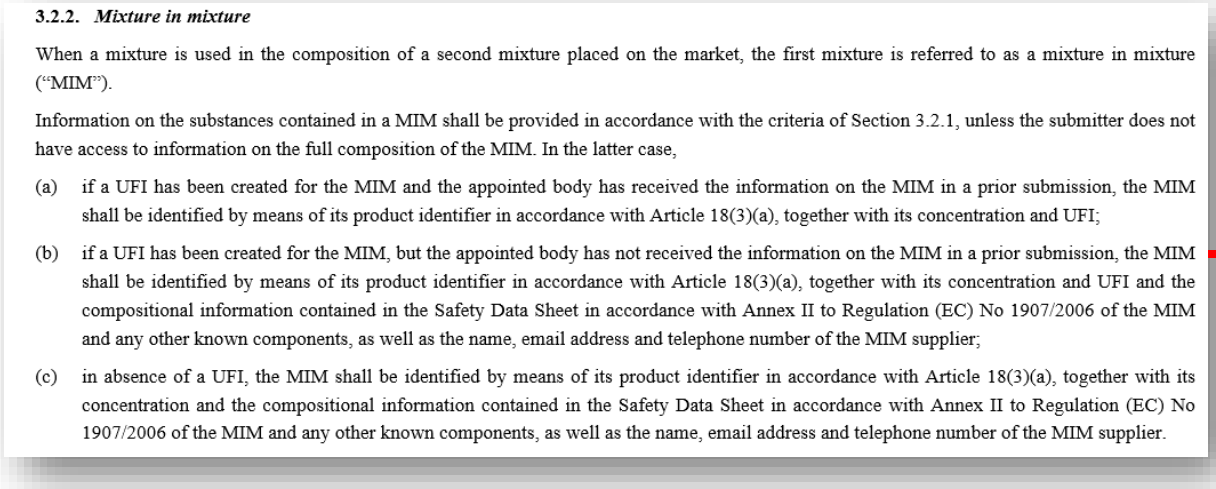
Identify components at the correct level

- 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 it's name, and either the UFI/compositional information/supplier details



3.2.2. *Mixture in mixture*

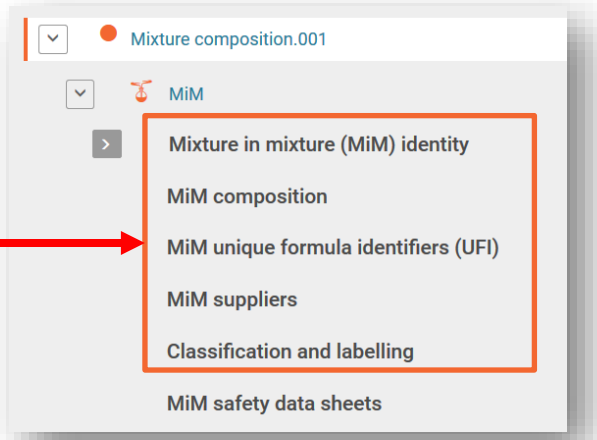
When a mixture is used in the composition of a second mixture placed on the market, the first mixture is referred to as a mixture in mixture ("MIM").

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,

(a) 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;

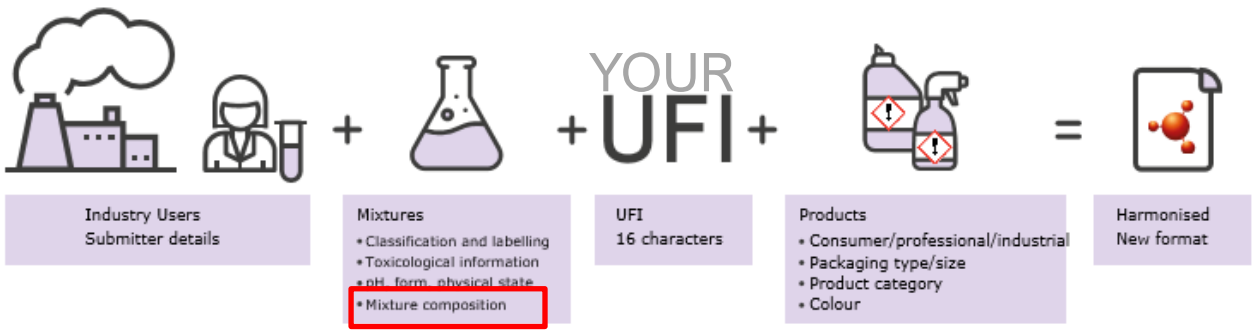
(b) if a UFI has been created for the MIM, but the appointed body has not received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI and the compositional information 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;

(c) 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.



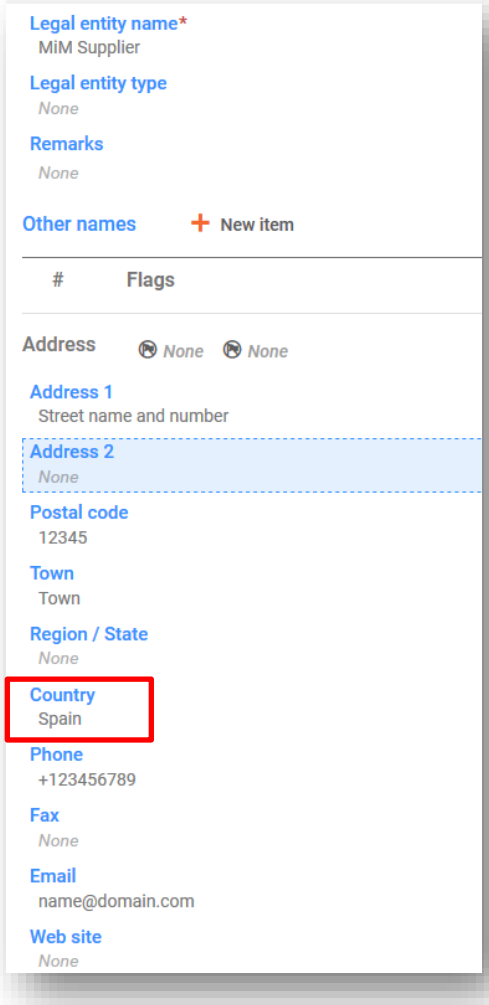
Notifying 100% MiM

- 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



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

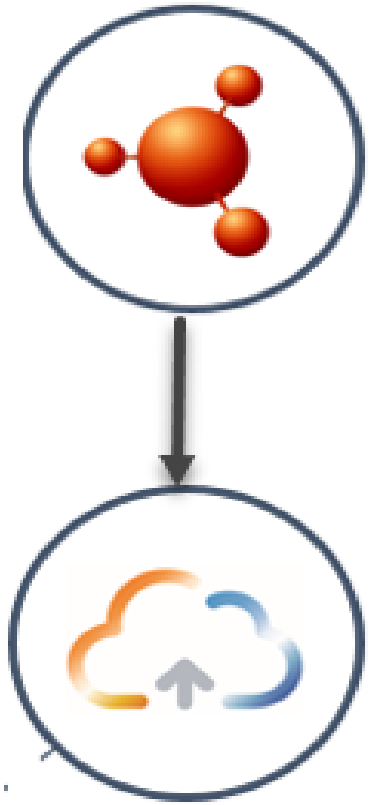
Tips for most commononly failed validation rules

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)

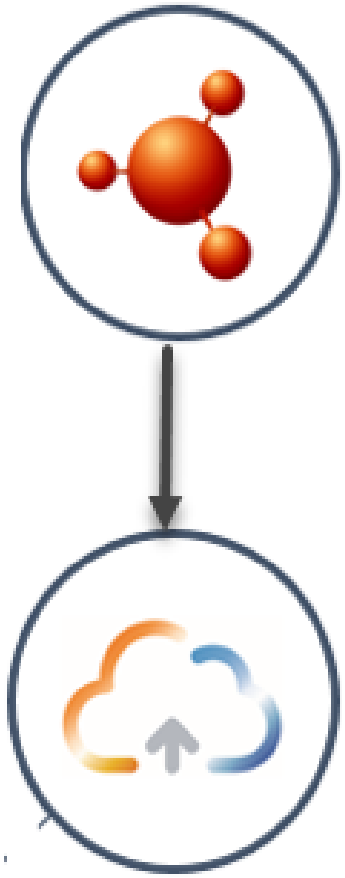
IUCLID validation rules

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

ECHA submission portal rules ('contextual rules')

* Checked upon submission to Portal

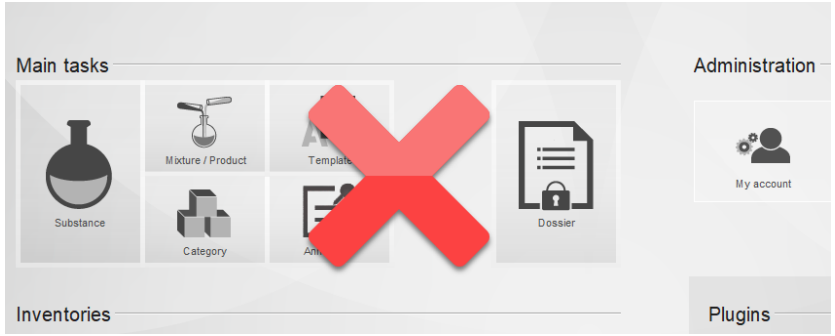
Field validation

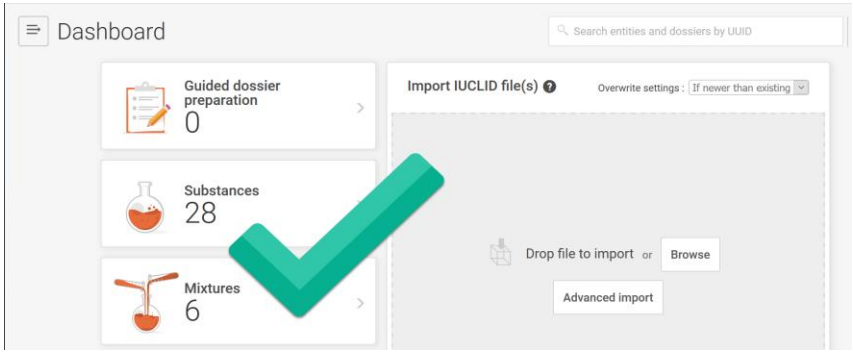


BR538	Toxicological information must be provided (at least 200 characters) in 'Toxicological information (section 11 of SDS)' field(s) in all relevant languages.
QLT634	If 'IUPAC name/International chemical name' was provided, then it should be meaningful. For instance '*not available*' or '*proprietary 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.).

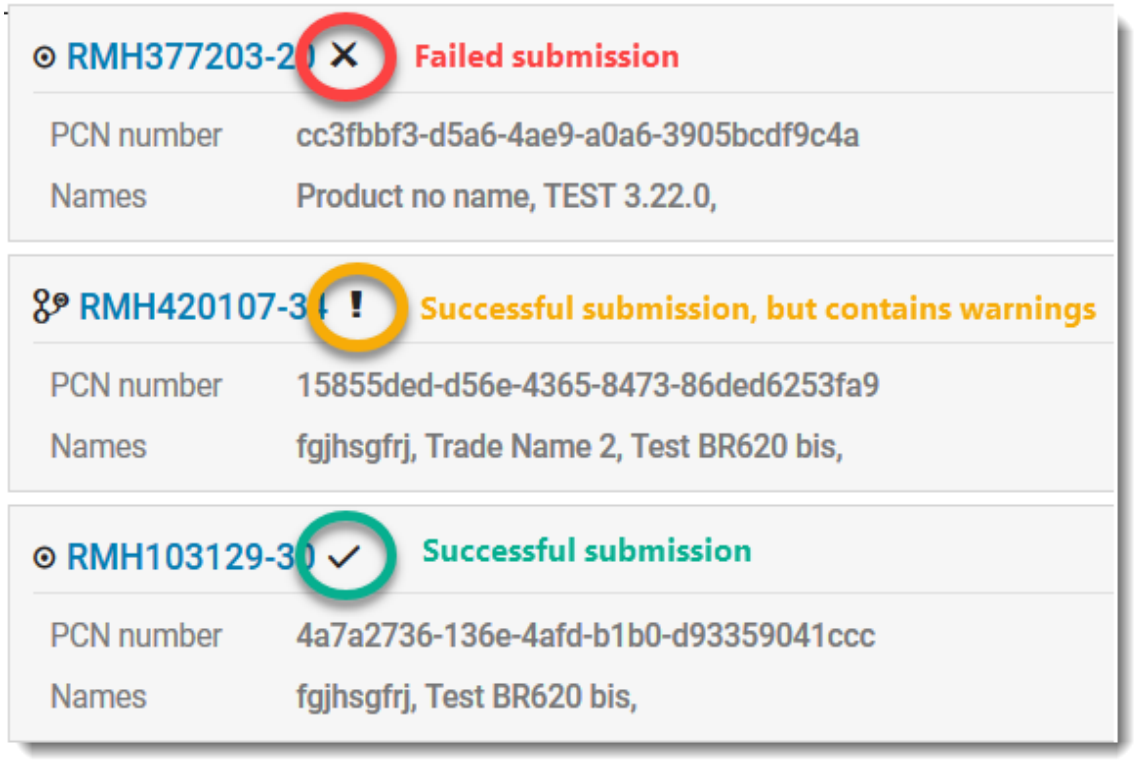
Validation rules – tips (ii)

- 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)



Common issues (1#)
Inexplicable Update failures

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

Why now the submisison **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

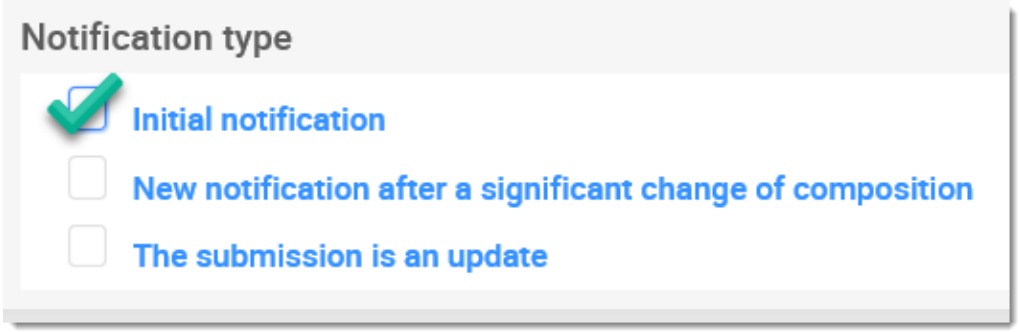
What happened is that…

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.



Common issues (2#)
Missing dossier header

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

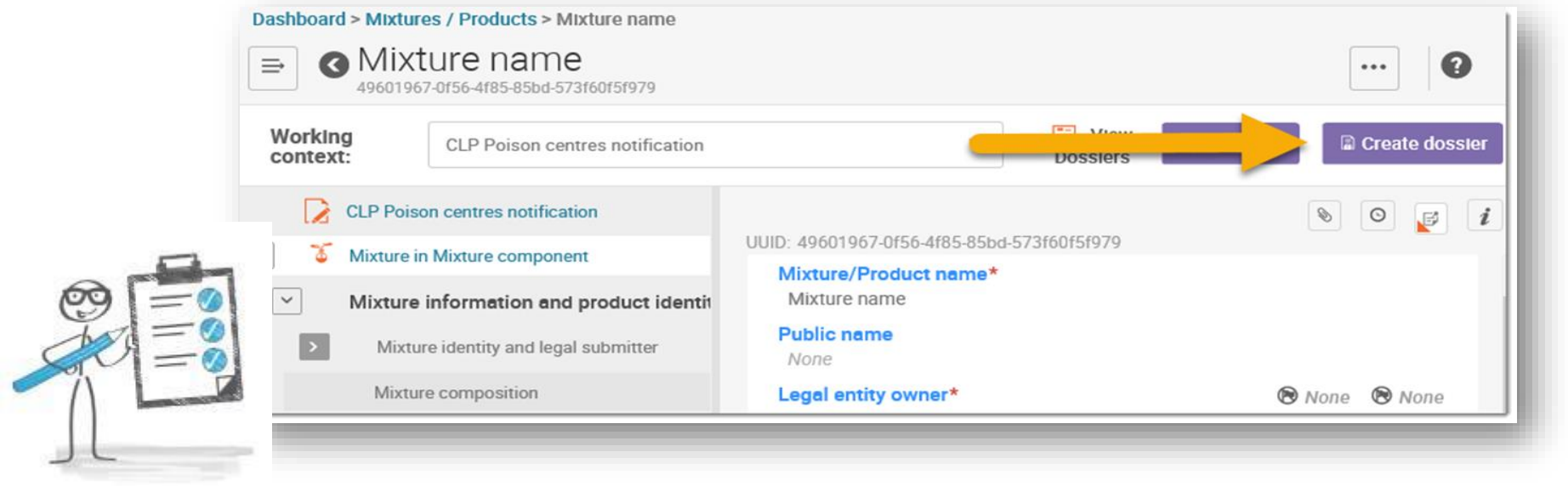
Level	Rule	Document name Section number and name	Message
⊗	IMPORT		Missing dossier header

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

Common issues (2#)
Missing dossier header

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.



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?

Common issues (4#)
Inexplicable failure…

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.

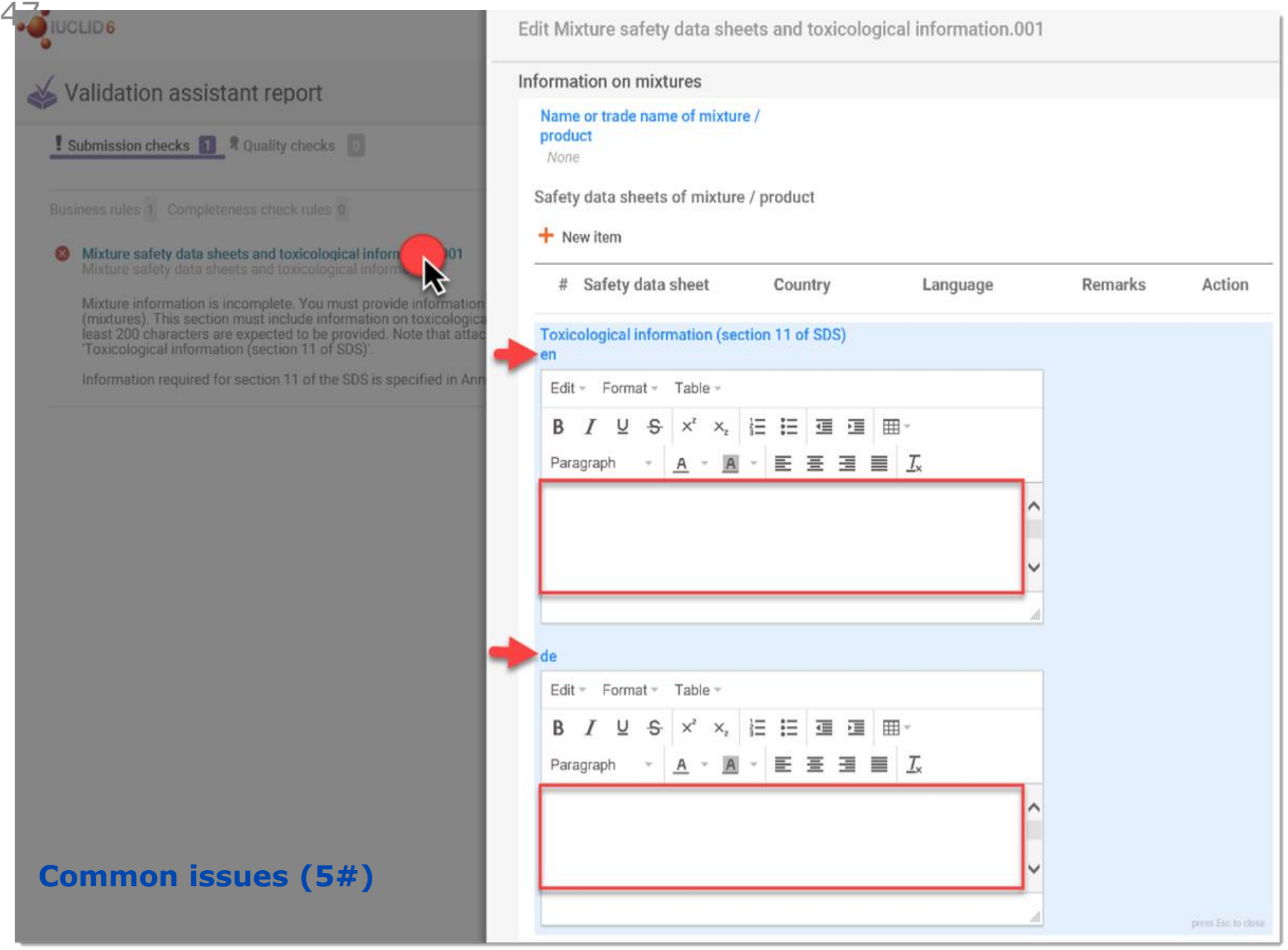
What could be wrong?

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.



Common issues (5#)

Fixing errors – The validation assistant report

Mixture composition.001

Mixture composition Component (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)	Standard formula (SF) component	Interchangeable component group (ICG)	Generic component identifier (GCI)	
2	Calcium dihydroxide | Calcium dihydroxide	None	None	> 20 < 35 % (w/w)	Standard formula (SF) component	Interchangeable component group (ICG)	Generic component identifier (GCI)	
3	Water | Water | Water | 7732-18-5	None	None	> 50 < 60 % (w/w)	Standard formula (SF) component	Interchangeable component group (ICG)	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 rues available on the ECHA Poison Centre website at https://poisoncentres.echa.europa.eu/poison-centres-notification-format

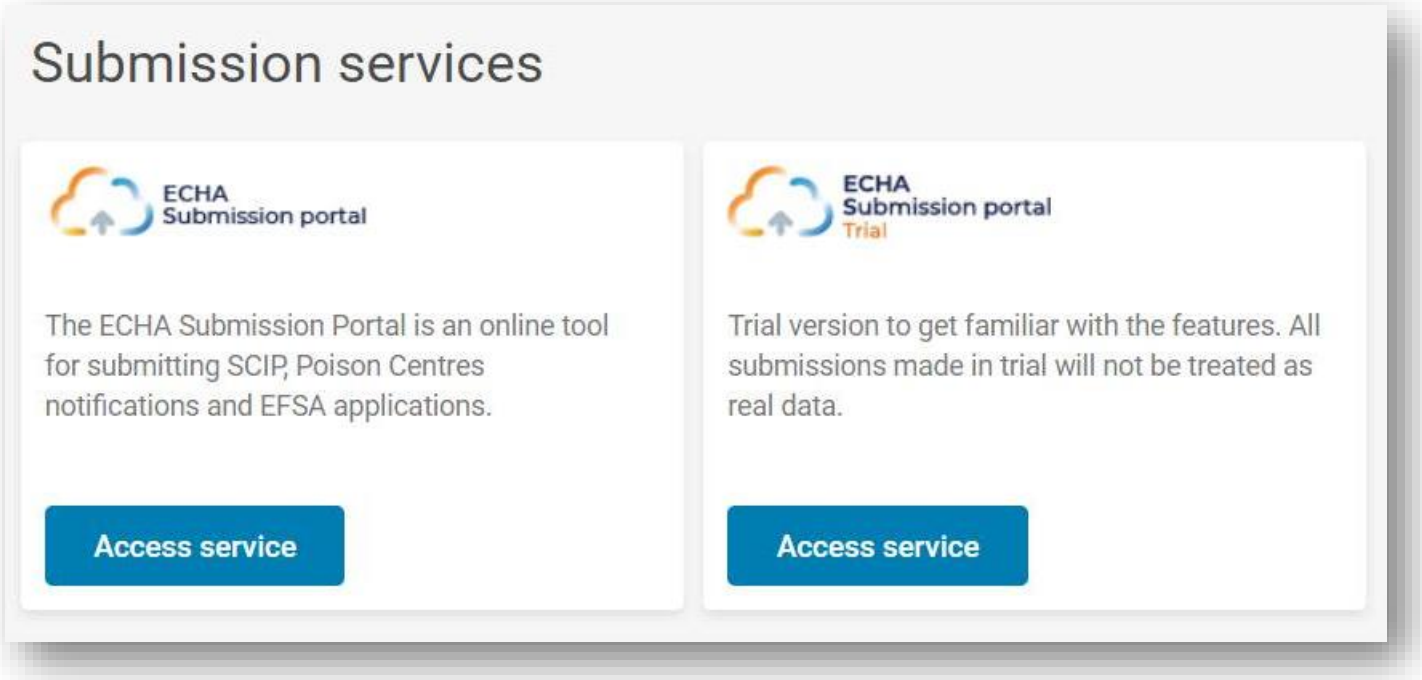
Guidelines for using the Submission Portal

March 2021

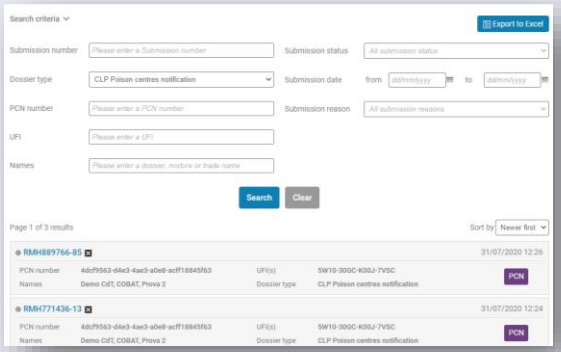
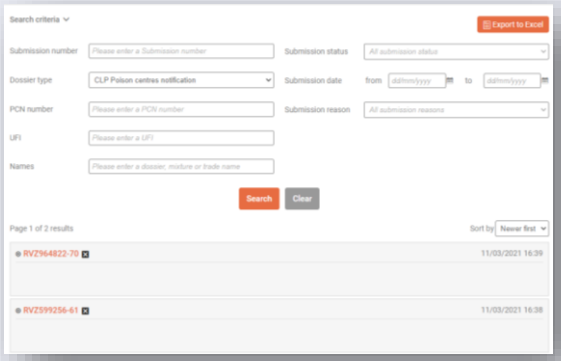
Webinar PCN – best practices from start to market

Claudia RIMONDO
Poison Centres Team
Submission and Processing Unit
European Chemicals Agency

Pick the right submission environment



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

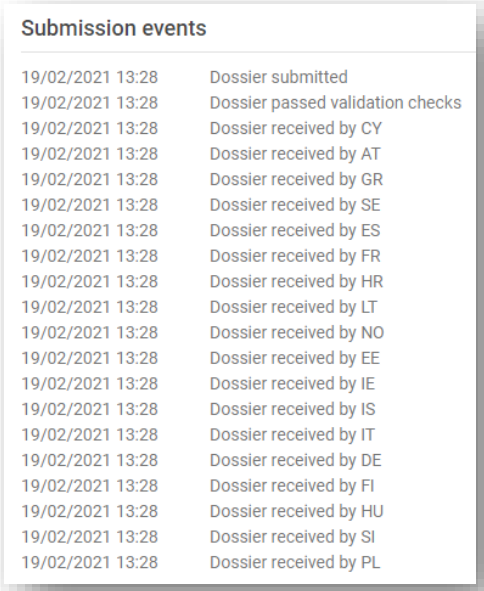
Item	ECHA Submission portal PRODUCTION	ECHA Submission portal TRIAL
Outcome	Dossiers **dispatched** to Appointed Bodies	Dossiers **NOT dispatched** to Appointed Bodies
URL	https://ecs.echa.europa.eu/cloud/submissions/home	https://**test-env**.ecs.echa.europa.eu/cloud/submissions/home
Logo	ECHA Submission portal	ECHA Submission portal Trial
Layout		
Disclaimer	None	*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 Production version.*

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

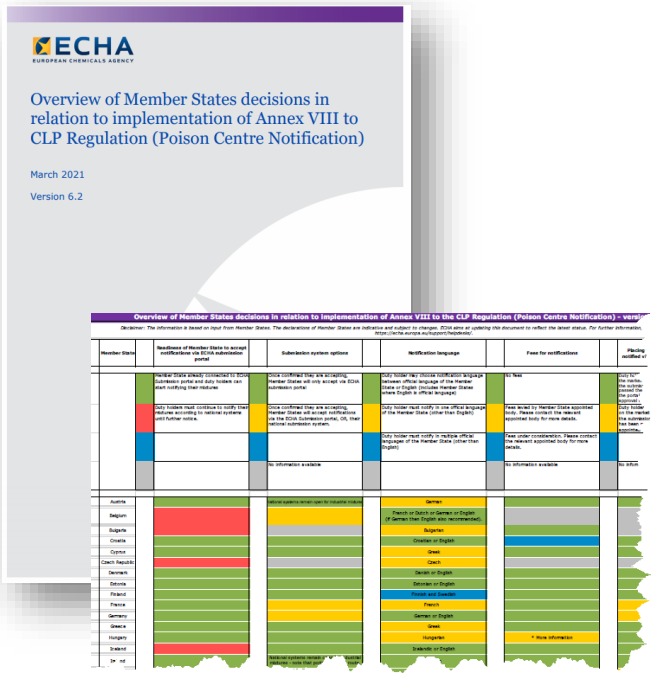


Submission events

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 ≠ Dossiers accepted

- "*Dossier received by [country code]*" ≠ Notification accepted
- ≠ 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



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

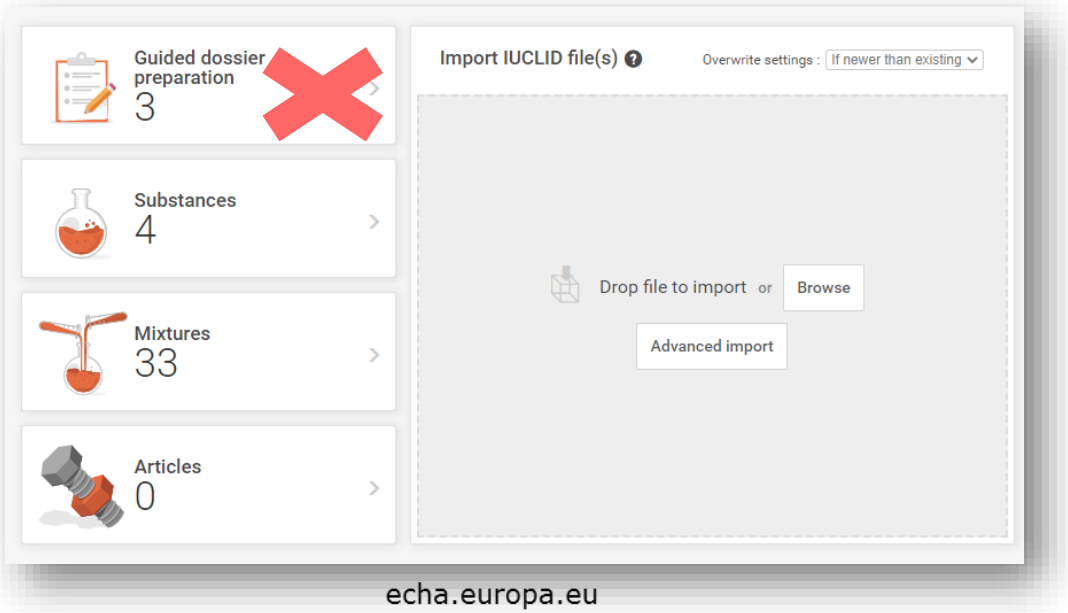
October 2021

- 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:
  - ≤ 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

Heidi RASIKARI
Poison Centres Team
Submission and Processing Unit
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!

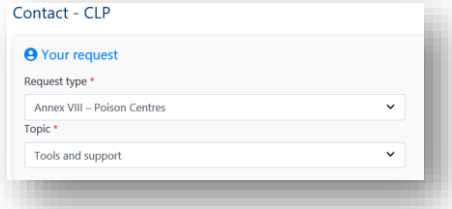
https://poisoncentres.echa.europa.eu/training-material

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



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