Poison Centres -

Closing in on the first compliance date

4 November 2020

Webinar

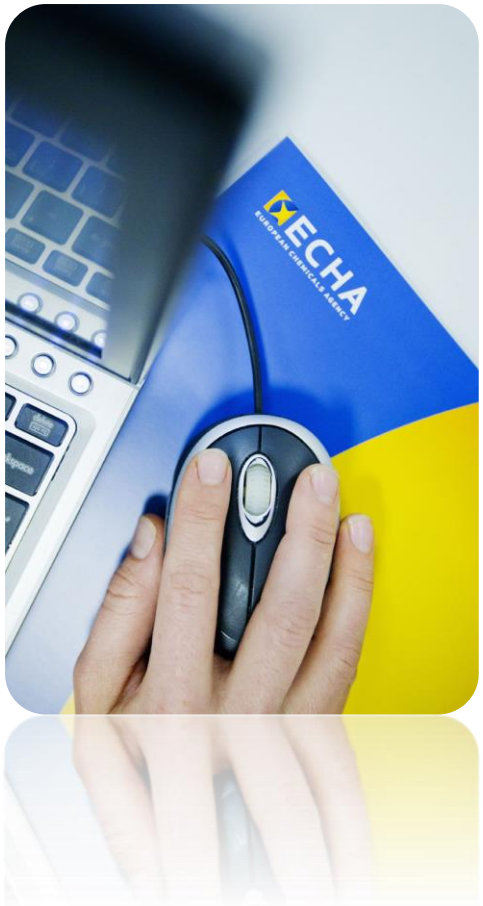
Poison Centres Team
Submission and Processing Unit
European Chemicals Agency

Agenda

11:00	**Introduction** (webinar open for questions) Heidi Rasikari
11:05	**Annex VIII – 2nd amendment solutions** Daniele Ape
11:15	**PCN IT solution** Claudia Rimondo
11:35	**The latest in system to system** Stefen Supanic
11:45	**Validation tips for successful submissions** Saara Sumiala
11:55	**Guidance – what you need to know** Pedro Roselló Vilarroig
12:05	**Hot topics - support and practical advice** Heidi Rasikari
13:00	Webinar closed for questions

What you can expect from today

- Learn about the key changes of the 2nd amendment to Annex VIII
- Learn how the dossier preparation tools support new changes
- Tips for a successful submission
- Identify key support and Guidance material
- Practical advice on most commonly asked questions
- Ask your questions from our online panellists



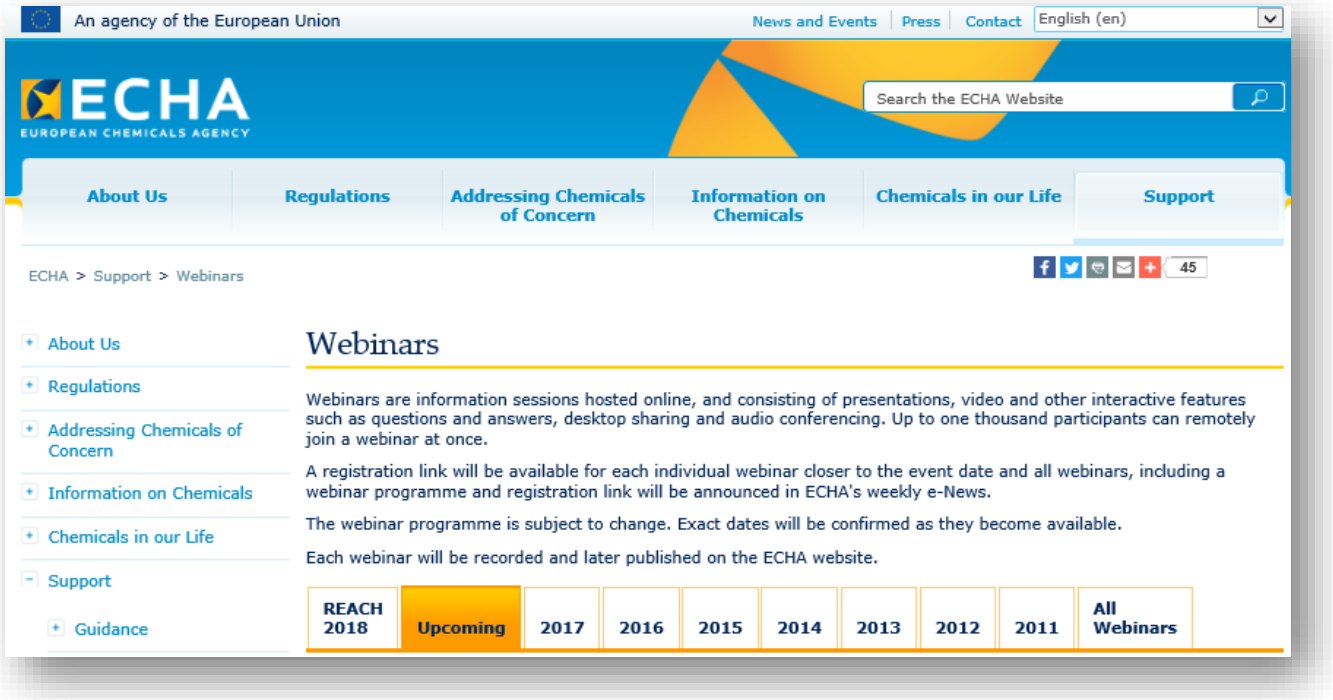
Questions

- Join Q&A at: slido.com
  Event code: # pc2020
- Send questions from **11:00 to 13:00 Helsinki time**
- 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



Annex VIII – 2nd amendment solutions

4 November 2020

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Daniele APE
Poison Centres Team
Submission and Processing Unit
European Chemicals Agency

Points to consider

Focus on workability issues raised by specific industry sectors: paints, construction, petroleum

Cross-sector solution for unpredictability of composition

No changes in compliance dates

No (main) changes in standard information requirements

2nd Amendment of Annex VIII

- 'Workability' amendment (2020) following identification of generic and sector specific issues
- Solutions sought to balance the need for information required and administrative burden/difficulty to comply
- Publication in the Official Journal in October
- Relaxed requirements for construction products and fuels, exemption for bespoke paints, interchangeable component groups

Construction products

Issue: high composition variability of raw materials - exact composition is unknown/concentrations are out of allowable ranges.

Annex VIII: Mixtures that conform with composition corresponding to specific **Standard Formulas** (Part D Annex VIII) can be notified according to that formula (identity and concentration) - for cement, gypsum binder, ready-mixed concrete

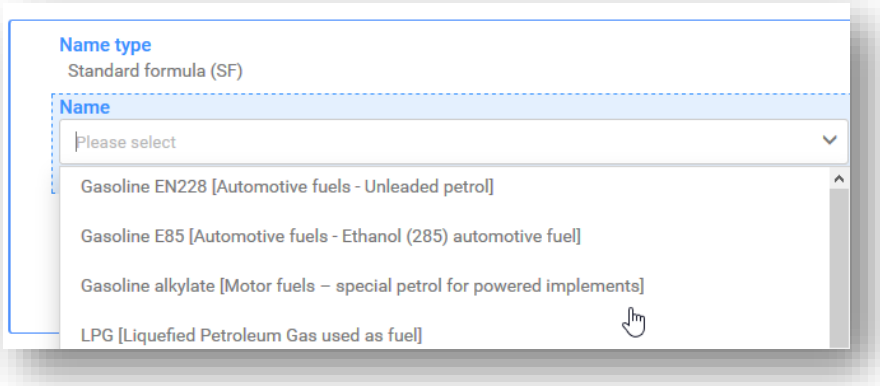
PCN: Flagging Standard Formula components in the notification allow the submitter to deviate from standard information requirements

Fuels

Issue: high composition variability of raw materials - exact composition is unknown/concentrations are out of allowable ranges.

Annex VIII: Fuels listed in Table 3 Annex VIII- composition according to safety data sheet (plus other known components).

PCN: Flagged as Standard Formula in the notification and the name of the fuel selected. Rules for fuels differ from rules for Standard Formulas.



Bespoke paints (point of sale)

Issue: High number of different mixtures requiring notifications and UFI to be generated by the retailer before selling the paint to individual professional and consumer users.

Annex VIII: No need to notify the bespoke paint and generate UFI, but final bespoke paint's label to include:

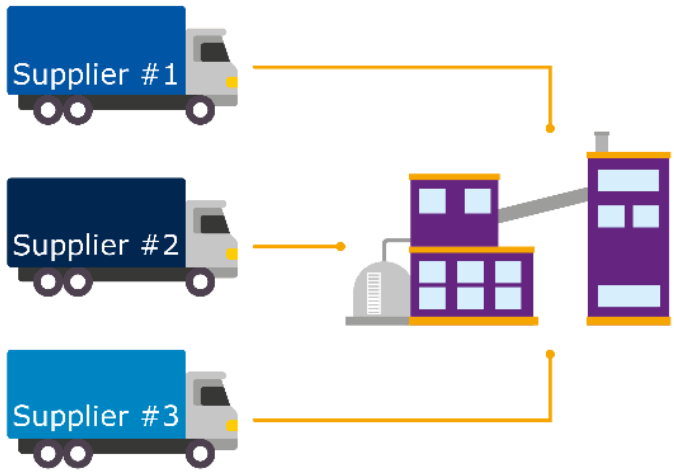
- UFI of base paint; and
- UFI of other hazardous mixtures present in the >0.1% (including concentration if > 5%)

Cross sector use - interchangeable component groups

Issue: Unknown exact mixture composition due to unforeseeable change in component(s) - e.g. ‘same’ component from different suppliers.

Annex VIII: ICG to group multiple components (fitting certain criteria), not all necessarily present in specific concentrations in each batch – no changes in overall classification, hazard or emergency health response.

PCN: ICG is flagged and standard rules regarding composition waived resulting in reduction of multiple notifications of the ‘same’ mixture.



2nd amendment: other changes

- Clarification of mixture's end-use - concept of "end-use not subject to Article 45"
- Extension of derogation from obligation to notify only components which are present (i.e. concentration ranges in SFs including "0", Interchangeable Components not always present)
- Clarification about MiM identification and UFI
- Classification of MiM's components required

PCN IT solution

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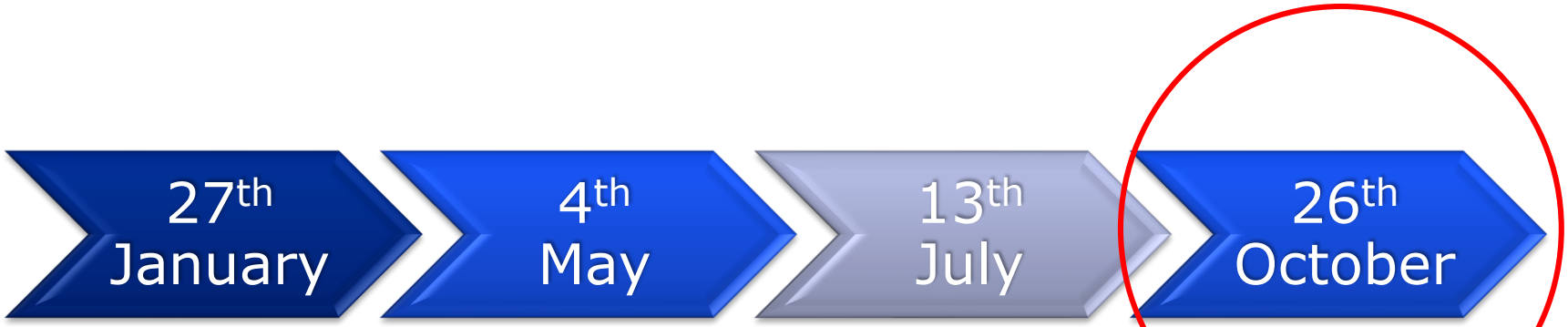
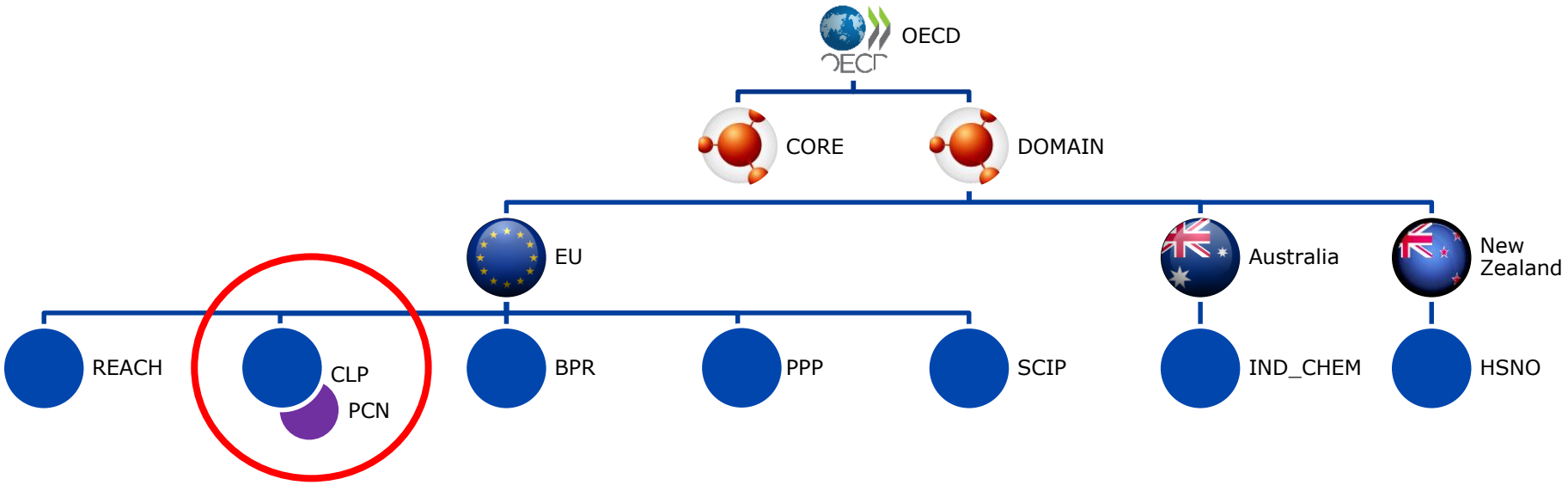
Claudia RIMONDO
Poison Centres Team
Submission and Processing Unit
European Chemicals Agency

2020 release timeline



- PCN format changes coming from amendments to the legal text
- Improved functionalities to prepare and submit PCN notifications
- General improvements to the navigation and the user interface

Customised PCN format



- PCN format is a customised subset within IUCLID format
- IUCLID format support different legislations in EU and beyond
- Changes initiated need to be in agreement with each other
- The IUCLID core format/PCN format updated yearly

October release new features (I)

Dossier preparation

1. Support for Standard Formulas (SF)
2. Support for Interchangeable Component Group (ICG)
3. 'Generic product identifier (GPI)' changed to the 'Generic component identifier (GCI)'
4. Updated EuPCS list (for main intended and secondary use)
5. List of justifications added in case pH is not available
6. Multiple packaging sizes now possible for the same product in one record
7. New reasons for update: correction/deletion of trade name, expansion of market area
8. GHS changes to include the GHS Rev.8, 2019

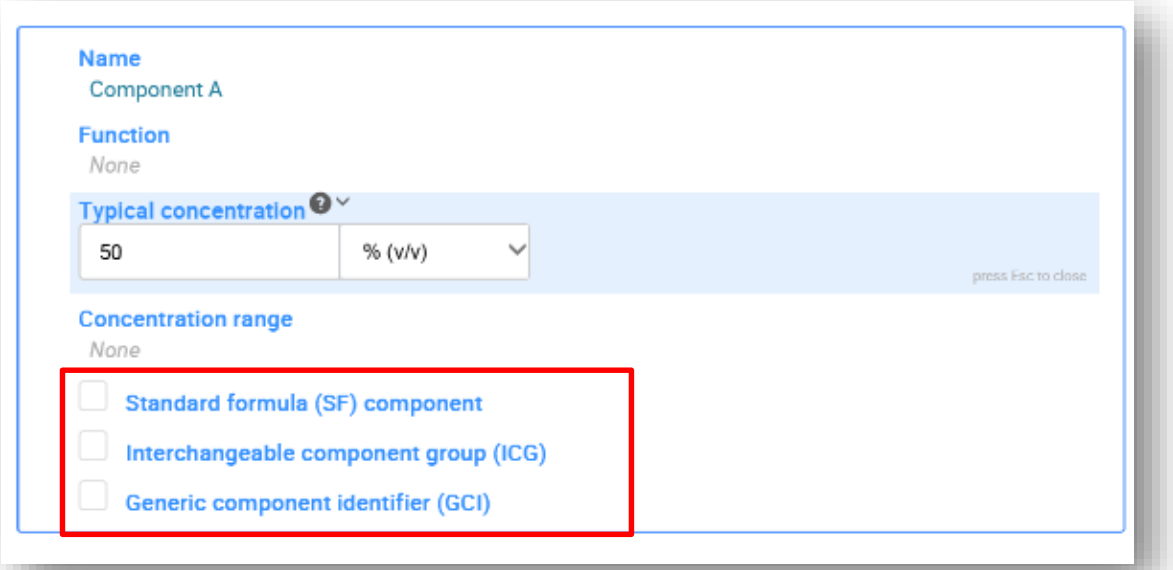
October release new features (II)

Dossier preparation

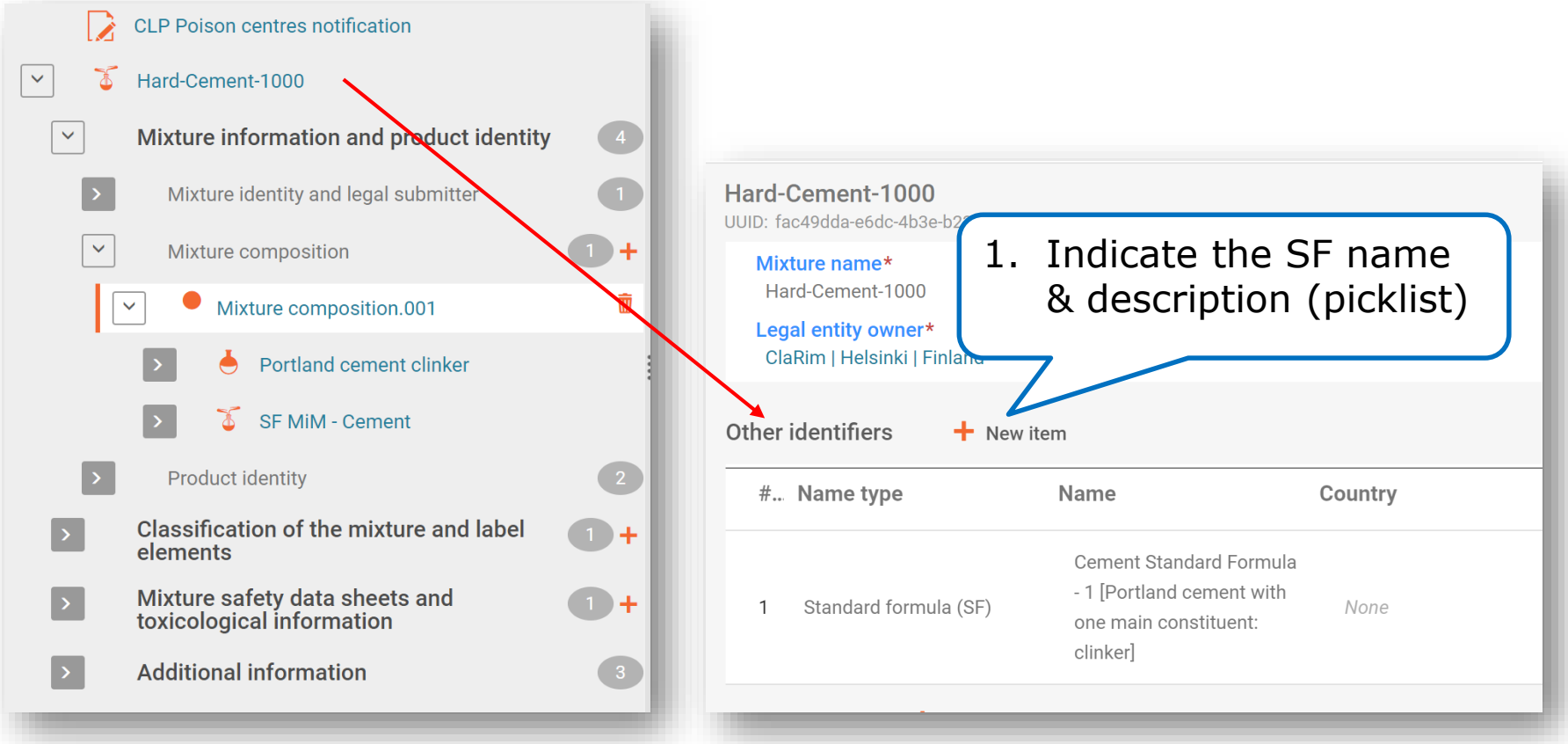
9. EuPCS codes -> shown as hierarchical list
10. New BR related to ICG and SFs + latest amendment of the Annex VIII
11. Navigation tree improvements
12. View document inbound references (check other documents referencing the current one before deleting it)

New terms and concepts

- 'SF' Standard Formula – New!
- 'ICG' Interchangeable Component Group – New!
- 'GPI' Generic product identifier to Generic Component Identifier 'GCI'



Indicating Standard Formula in a notification

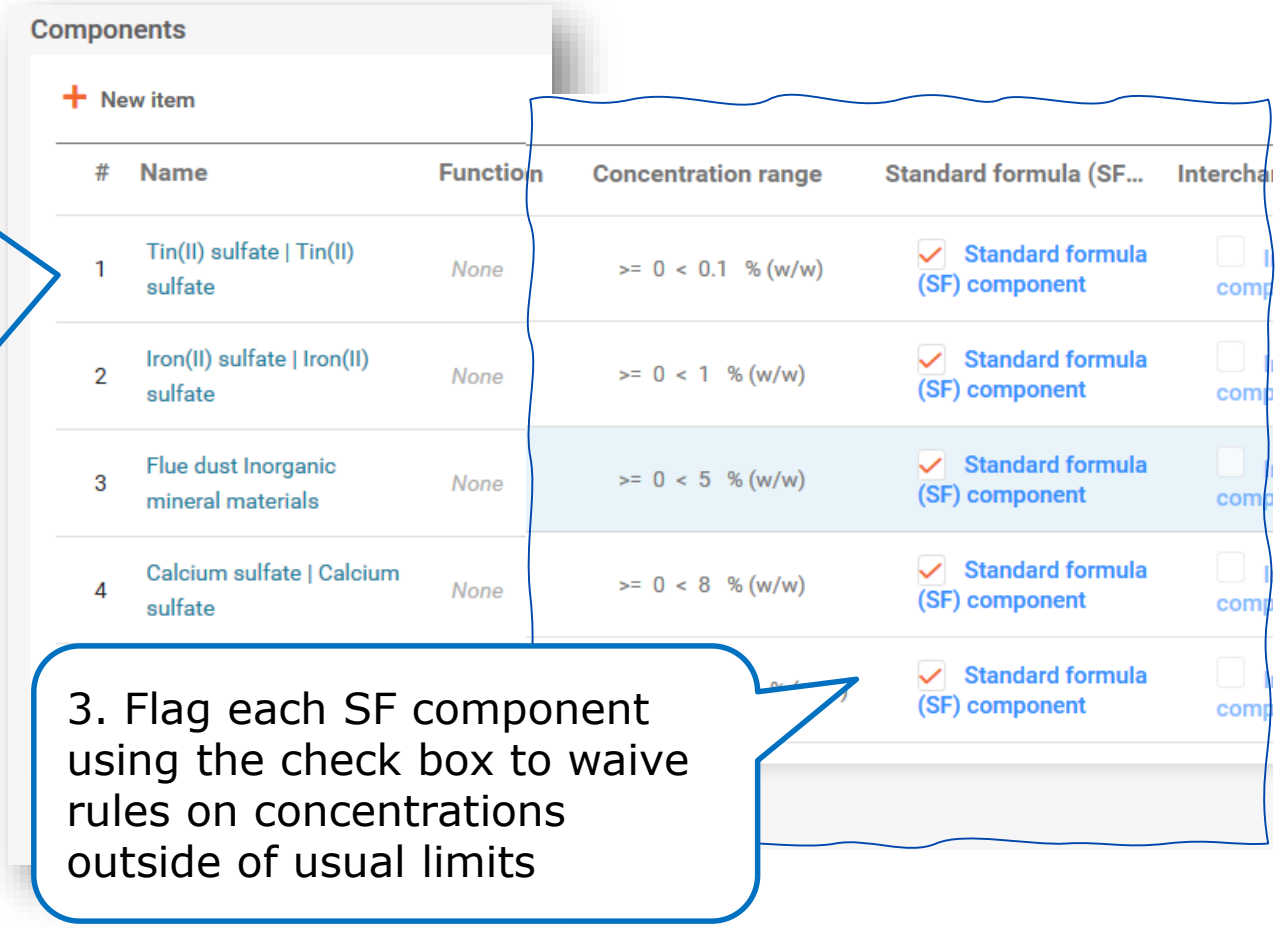


Reporting Standard Formula components

2. In Mixture composition document, add each components:

- identity
&
- concentration

… as given in Part D Annex VIII

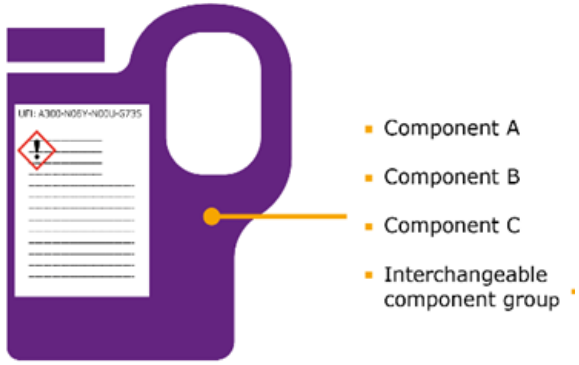


3. Flag each SF component using the check box to waive rules on concentrations outside of usual limits

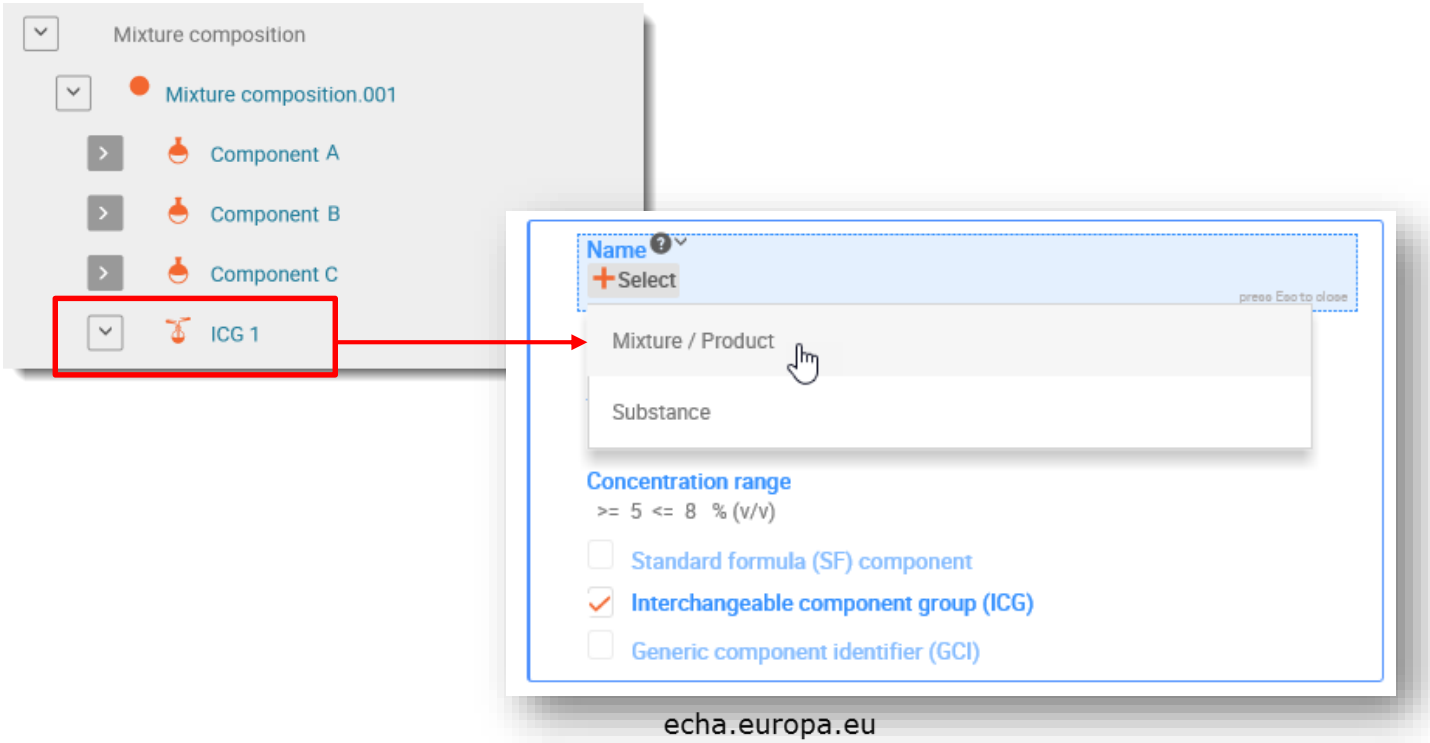
Standard Formula datasets available

- ECHA has prepared Standard Formula datasets in cooperation with CEMBUREAU
- Standard Formula datasets available from https://poisoncentres.echa.europa.eu/poison-centres-notification-format
- *Use of the Standard Formula datasets remains under the sole responsibility of the user. ECHA does not give any warranty, expressed or implied, including but not limited to its fitness or usability for a particular purpose, completeness, or otherwise. ECHA does not accept any liability with regard to the use of the data made available.*

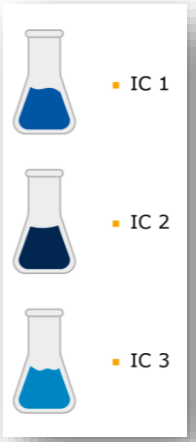
Indicating ICGs

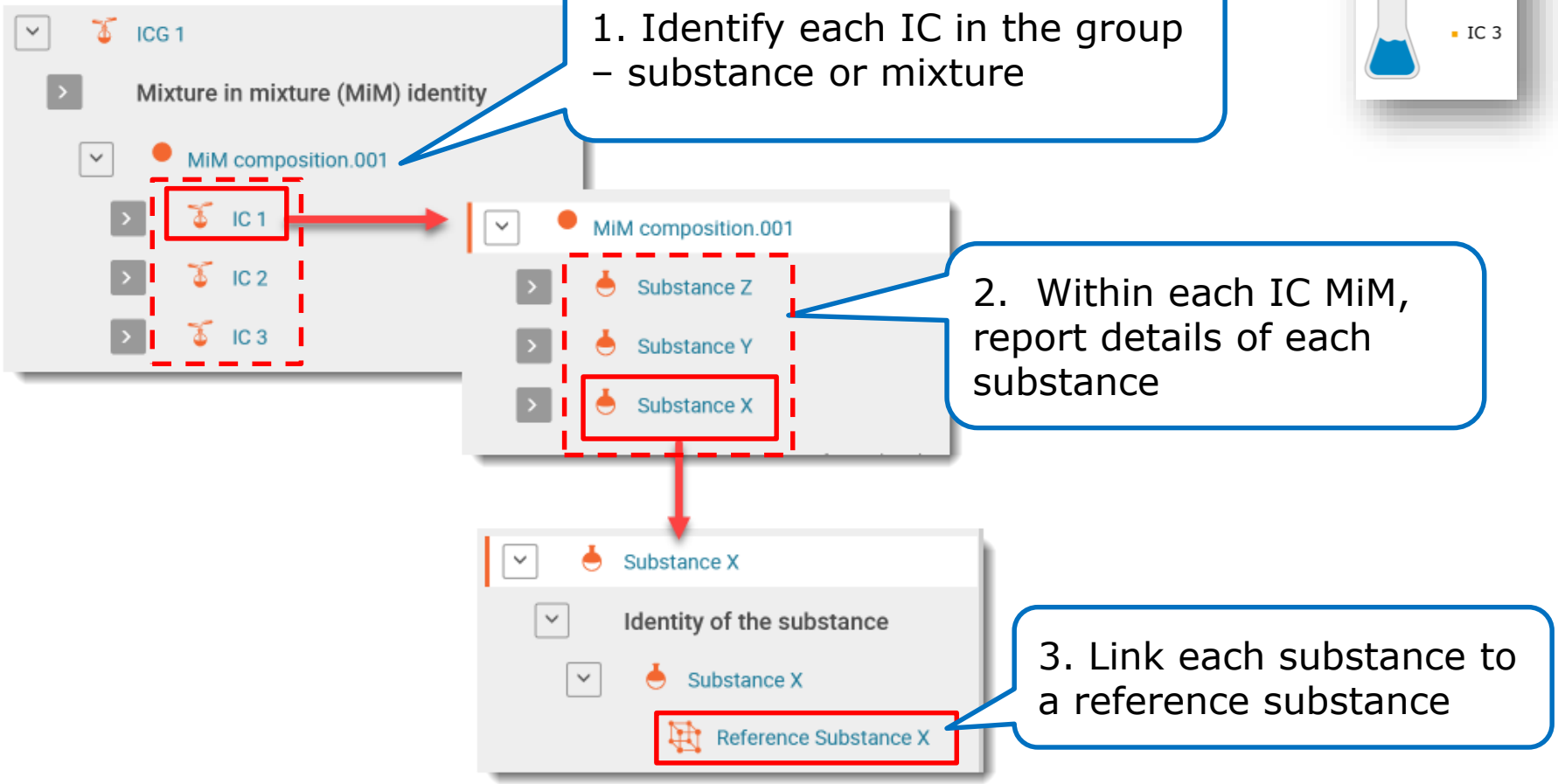


- Mixture composition document includes all components
- ICG is included as a 'Mixture (in mixture)' component and ICG check box flagged - allows the system to waive default rules for components.



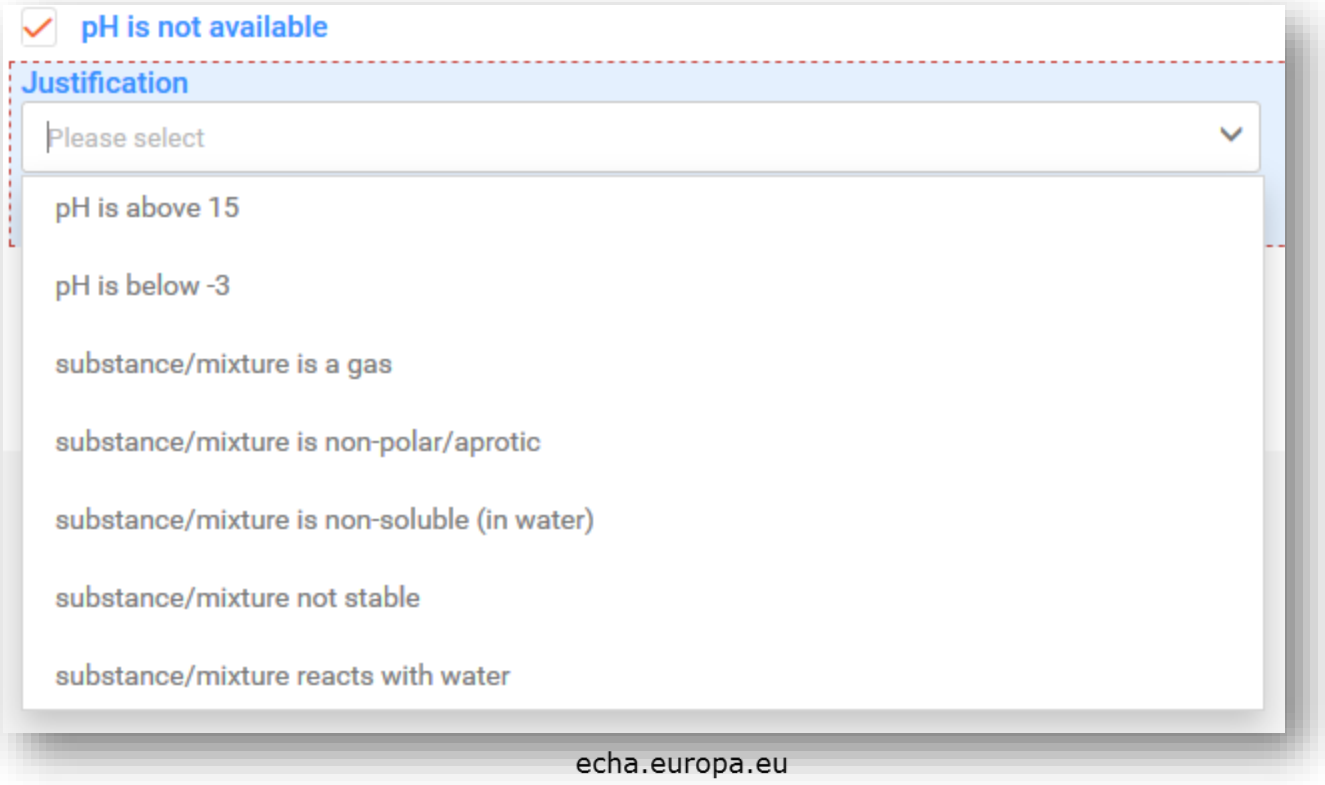
Reporting the composition of ICs





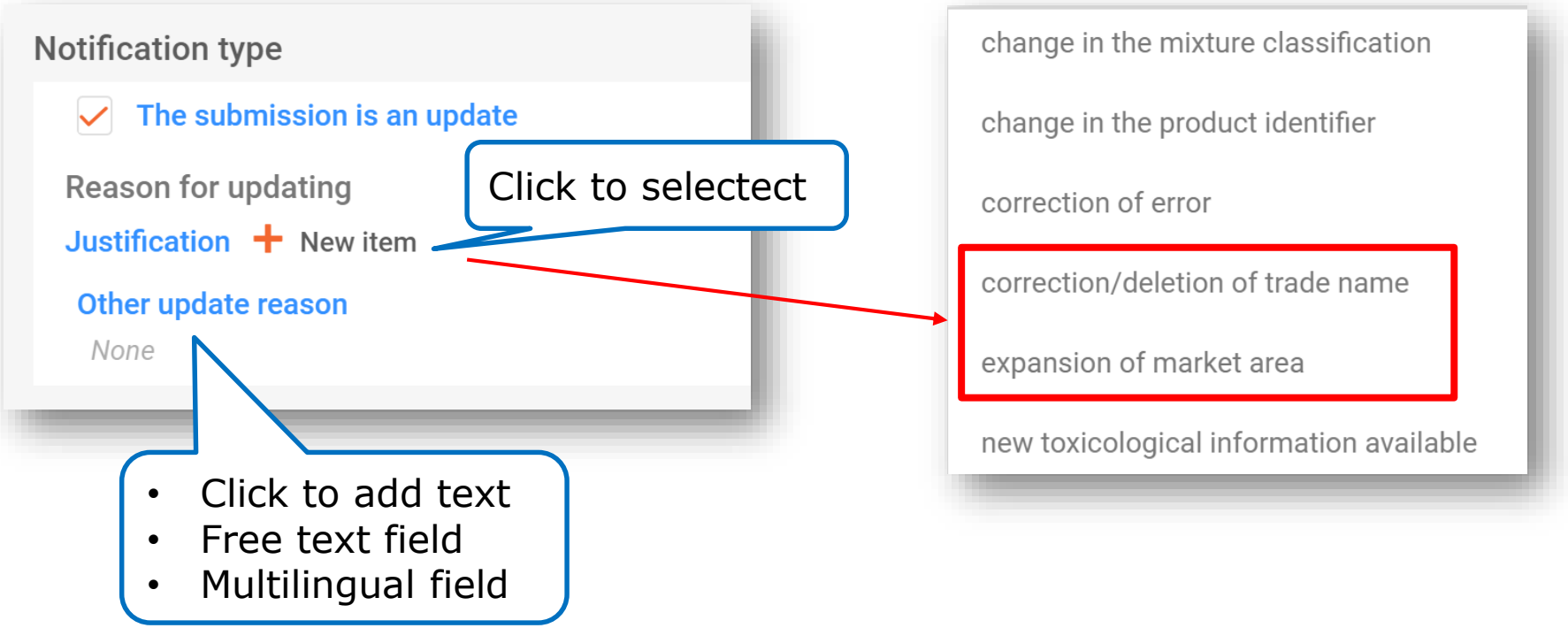
List of justifications when pH is not available

- When pH is not available, a justification must be given



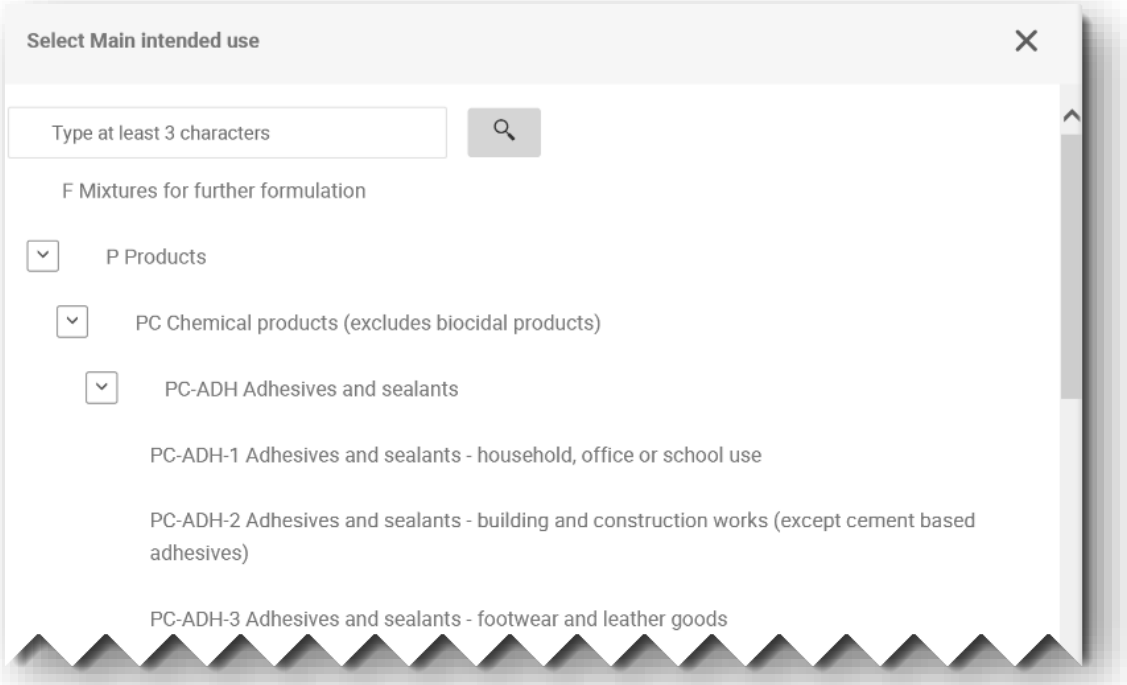
New reasons for update

- New update justifications included in the list



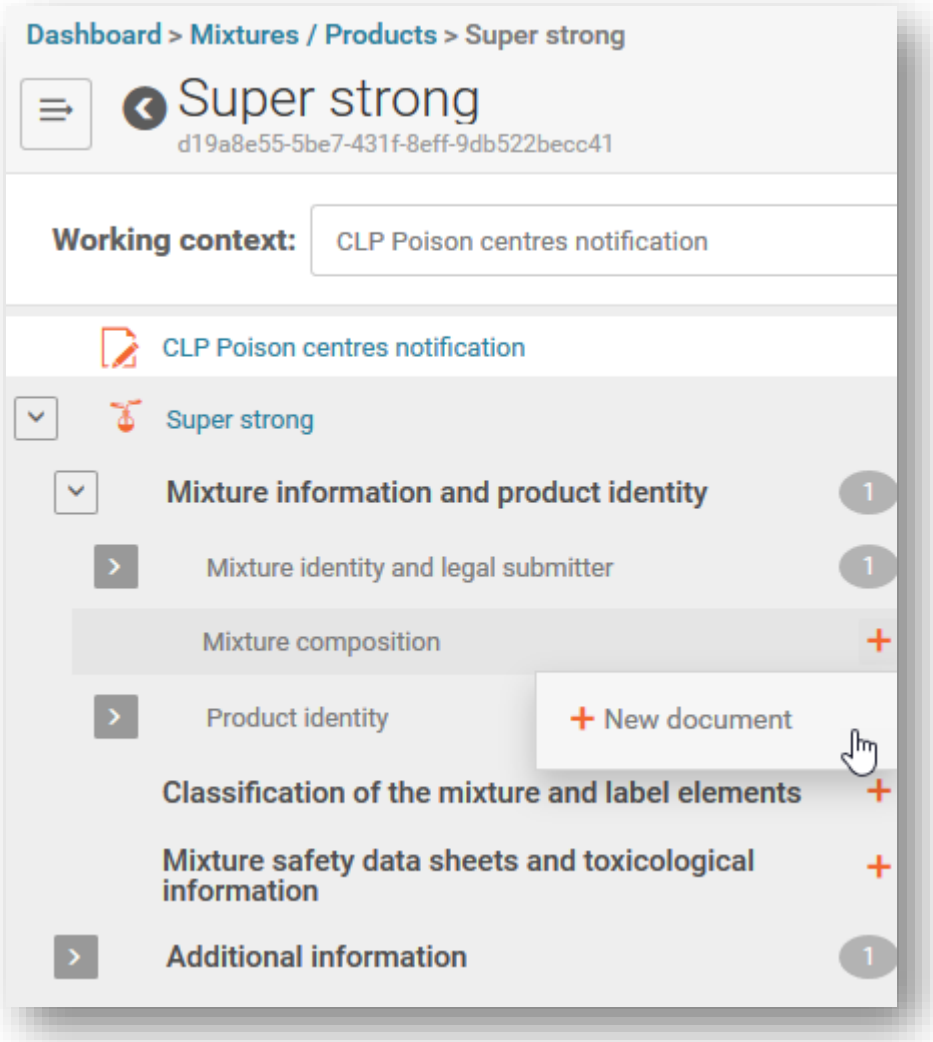
EuPCS version 2 included

- New categories for ‘Medical devices’
- Split categories from ‘E-liquids’
- Merged categories of ‘Pyrotechnic products’



Improvements to navigation tree

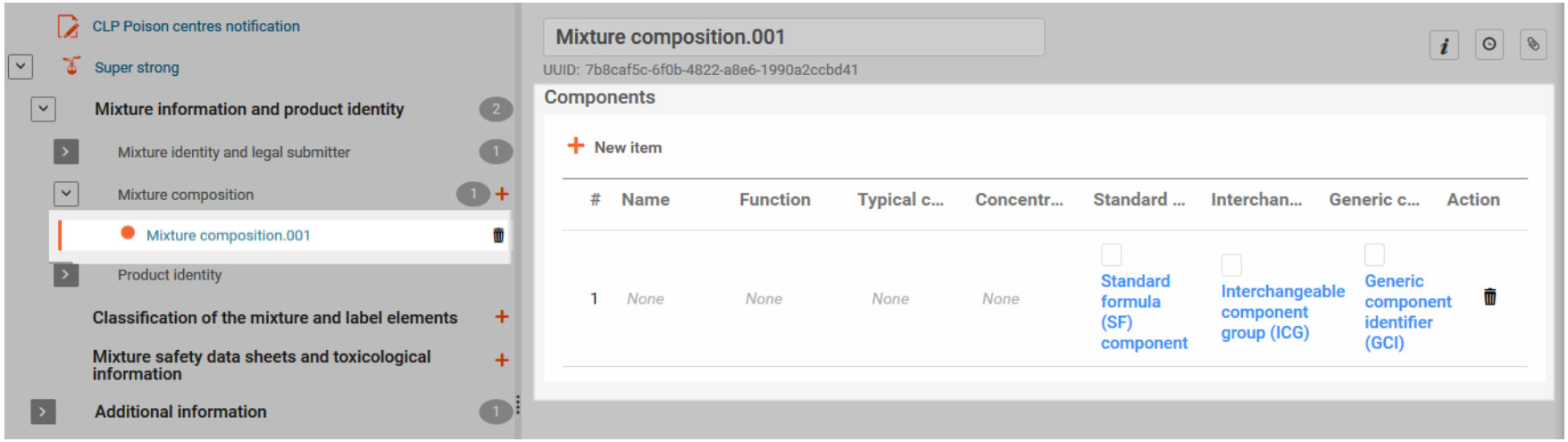
- Easily move from dossier header to other areas of the notification
- Expand & collapse
- Also possible to create or delete documents from the navigation tree

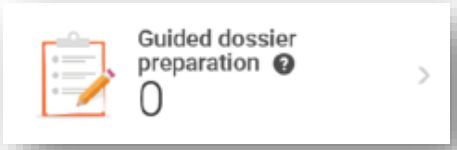


Creation of components made easier

Before: Create substance & MiM datasets outside the main notification, then link

Now: Possible to create component datasets from within the main notification

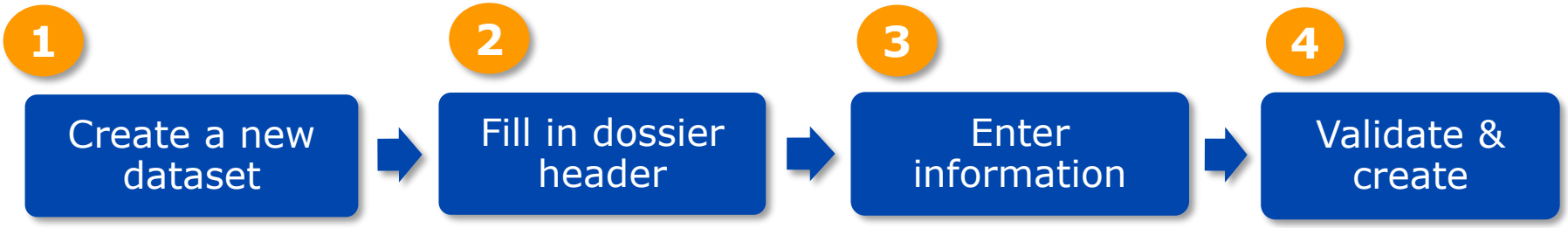




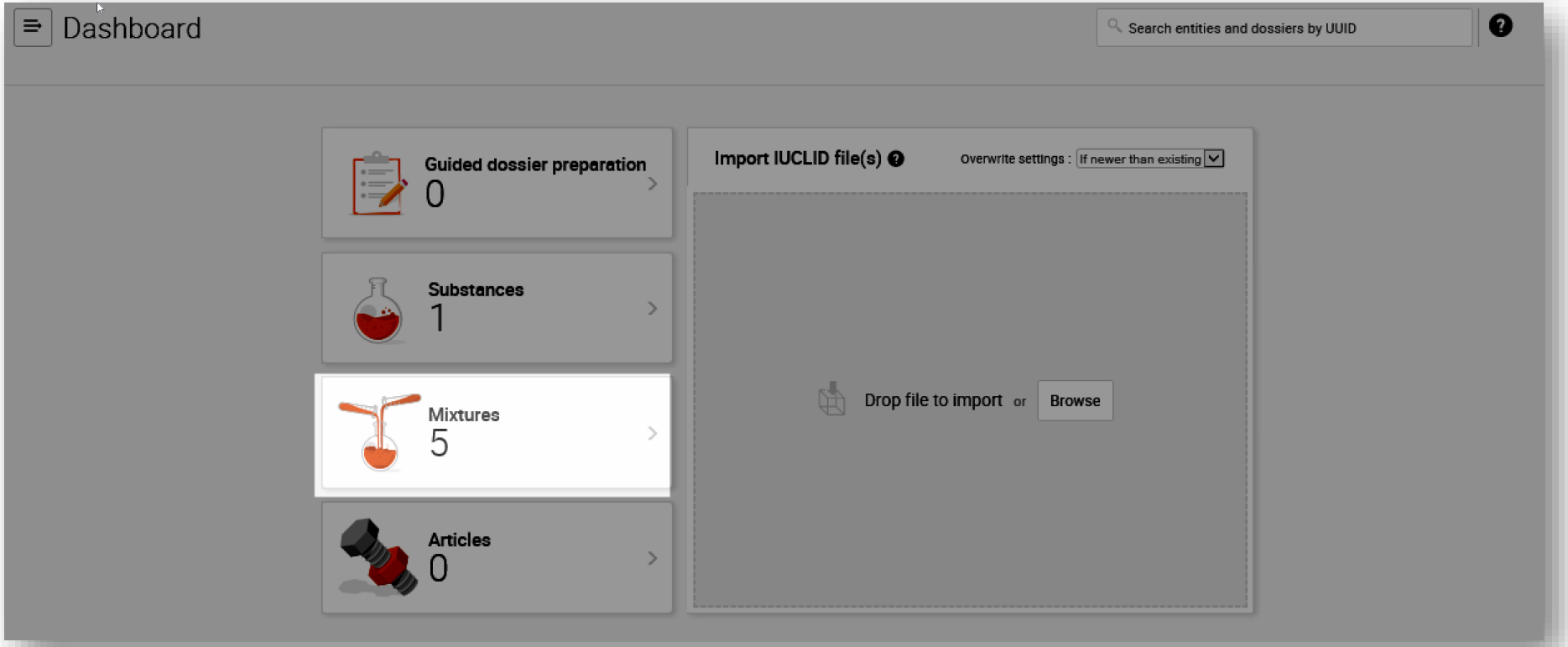
Decommissioning of Guided Dossier tool

- Navigation tree improvements
- Feedback from users on the dataset view mostly positive (PCN customised documents)
- Guided dossier tool will be decommissioned in April 2021
  - Transition started in April 2020
- ECHA providing training, tutorials and up-to-date support material to make the transition easier

PCN dossier preparation overview

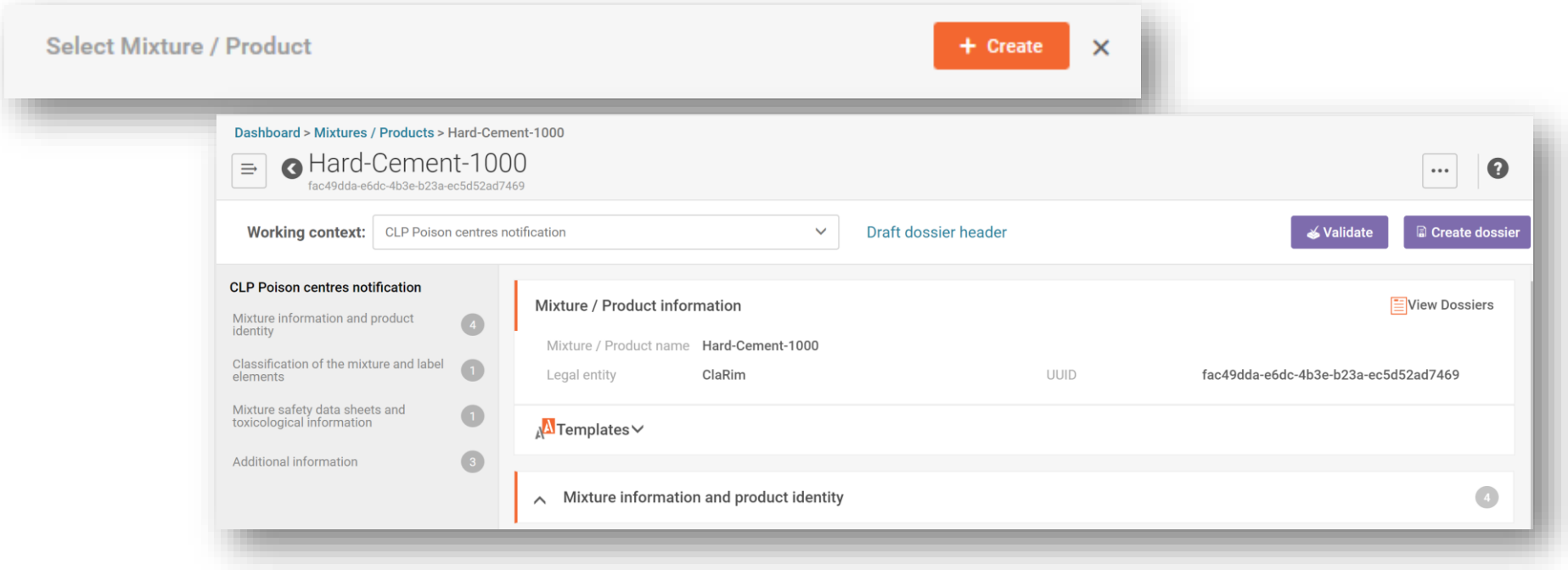


IUCLID dashboard



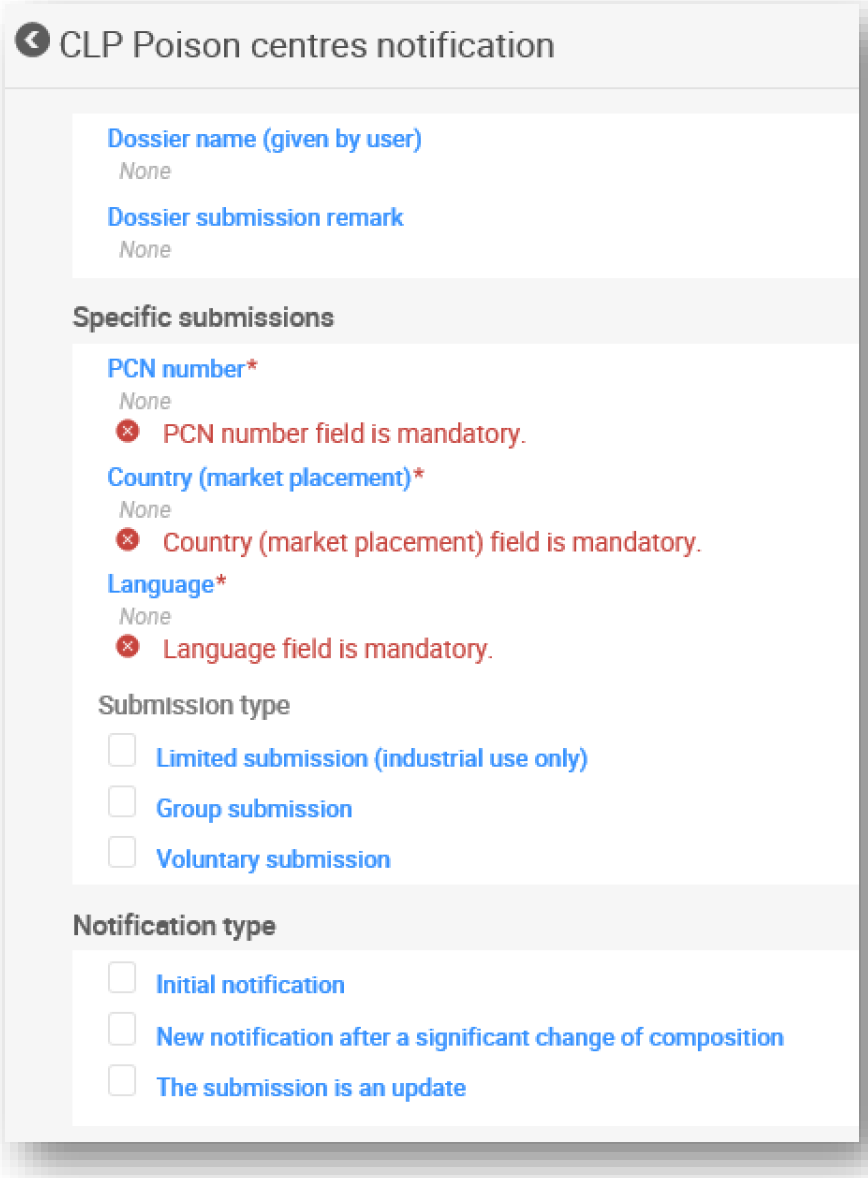
1. Create a new mixture dataset

- Enter a name for the mixture dataset
- Specify ‘Working context’: ‘CLP poison centre notification’
- Open the draft dossier header



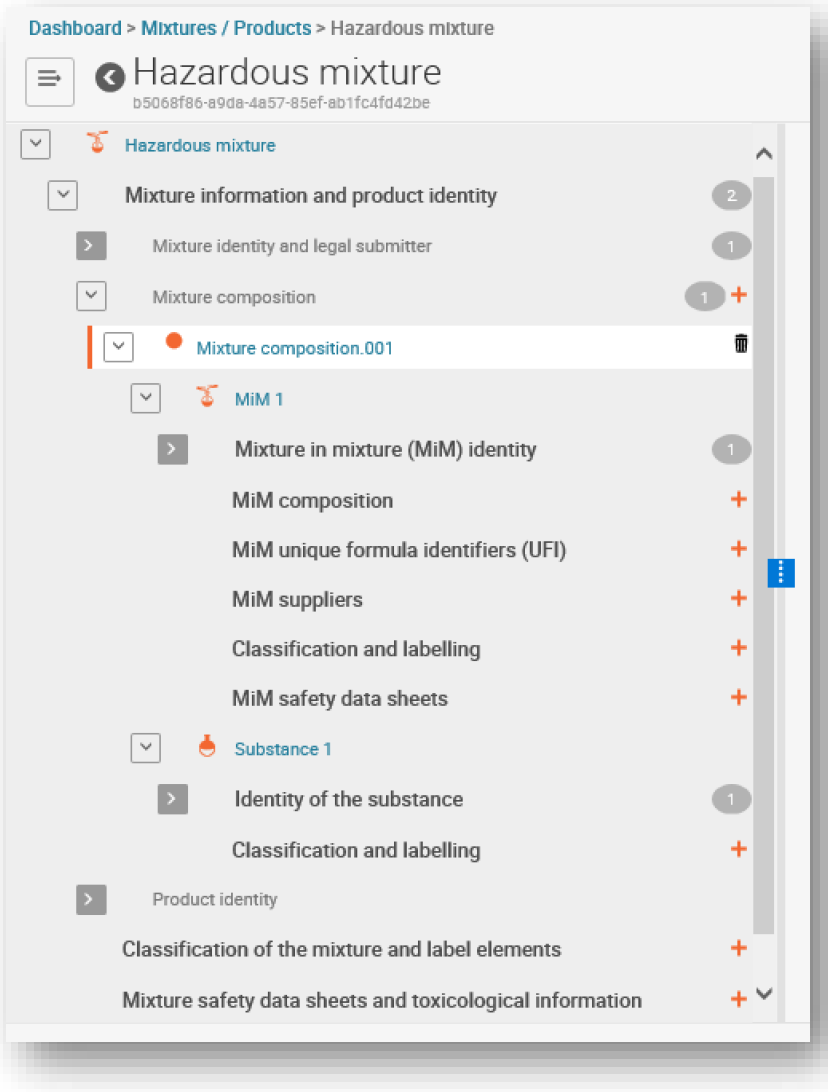
2. Dossier header

- Contains the information that defines the validation rules
- Establishes the free text fields for specific languages
- NOTE: Submission type selection only if relevant
  - Group (not supported)
  - Limited (industrial use only)
  - Voluntary (for non-duty holders or mixtures out of scope)



3. Enter information

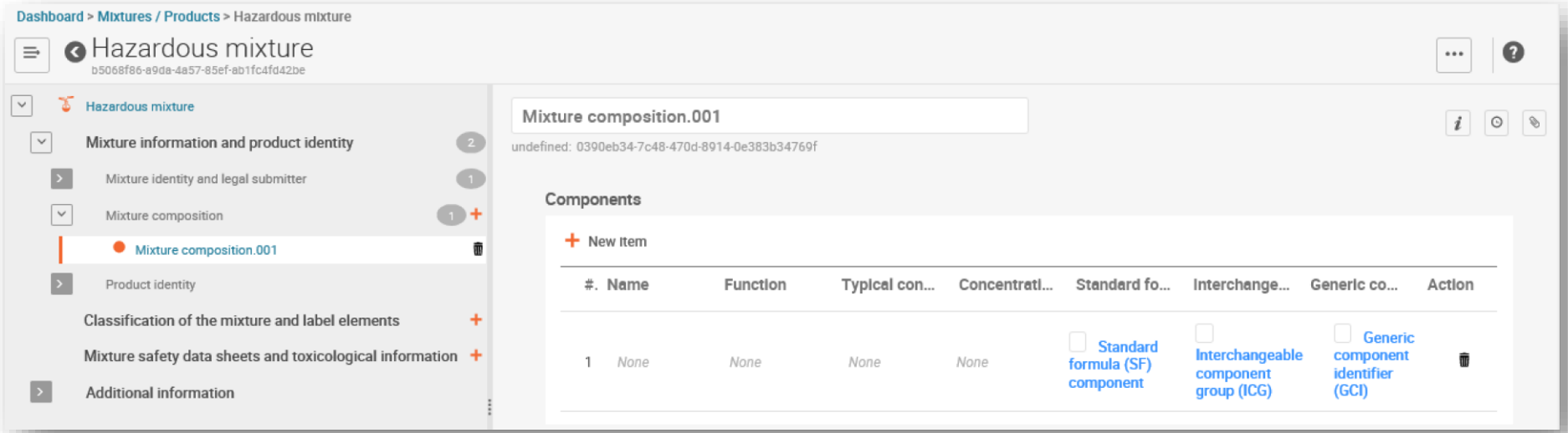
- Navigation tree to move from dossier header to other sections
- Uses expandable and collapsible windows
- Create new ‘document’ **+** to enter information
- New support material (step by step) in ‘PCN practical guide’ and video tutorial



Special consideration:

3.1 Mixture composition document

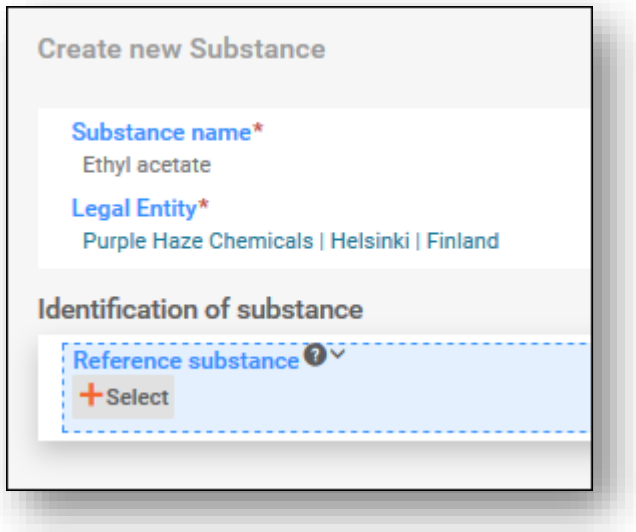
- All components (substances, mixture in mixtures) added in the mixture composition
- Use checkboxes to flag 'special' components: generic component identifiers, interchangeable component groups, standard formulas



Special consideration:

3.2 Reference substance

- Every substance component must be linked to a reference substance dataset (except for GCI)
- Defines the identity of a substance
- Can be created on the spot or downloaded from the IUCLID website
- Reference substance datasets can be selected for re-use once in the IUCLID working environment

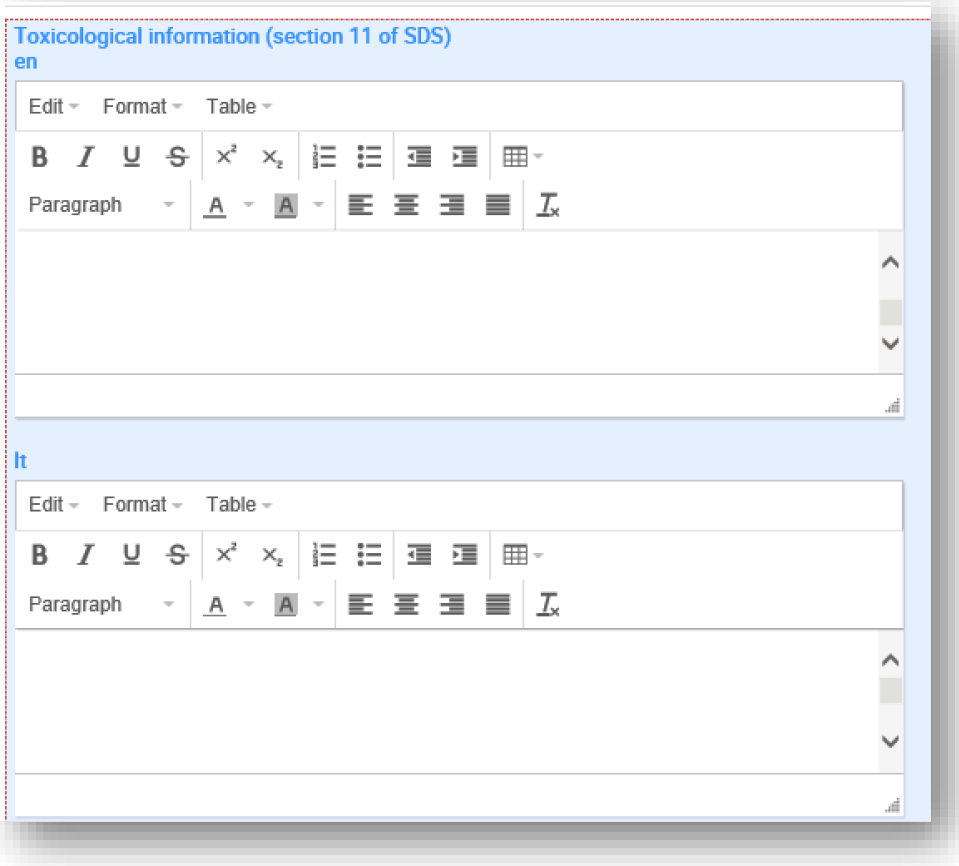


https://iuclid6.echa.europa.eu/web/iuclid/get-reference-substances

Special consideration:

3.3 Toxicological information

- Free text fields according to section 11 of the safety data sheet
- Required in all languages as indicated in the dossier header

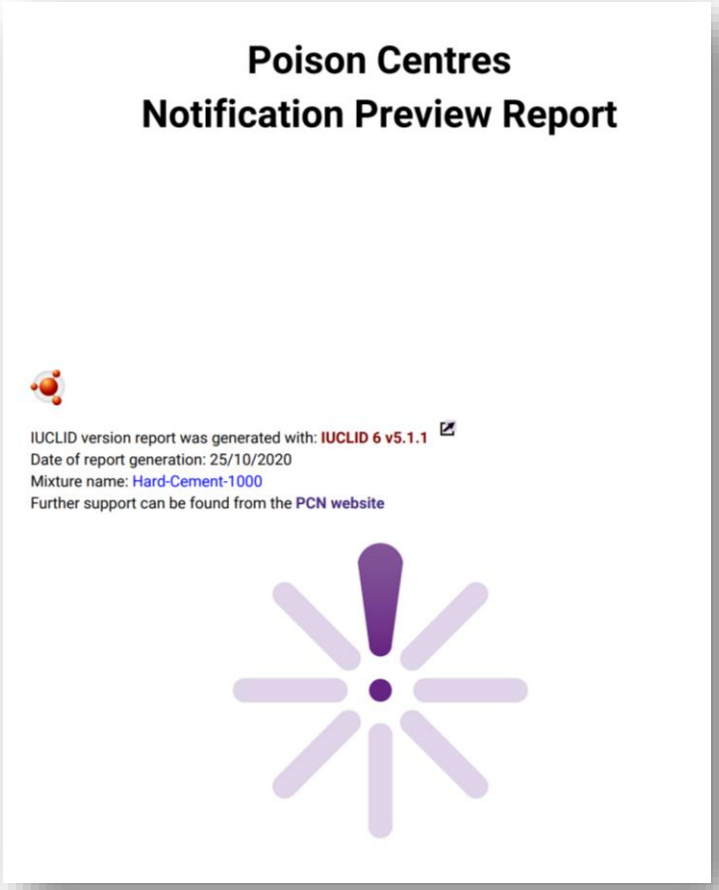


4. Validation Assistant rules

- Run the Validation Assistant and create a valid dossier
- New rules implemented
- Old rules updated according to:
  - Feedback received
  - Amendment of the legal text
- Complete list of rules available on the Poison Centre website https://poisoncentres.echa.europa.eu/poison-centres-notification-format

PDF report

- Updated to include Standard Formulas and Interchangeable Component Groups
- Improved based on received feedback (e.g. MiM components classification)

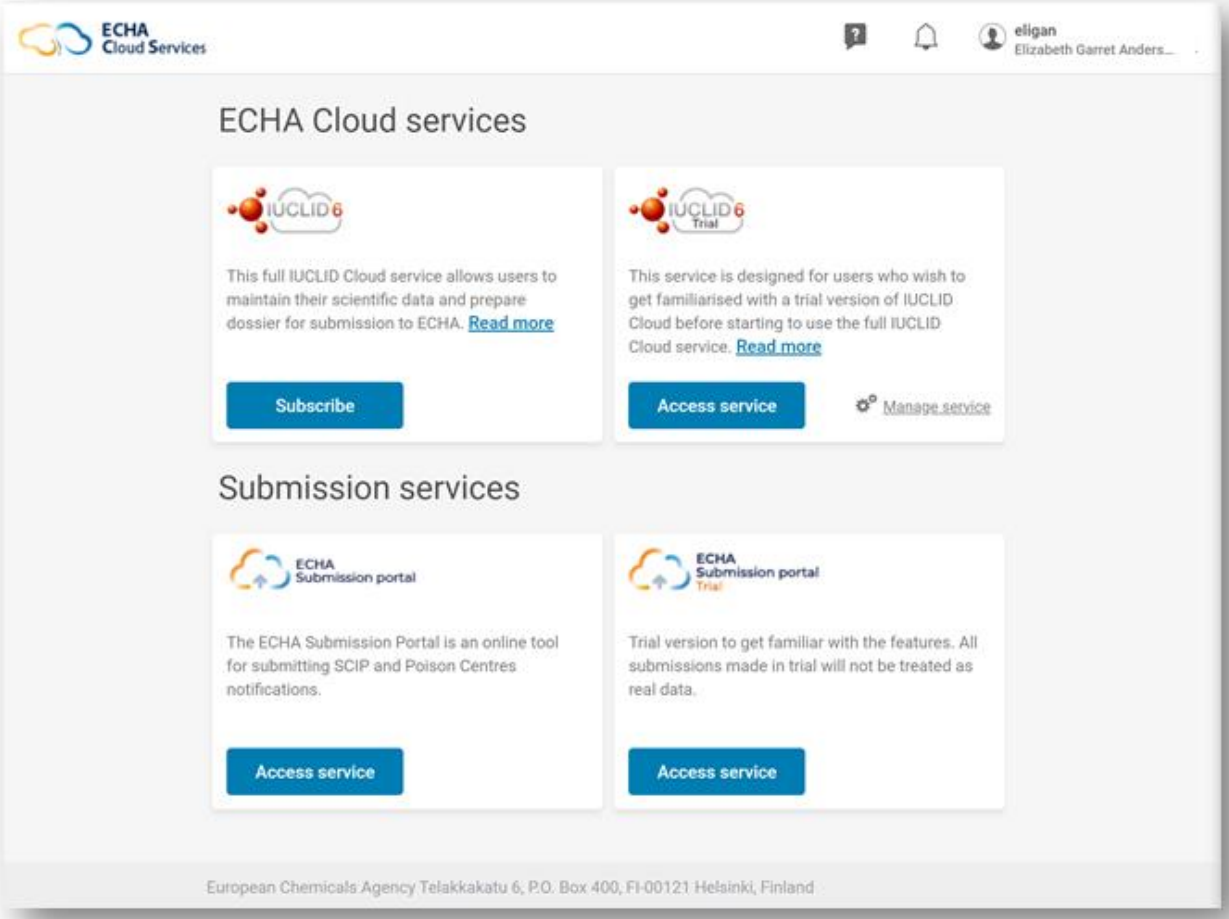


October release new features (II)

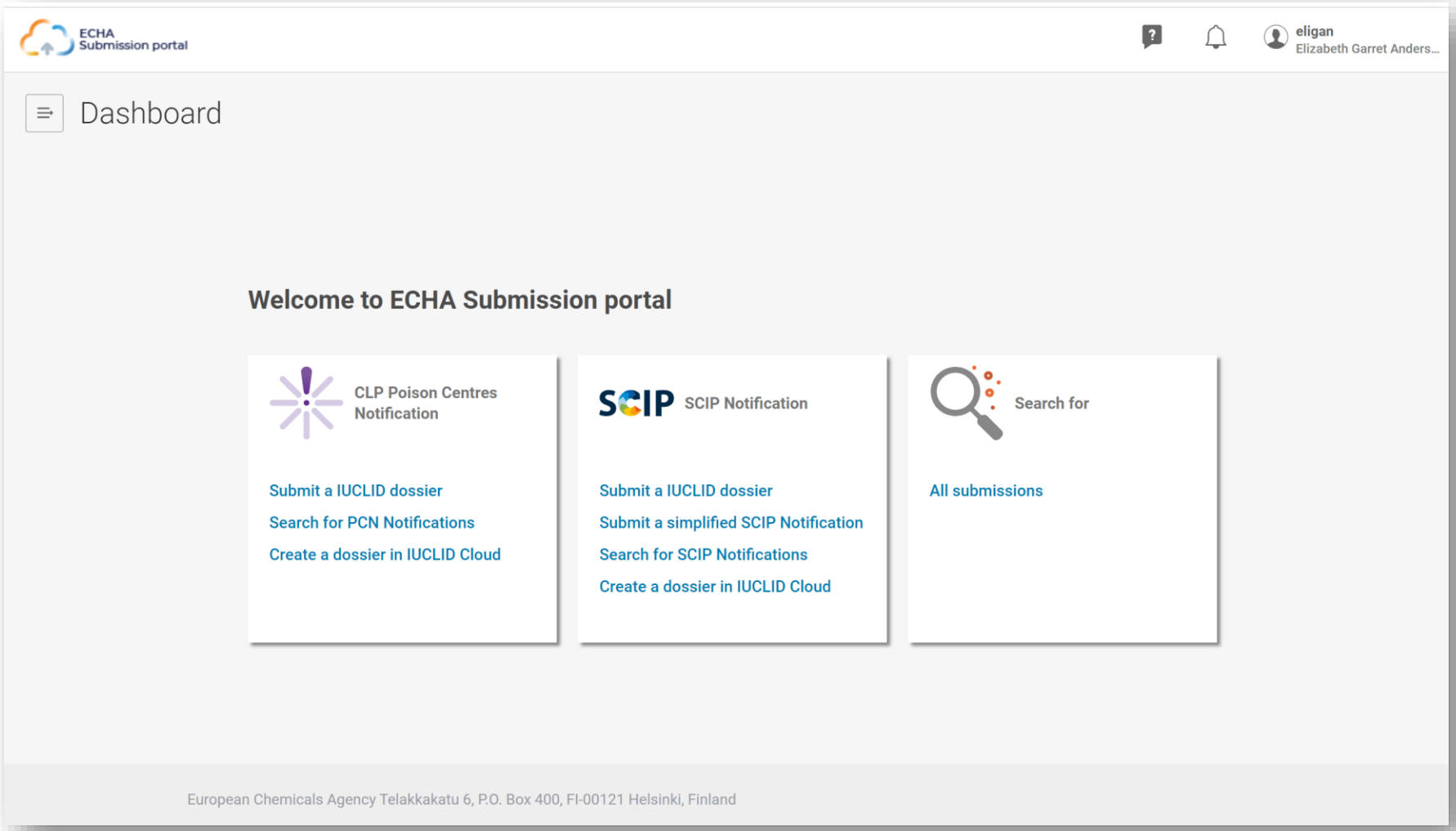
Dossier submission

- Improved ECHA Cloud services landing page
- Improved ECHA Submission portal User Interface
- New messages from authorities to industry displayed in the Submission report
- Submission report printable version
- New Terms and Conditions
- Validation rule implementation/improvement

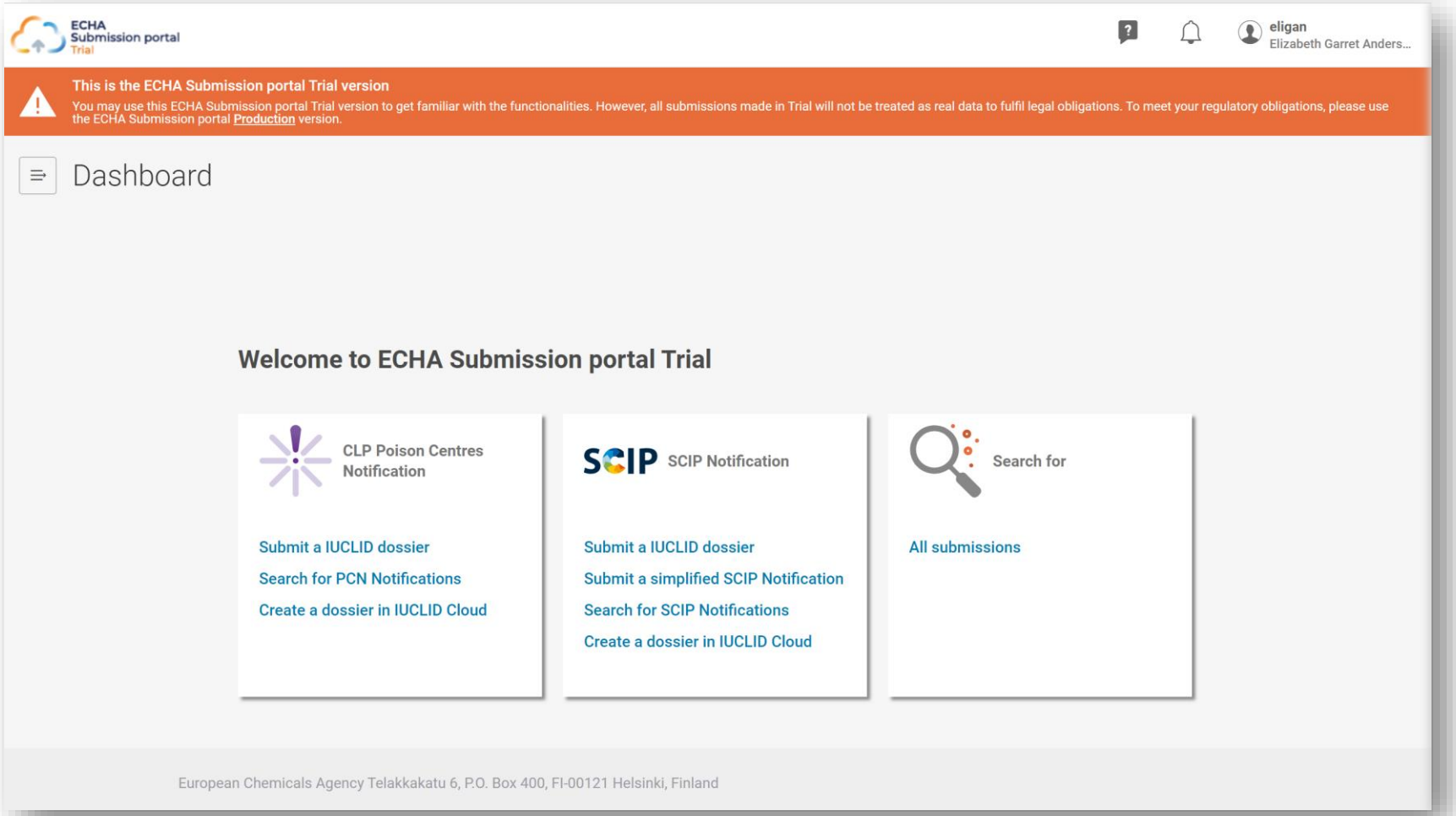
ECHA Cloud services landing page



New ECHA Submission portal user interface



ECHA Submission portal TRIAL version



New messages from AB to industry in the Submission report

- Submission events (e.g.)
  - 08/11/2020 10:51 Dossier submitted
  - 08/11/2020 10:51 Dossier passed validation checks
  - 08/11/2020 10:52 Dossier received by [country code A]
  - 08/11/2020 10:52 Dossier received by [country code B]
  - 08/11/2020 10:52 Dossier received by [country code C]

- To know whether each Appointed Body considers the dossier as "accepted", please contact them. Reference Table: Overview of Member states decisions on implementing Annex VIII to the CLP

Continuous improvement

- Release of new PCN database in November 2020
- Additional releases in 2021
  - Plan will be communicated accordingly
- We value your feedback!
  - ECHA Contact form

https://comments.echa.europa.eu/comments_cms/Contact_CLP.aspx

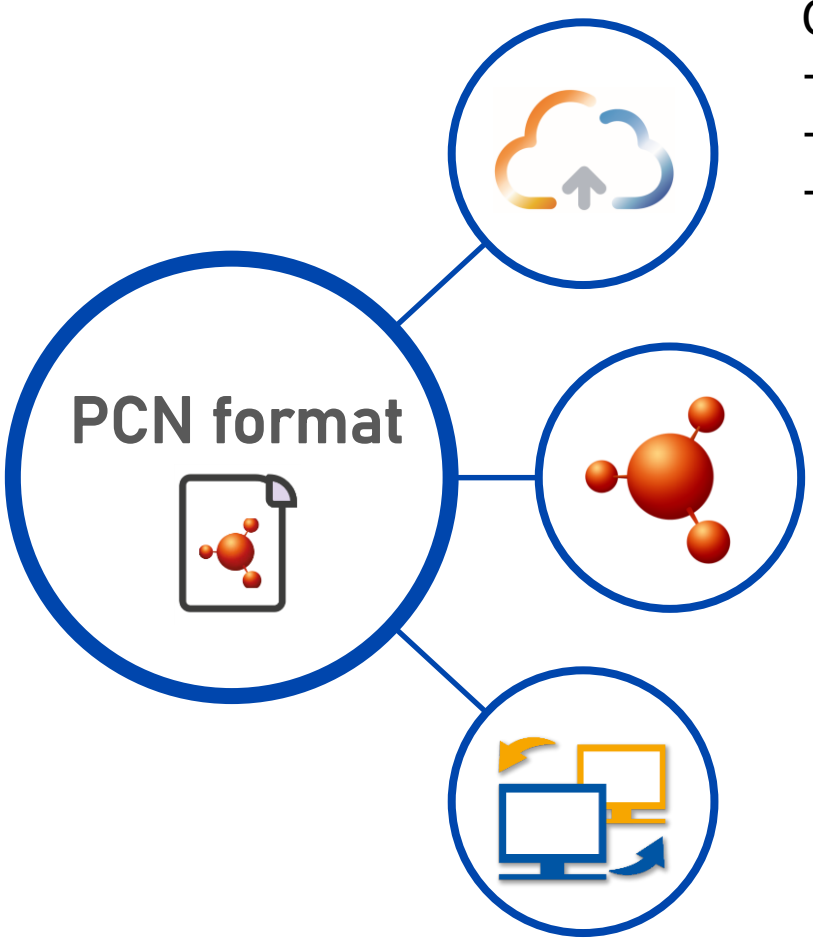
Latest developments in system to system

4 November 2020

Webinar Posion centres – closing in on the first compliance date

Stefen SUPANIC
Poison Centres Team
Submission and Processing Unit
European Chemicals Agency

Ways to prepare a PCN notification

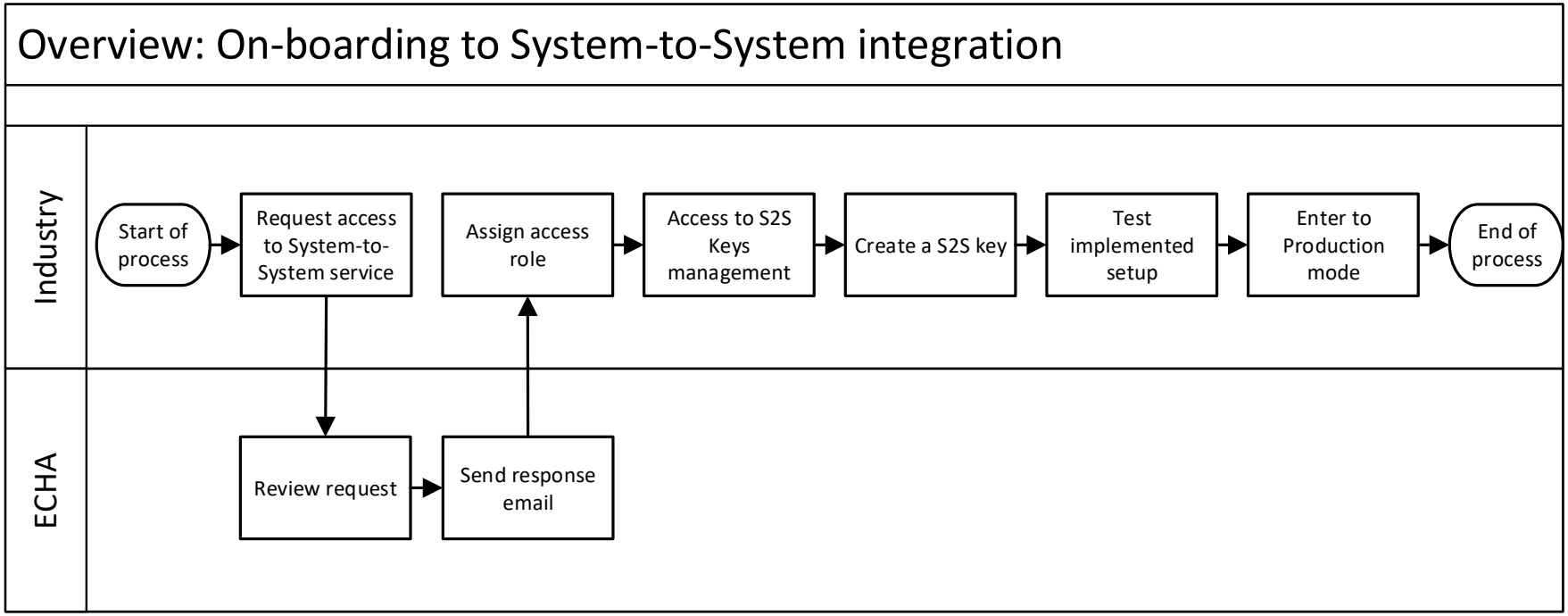


Online in ECHA Cloud service
- Maintained by ECHA
- Secure data storage
- More: https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services

Offline in IUCLID 6
- Downloaded from IUCLID website
- Desktop and server versions
- More: https://iuclid6.echa.europa.eu/

System-to-system service
- Prepared in company's system
- Automated approach
- Bulk submissions

How to get on-board?



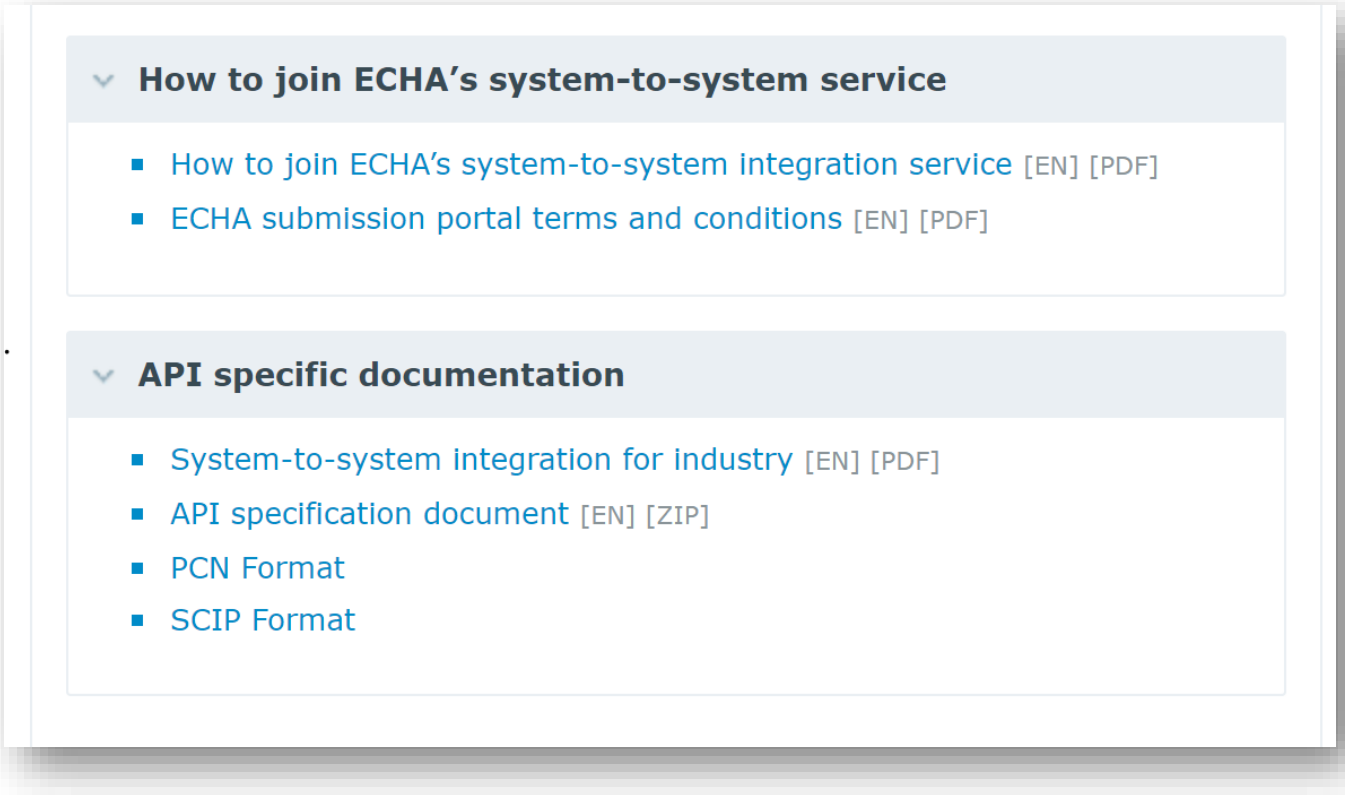
Service request

- When you ask for S2S service you may
  - Ask only for one Legal Entity
    - ECHA account username
    - Legal Entity UUID that wants to submit dossier
    - Legal Entity name
    - Software used to connect to ECHA system
  - Ask for multiple Legal Entities
    - Information about your company
    - Process you have in place to legitimate your member companies
    - Excel file containing Legal Entity name and UUI

Test Environment

- A realistic dossier submission and processing experience
- Submissions made in the context of the integration tests will not be further processed i.e. will not dispatched to the Appointed Bodies.
- See technical documentation for further information

Documentation



https://echa.europa.eu/de/manuals?panel=s2s#s2s

Summary

- S2S is an automatic way of submitting to ECHA
- Documentation: https://echa.europa.eu/de/manuals?panel=s2s#s2s
- Access requests and support questions via ECHA's contact form: https://echa.europa.eu/contact

Validation rules – tips for a successful submission

4 November 2020

Webinar Posion centres – closing in on the first compliance date

Saara SUMIALA
Data Quality team
Data Availability Unit
European Chemicals Agency

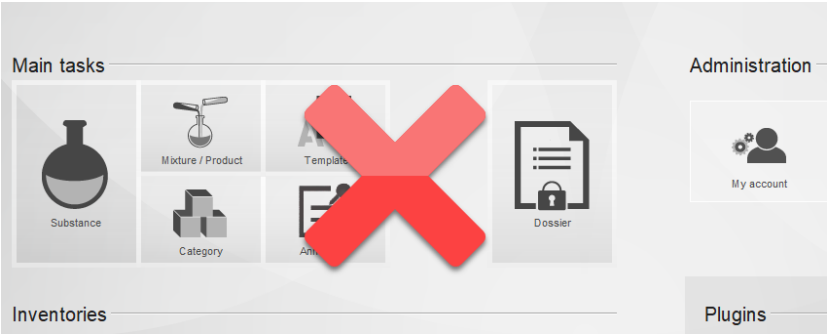
Covered today…

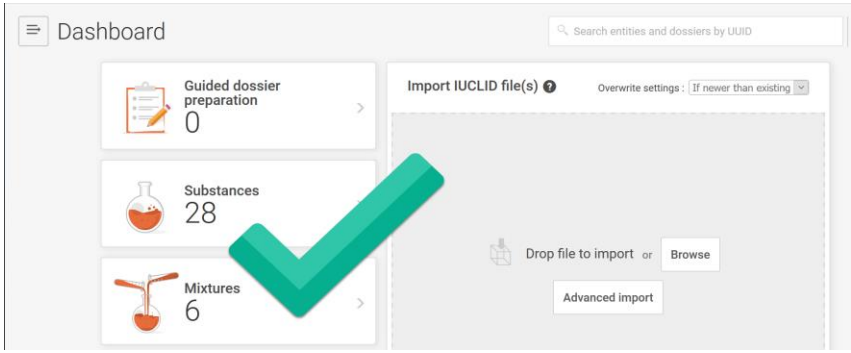
- Tips how to fix Validation rule failures
- Three most common questions in Helpdesk
- October 2020 changes
- Help

Tips how to fix Validation rules

Validation rules - tips

- Use the latest version of IUCLID.
  - IUCLID Cloud is automatically updated to the latest version
  - IUCLID Standalone latest version was released October2020 (IUCLID6.5)
  - 'Classical' IUCLID interface does not have language specific fields





Validation rules - tips

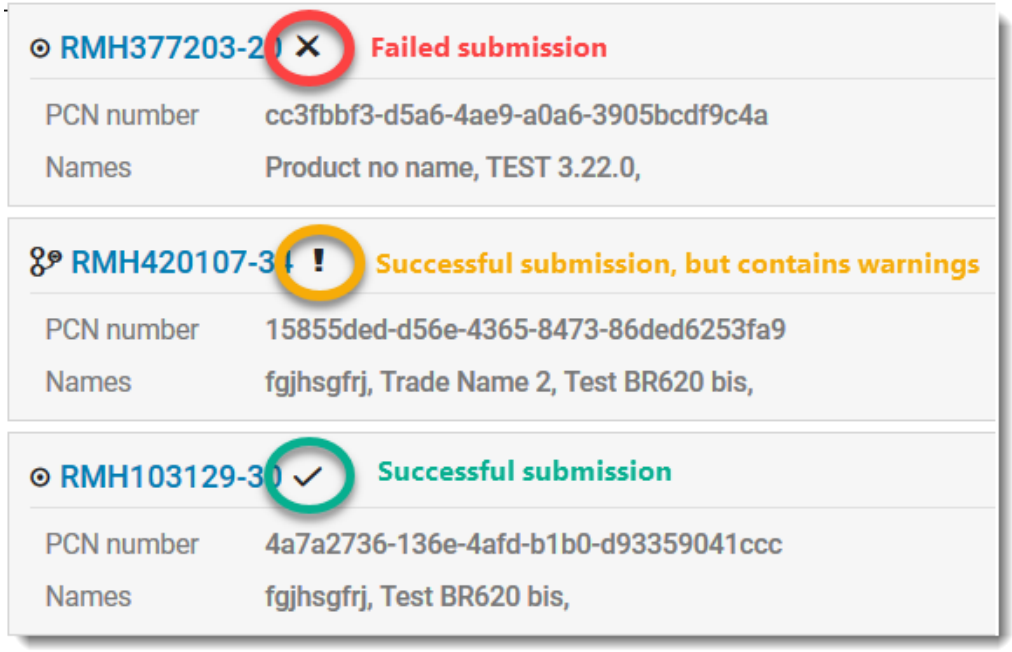
IUCLID validation rules

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

ECHA submission portal rules (‘contextual rules’)

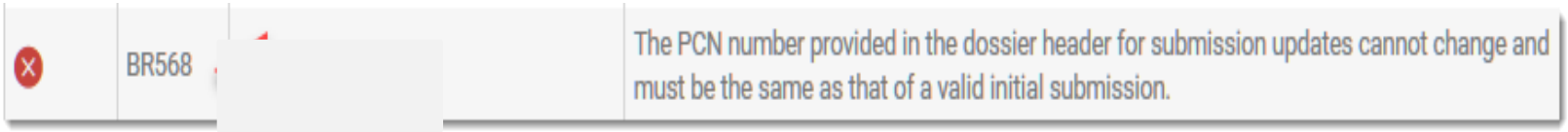
* Checked upon submission to Portal

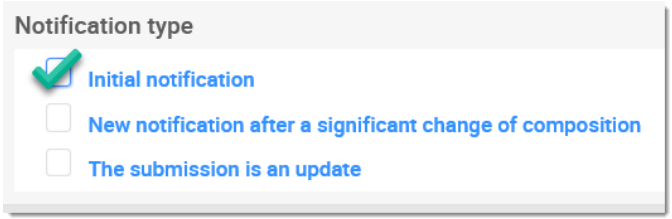
Validation rules - tips



3 most common topics in HelpDesk questions

[BR568]





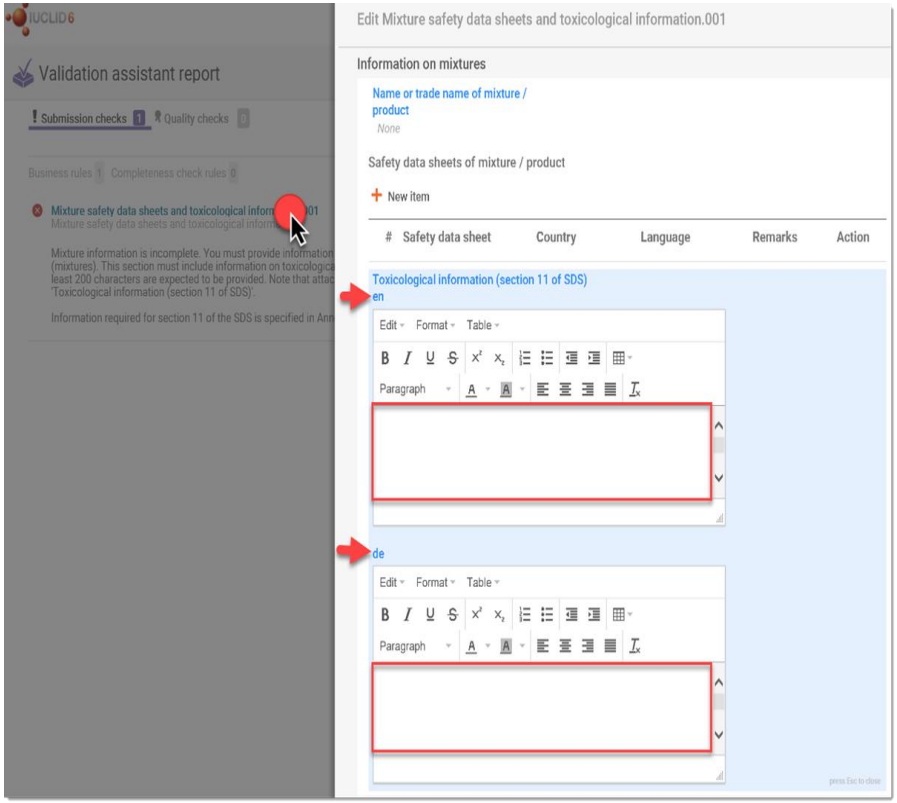
If your first 'Initial notification' failed rules upon submission to Portal, then the next dossier has to be marked as 'Initial notification' as well (not 'The submission is an update').

[BR538]

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

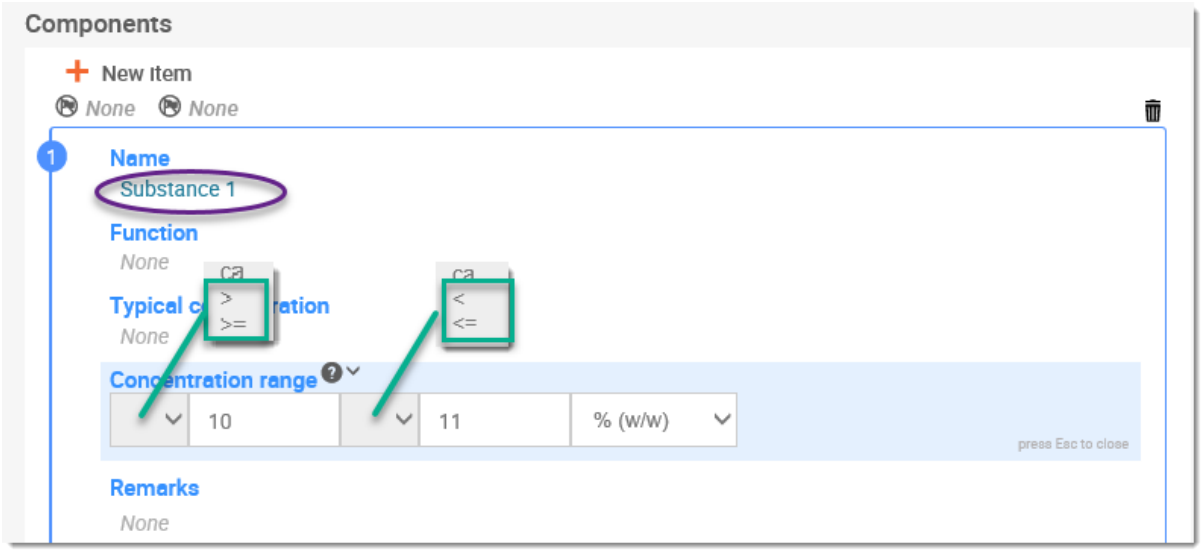
Languages are specified in dossier header.

Each language specific field must be filled in.



[BR625]

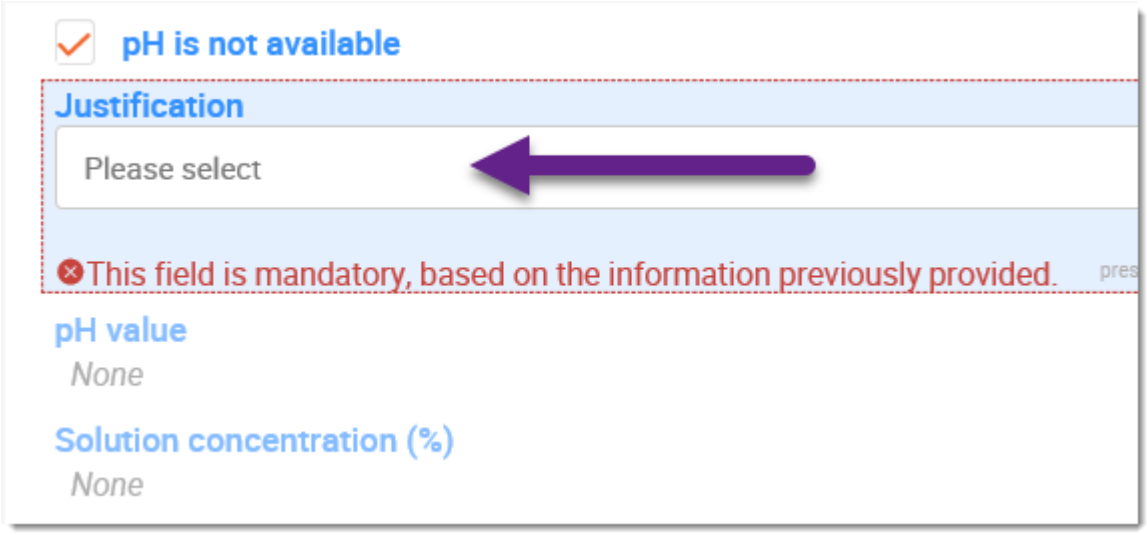
'**Qualifiers**' must be provided for concentration range.



Latest changes

BR621 *new*

If '**pH not available**' was indicated then '**Justification**' must be included.



[BR633] *new*

Exactly one '**Classification and labelling information**' record must be provided for each '**Substance**' component included in 'Mixture' **(MiM).**

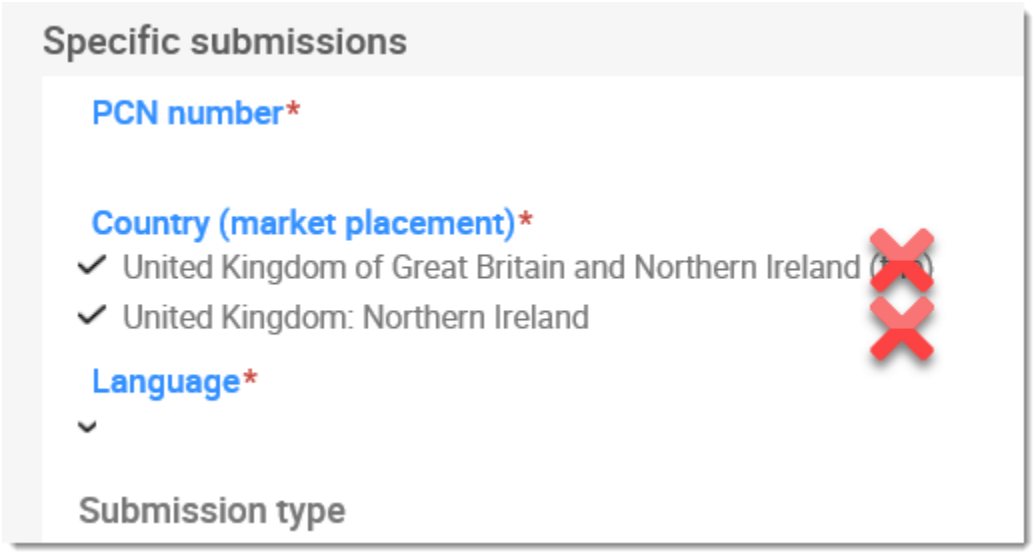
[BR632] *new*

'**Country** (market placement)' indicated in dossier header cannot be:

- 'United Kingdom of Great Britain and Northern Ireland'

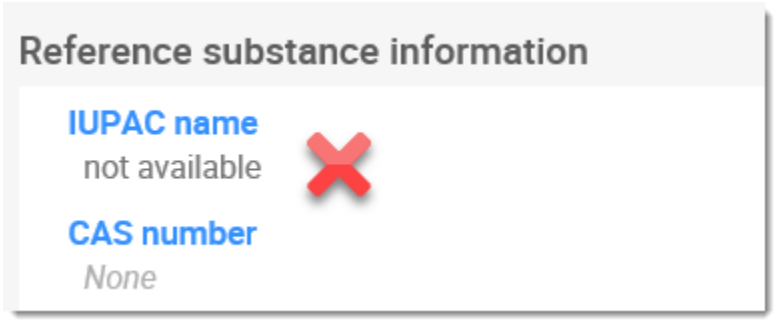
  or

- 'United Kingdom: Northern Ireland



[QLT634] *new*

The provided '**IUPAC name/International chemical name**' should be meaningful.

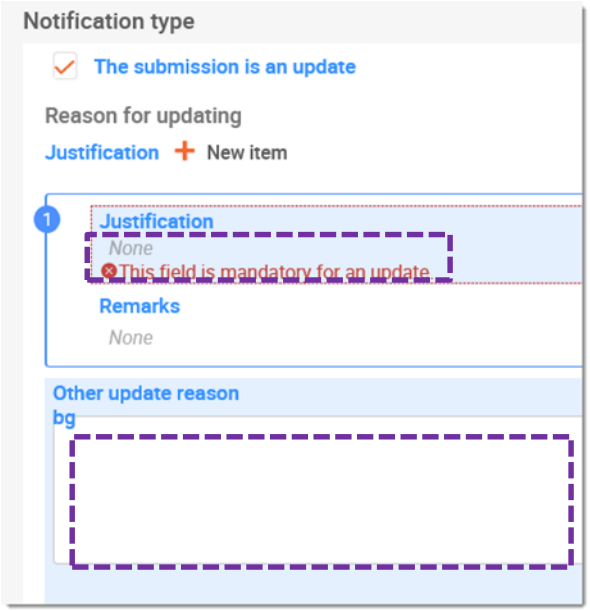


[QLT635] *new*

The provided '**Substance name**' should be meaningful.

[BR543] *modified*

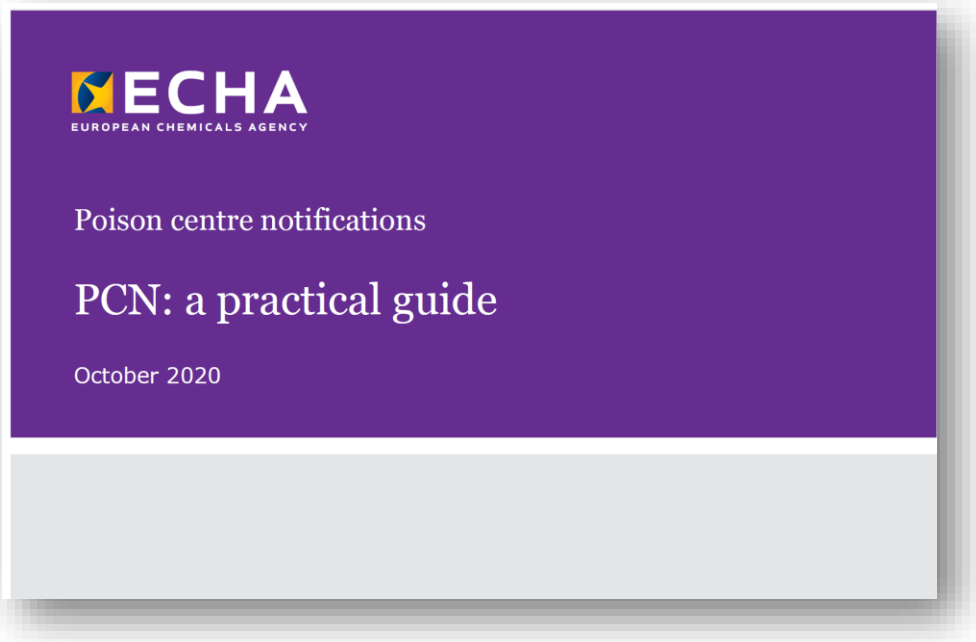
If 'Notification type' is indicated to be '**The submission is an update**' then reason for updating must be provided by either selecting '**Justification**' from dropdown list and/or providing explanation in all the relevant languages in the field(s) for '**Other update reason**'.



Help

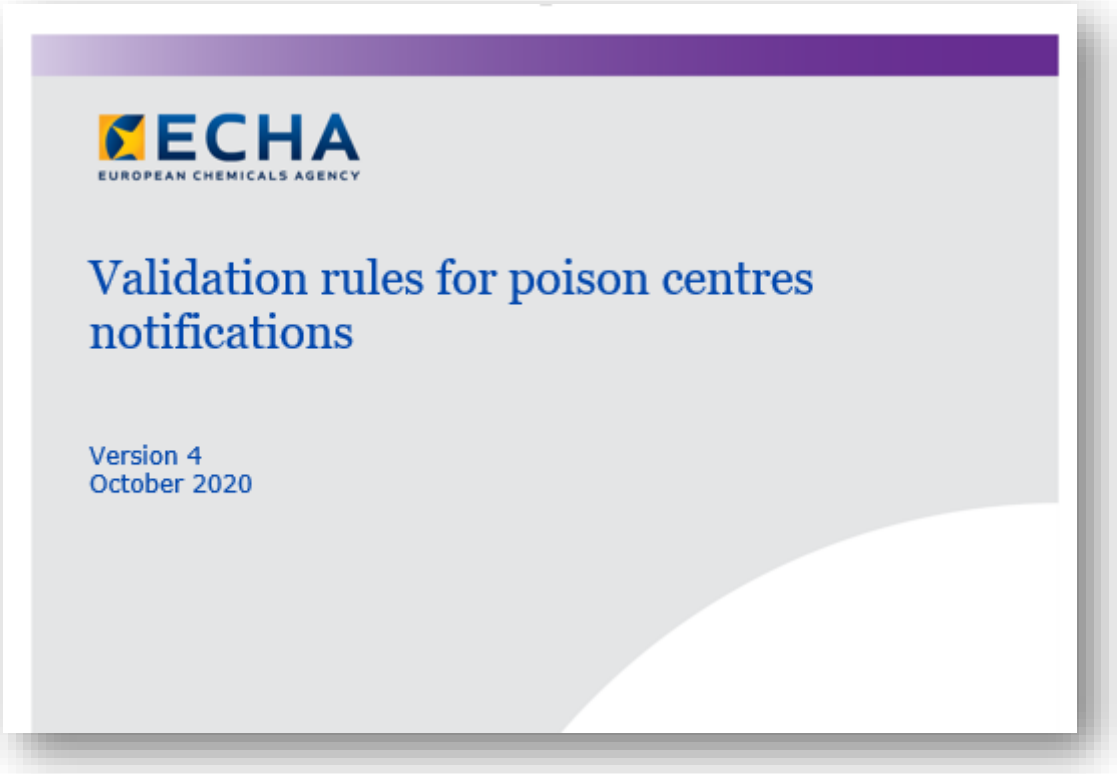
Help – ‘PCN: a practical guide’

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



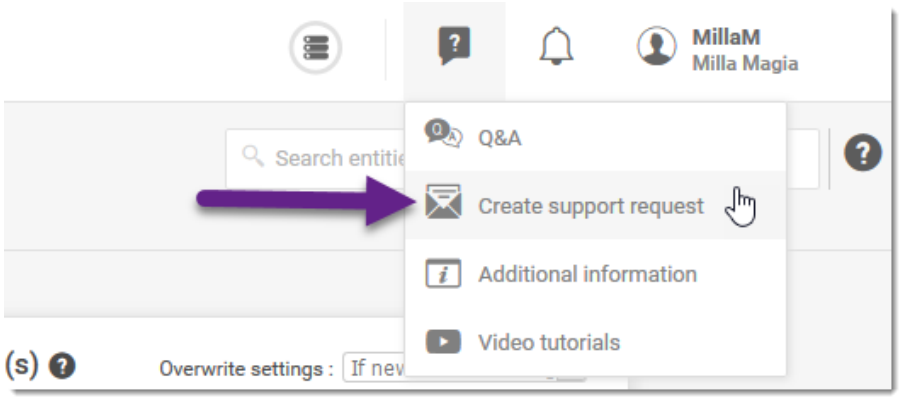
Help – List of Validation rules

https://poisoncentres.echa.europa.eu/poison-centres-notification-format

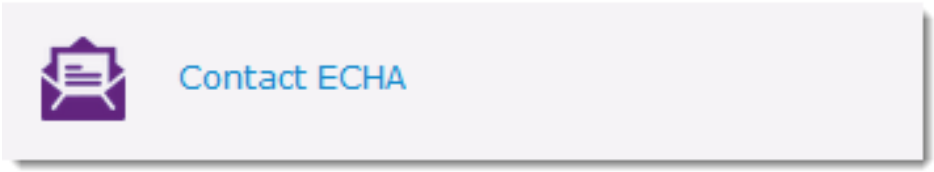


Help – HelpDesk

Directly from IUCLID Cloud or ECHA Submission Portal:



Via ECHAs webpage:
https://poisoncentres.echa.europa.eu/support



Help – HelpDesk

- Include information which system you are using:
  - IUCLID Cloud
  - IUCLID standalone (desktop version), include also version number
  - System to system
  - other software

- Indicate the rule number that you have question (e.g. **BR562**)

- If you have already sent the notification to Portal, indicate the submission number (e.g. RMH37723-20)
- If you have not yet sent the notification then include information how you have filled in the relevant information (e.g. screen shots(s), PDF)

Guidance and support – What you need to know

4 November 2020

Webinar Posion centres – closing in on the first compliance date

Pedro ROSELLÓ VILARROIG
Poison Centres Team
Submission and Processing Unit
European Chemicals Agency

Relevant ECHA Guidance

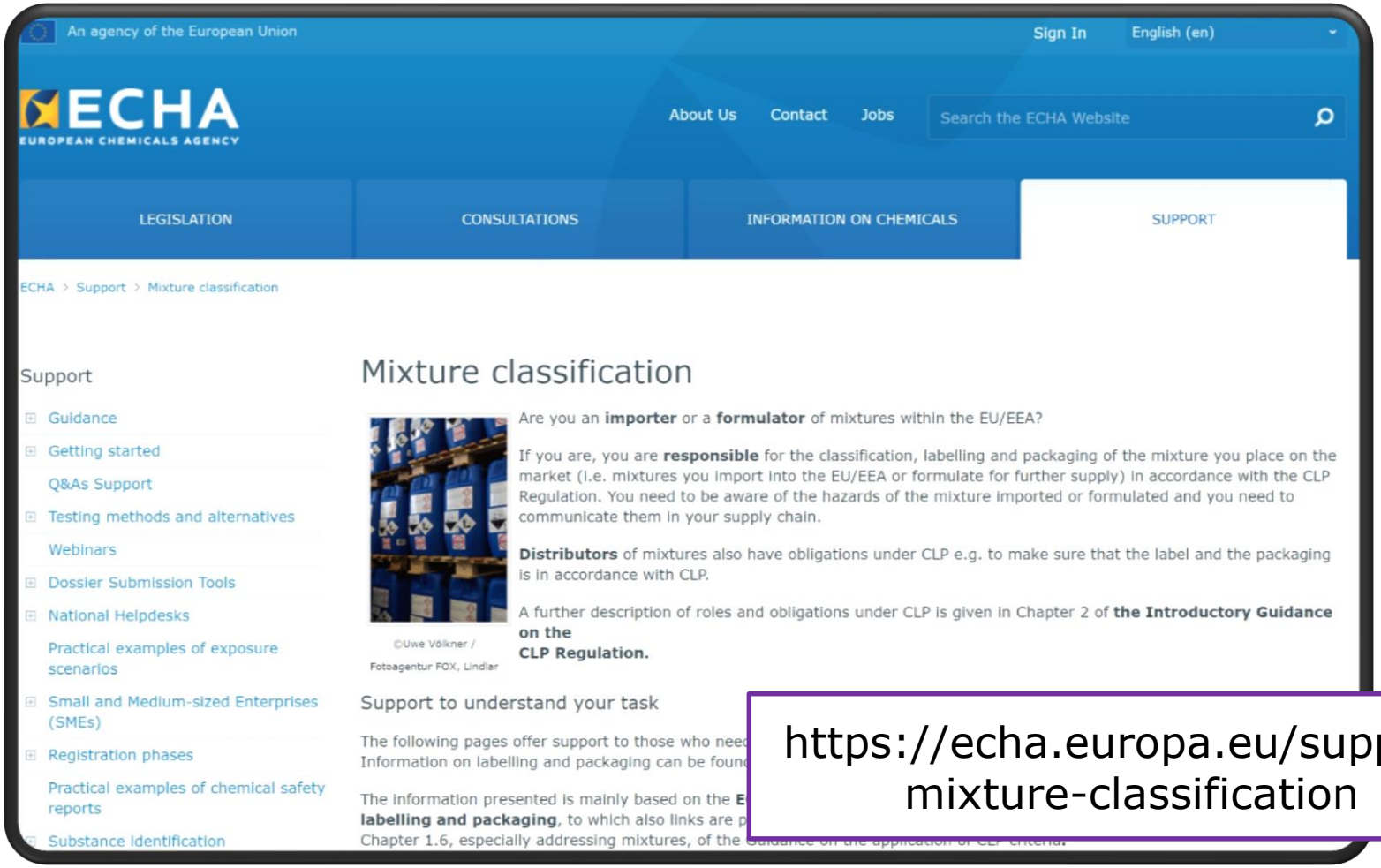
- Guidance on harmonised information relating to health emergency response (Annex VIII)
- V 3.0 – translations already available
- V 4.0 – expected by 2021. PEG consultation ongoing: drafts available in website

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

Classification and labelling

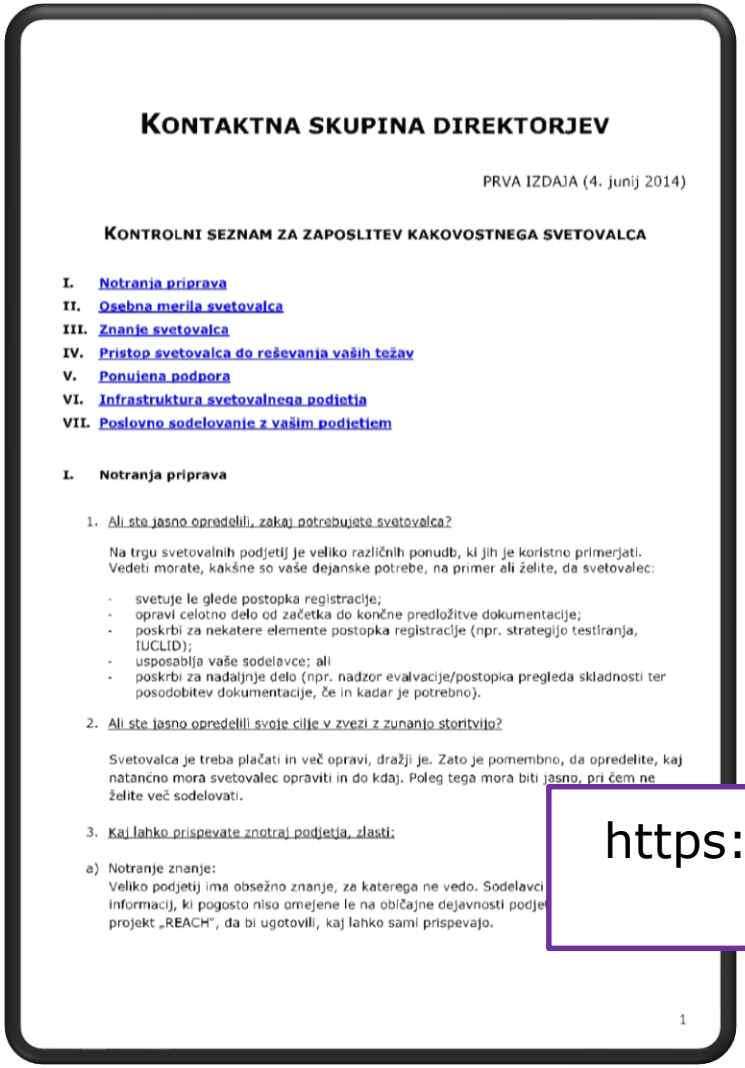
- **Introductory** guidance on the CLP Regulation
- Guidance on the application of the **CLP criteria**
- Guidance on **labelling and packaging** in accordance with CLP
  - Under revision

Classification of mixtures



https://echa.europa.eu/support/mixture-classification

Check list to hire a good consultant



KONTAKTNA SKUPINA DIREKTORJEV

PRVA IZDAJA (4. junij 2014)

KONTROLNI SEZNAM ZA ZAPOSLITEV KAKOVOSTNEGA SVETOVALCA

I. Notranja priprava
II. Osebna merila svetovalca
III. Znanje svetovalca
IV. Pristop svetovalca do reševanja vaših težav
V. Ponujena podpora
VI. Infrastruktura svetovalnega podjetja
VII. Poslovno sodelovanje z vašim podjetjem

I. Notranja priprava

1. Ali ste jasno opredelili, zakaj potrebujete svetovalca?

Na trgu svetovalnih podjetij je veliko različnih ponudb, ki jih je koristno primerjati. Vedeti morate, kakšne so vaše dejanske potrebe, na primer ali želite, da svetovalec:

- svetuje le glede postopka registracije;
- opravi celotno delo od začetka do končne predložitve dokumentacije;
- poskrbi za nekatere elemente postopka registracije (npr. strategijo testiranja, IUCLID);
- usposablja vaše sodelavce; ali
- poskrbi za nadaljnje delo (npr. nadzor evalvacije/postopka pregleda skladnosti ter posodobitev dokumentacije, če in kadar je potrebno).

2. Ali ste jasno opredelili svoje cilje v zvezi z zunanjo storitvijo?

Svetovalca je treba plačati in več opravi, dražji je. Zato je pomembno, da opredelite, kaj natančno mora svetovalec opraviti in do kdaj. Poleg tega mora biti jasno, pri čem ne želite več sodelovati.

3. Kaj lahko prispevate znotraj podjetja, zlasti:

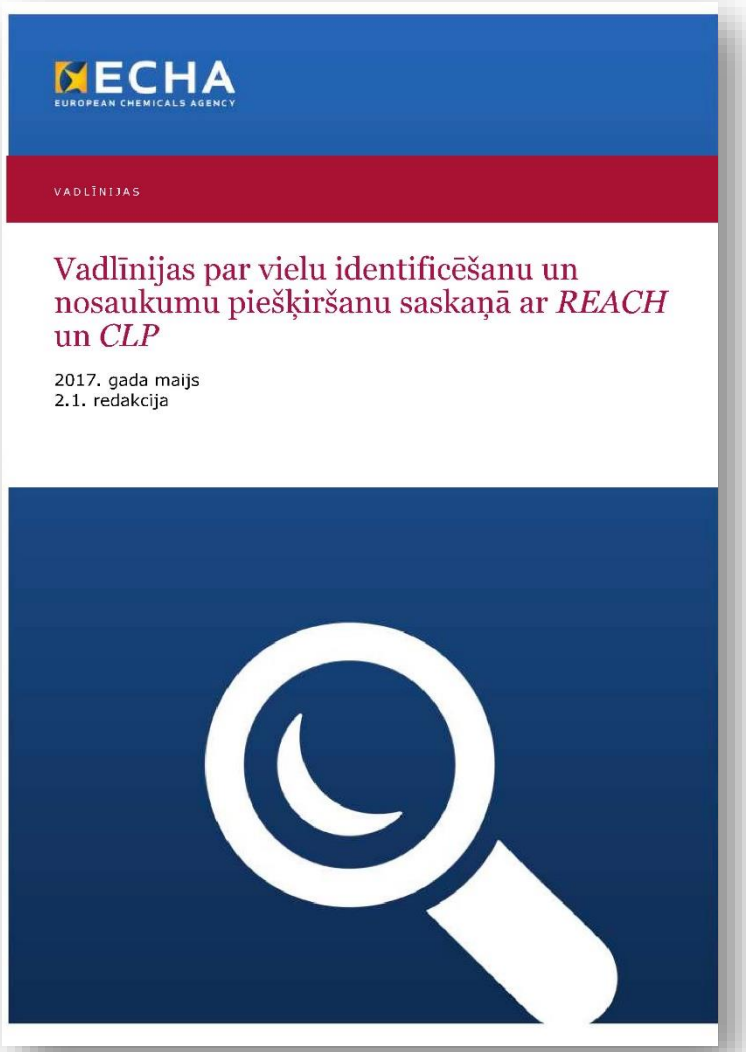
a) Notranje znanje:
Veliko podjetij ima obsežno znanje, za katerega ne vedo. Sodelavci informacij, ki pogosto niso omejene le na običajne dejavnosti podje projekt „REACH", da bi ugotovili, kaj lahko sami prispevajo.

1

- Developed by Directors' Contact Group in the context of REACH registration deadlines
- Still valuable for SME when looking for new consultant

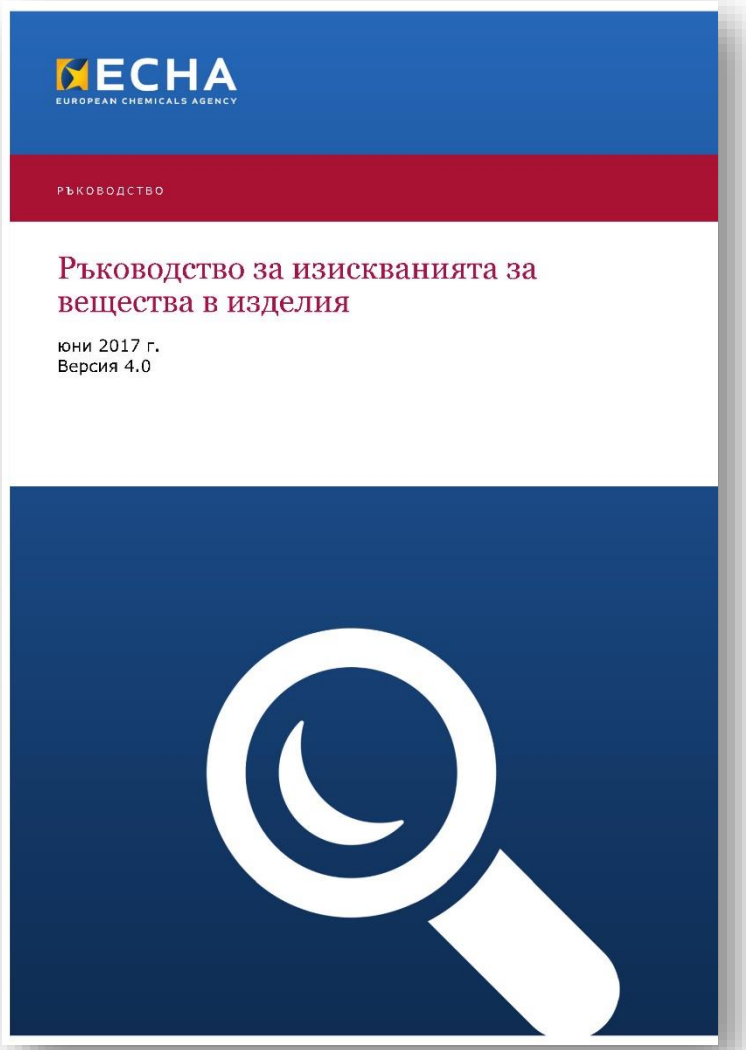
https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group

Substance identification



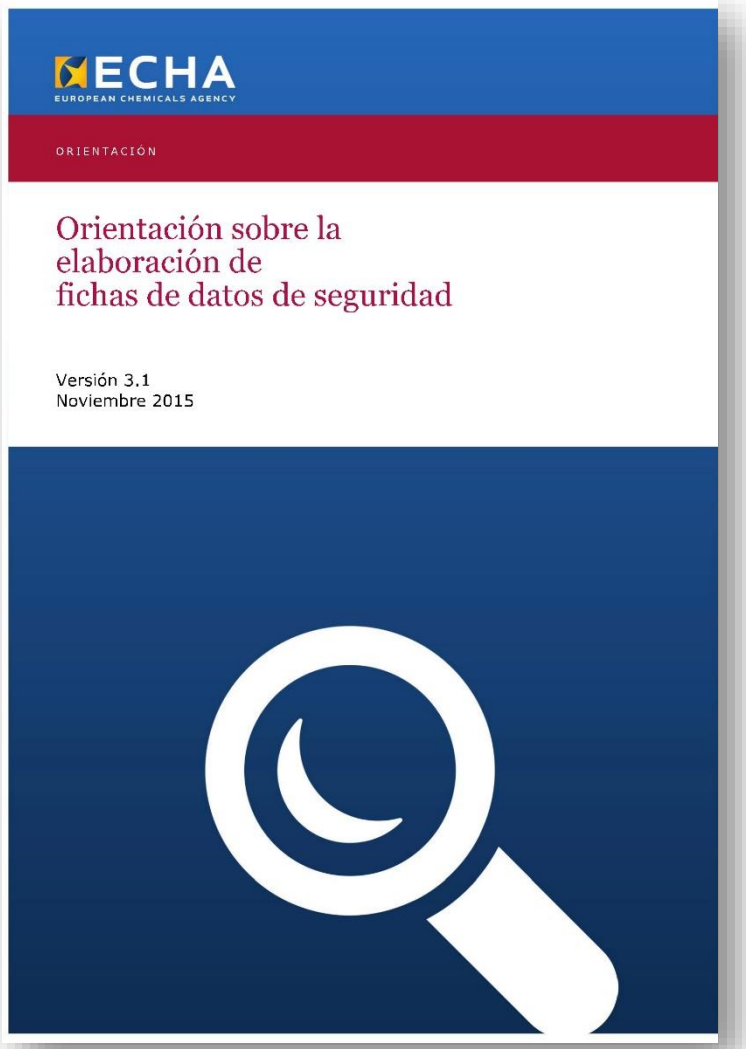
- Guidance for identification and naming of substances under REACH and CLP
- Mono and multi-constituents
- UVCB

Substances in articles



- Guidance on requirements for substances in articles
- PCN obligations apply to combination of mixtures and articles!

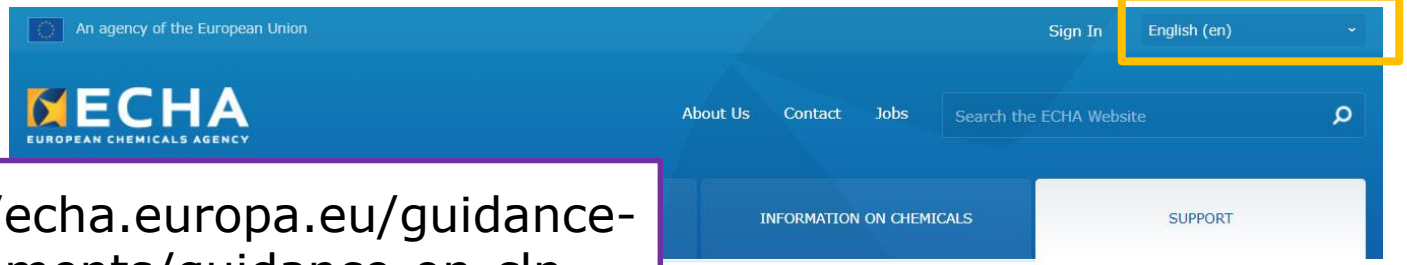
Safety data sheets



- Guidance on the compilation of safety data sheets
- Section 3: Composition
- Section 11: Toxicological information
- Under revision

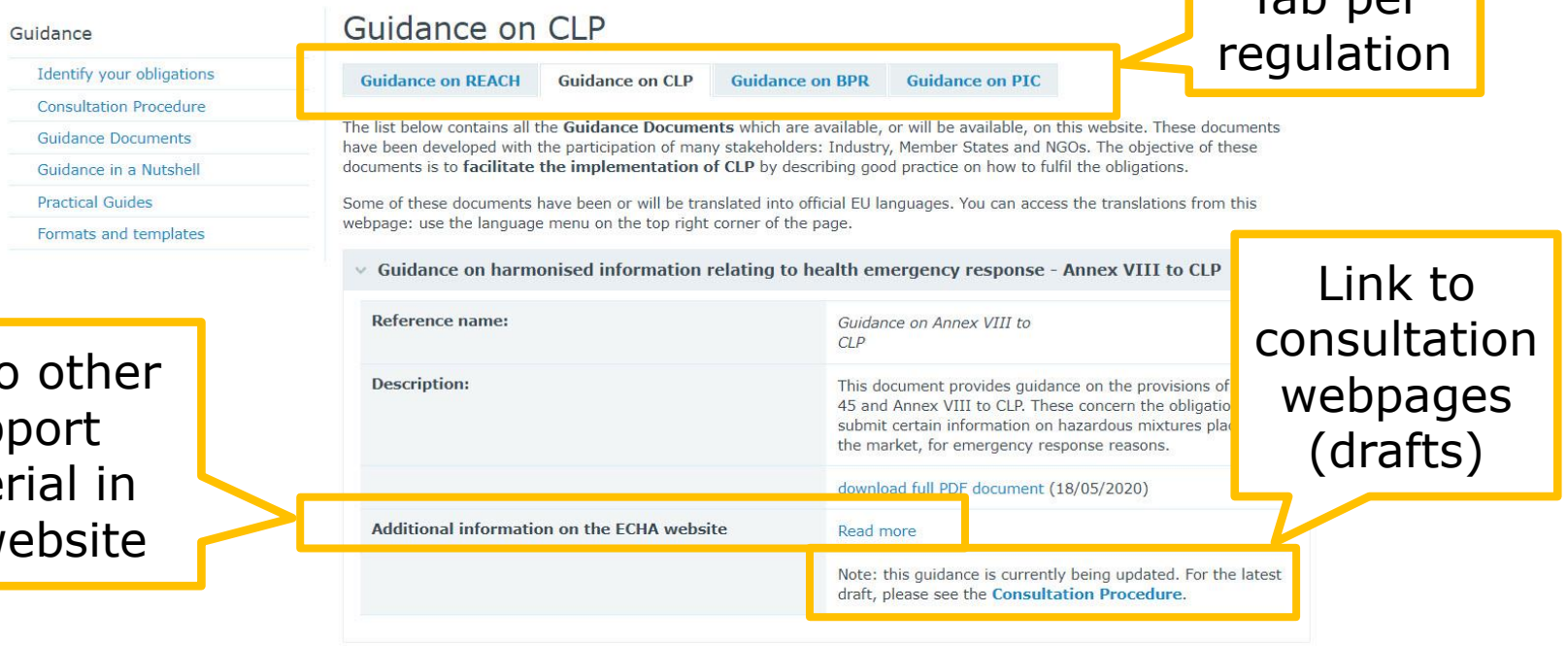
Other related support

Choose here your language for the webpage and the guidance document



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

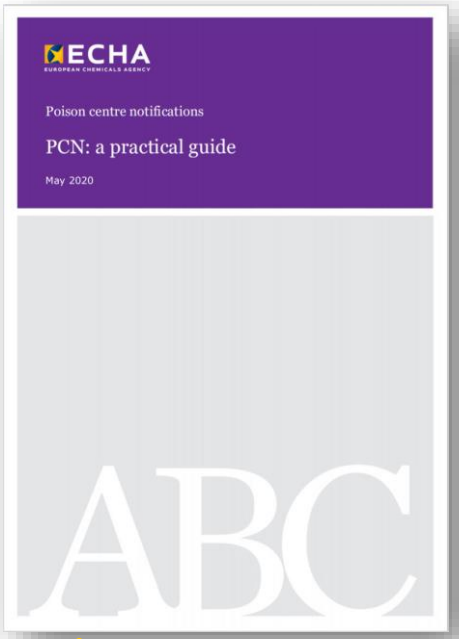
Tab per regulation



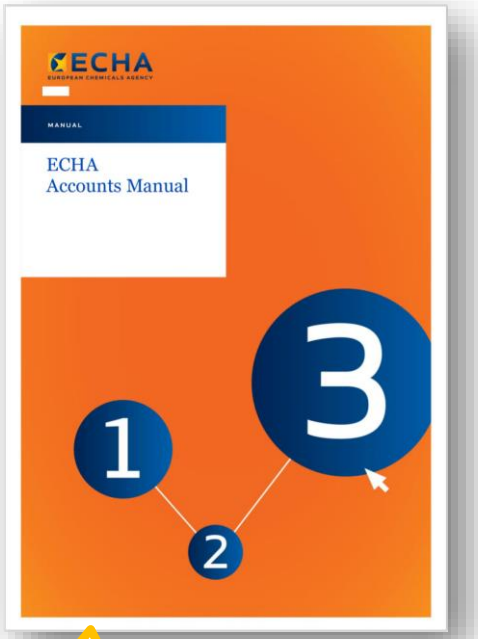
Link to other support material in our website

Link to consultation webpages (drafts)

Sources of information for IT tools

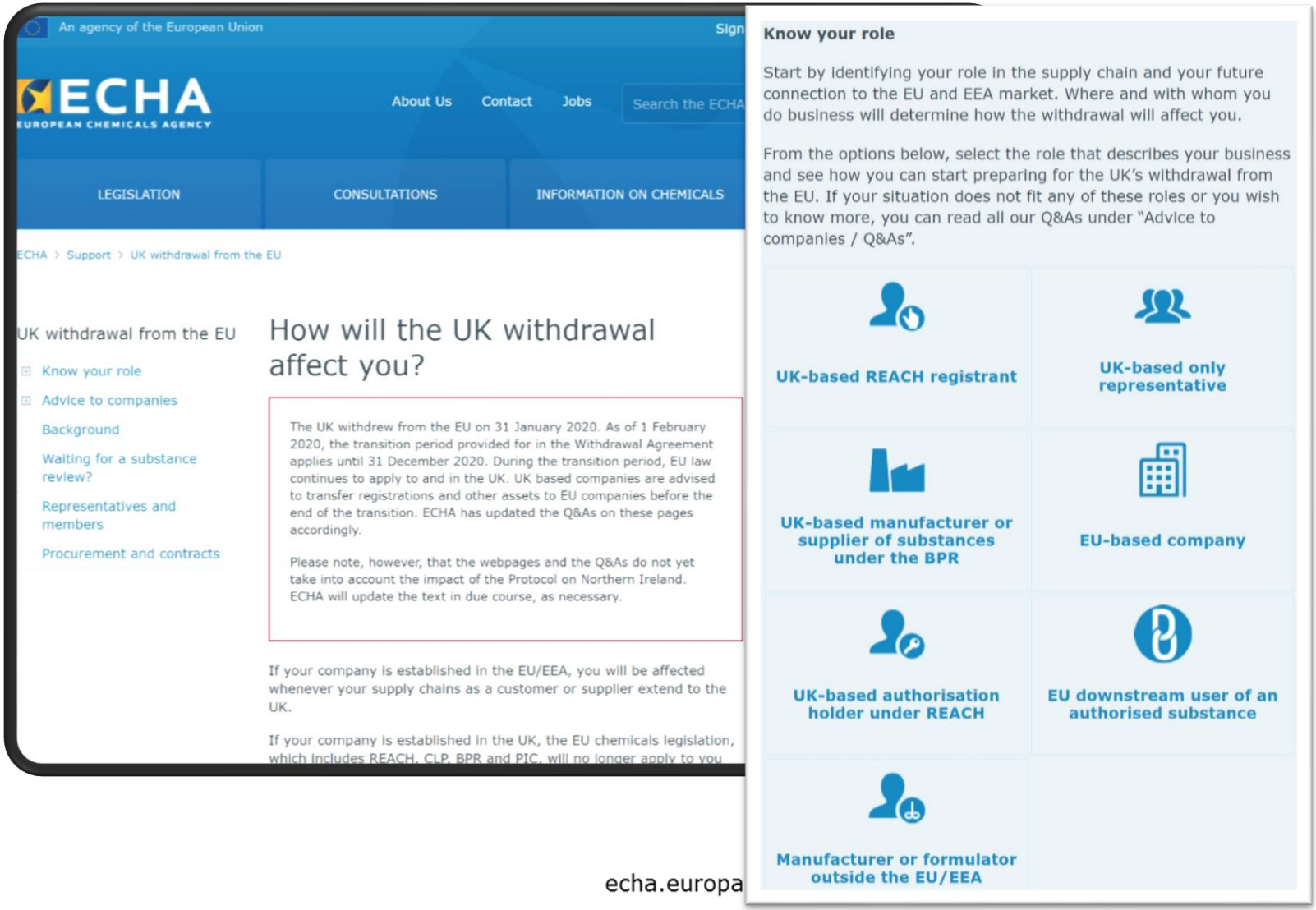


When using IUCLID



Any account with ECHA tools

UK withdrawal from the EU



Hot topics - support and practical advice

4 November 2020

Webinar Posion centres – closing in on the first compliance date

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

Your questions…

- Transition period
- Submissions before the compliance date
- EU importers & non-EU suppliers
- Legal entity changes
- UK withdrawal and handling of notifications

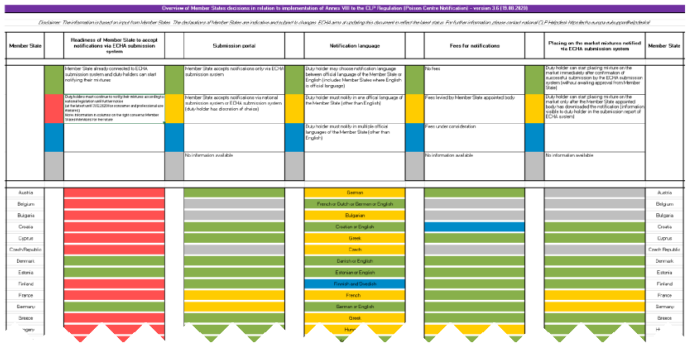
Transition period

- The notifier can only benefit from the transition period in a Member State when there
  - exists a valid notification for that Member State, and
  - have been no changes (listed in Part B section 4.1 Annex VIII) made to the original notification
- Benefitting means that you do not need to immediately comply with harmonised reporting or relabelling with UFI.
- Transition period ends 1st January 2025 – all mixtures notified in the harmonised format by then
- In some Member States, mixtures have been successfully notified according to national legislation via ECHA Portal –
  - the notification met the harmonised format requirements
  - benefit with respect to timing for placing the UFI on the label

Submitting before compliance date

- Before the compliance date, national obligations apply
- Submissions to Member States not connected will remain in the database **BUT** not fulfil any legal requirements (nor benefit from the transition period).
- Submission report indicates 'Submission events' when *Dossier received by [country code]* = entered the database and available **BUT**

➡ in terms of placing on the market - check the 'Overview of Member States' table to see if the Member State is accepting.



https://poisoncentres.echa.europa.eu/appointed-bodies

Facts about non-EU companies

- No obligations under CLP and subsequently Article 45
- Can hold an ECHA Account and prepare information in IUCLID
- Cannot submit in the ECHA Submission portal
- Can support the EU importer by
  - Providing importer information for their submission
  - Working as a foreign user on importer's behalf
  - CBI concerns? Work-around covered in the Annex VIII Guidance https://echa.europa.eu/guidance-documents/guidance-on-clp

EU importer / non-EU supplier

- The non-EU supplier notifies through an EU-based legal entity – agreement process outside ECHA's remit
  - ensure careful management of the UFI – it can be generated by either party using the VAT or without the VAT. UFI could also be provided by the EU importer.

- The EU-based legal entity
  - creates their own ECHA Account
  - preparation of datasets by either party
  - 'voluntary' submission by EU-based legal entity

EU importer / non-EU supplier

- EU importer is kept informed e.g.
  - which Member States notified
  - UFI communicated
  - if any changes occur to the mixture

- The EU importer fulfils Article 45 obligations
  - generates own UFI
  - refers to the previously submitted UFI in the composition as full composition (100% MiM) or a component (<100% MiM)
  - and makes a required submission

The EU importer remains the duty holder and responsible for the information provided in the notification

Legal entity changes

- Notifications submitted through the ECHA Portal cannot be transferred to another EU Legal Entity e.g. in the case of legal entity changes, merger or split
- 'New' legal entity needs to submit the information as an 'Initial notification'.
- Possible that datasets can be copied and shared to ease administrative burden

  ! The 'new' legal entity's UUID has to replace the previous legal entity's UUID (in the Main mixture identity)

- "PCN: a practical guide" available here https://poisoncentres.echa.europa.eu/documents/22284544/22295820/pcn_practical_guide_en.pdf/).

UK withdrawal

- Transition period provided for in the Withdrawal Agreement applies until 31 December 2020
- Protocol on Ireland and Northern Ireland will apply from 1 January 2021
- CLP Regulation will continue to apply to UK(Northern Ireland)
- Companies should follow the developments of UK national legislation on hazardous chemicals to understand their obligations when placing on the market in the UK https://www.hse.gov.uk/
- UK withdrawal website updated soon for PCN https://echa.europa.eu/uk-withdrawal-from-the-eu

Handling of notifications

- From January 2021 EU companies need to submit own notification before they import mixtures from the UK(Great Britain)
  - They are now duty holders and cannot rely on the notification made by the UK(GB) supplier
- UK(Northern Ireland) companies can submit notifications through ECHA Submission Portal to EU/EEA authorities: new legal entity must be created first!
- Notifications to UK(Northern Ireland) market area must be submitted directly to UK(Northern Ireland) authorities – not possible through the Portal
- UK companies maintain access to the datasets already created in the Cloud service

Ask for support

- National Helpdesk echa.europa.eu/support/helpdesks
- ECHA Helpdesk echa.europa.eu/contact/clp
- Nationally appointed bodies
  https://poisoncentres.echa.europa.eu/appointed-bodies
- Join our ever growing LinkedIn community!
  https://www.linkedin.com/groups/12364138/

Take home messages

Take home messages

- IT tools support solutions provided for in the 2nd amendment! Get familiar with the changes - use our testing environment and visit our support pages for upcoming tutorials and updated guides.
- Compliance dates ≠ deadlines. Current (national) obligations continue to apply.
- Check which Member States are receiving Annex VIII notifications - keep informed

Take home messages (2)

- Things are changing - know your role and obligations
- ECHA and Poison Centre websites should be your first point of reference – make use of the wealth of material available
- Stay tuned for news and updates – join our LinkedIn community!
- ECHA and National Helpdesks are here to support you – ask us if something is not clear!

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