

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](https://www.slido.com)
Event code:
- 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



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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.

REACH 2018	Upcoming	2017	2016	2015	2014	2013	2012	2011	All Webinars
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Annex VIII – 2nd amendment solutions

4 November 2020

Webinar Poison centres – closing in on the first compliance date

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.



Name type
Standard formula (SF)

Name

Please select

- Gasoline EN228 [Automotive fuels - Unleaded petrol]
- Gasoline E85 [Automotive fuels - Ethanol (285) automotive fuel]
- Gasoline alkylate [Motor fuels - special petrol for powered implements]
- LPG [Liquefied Petroleum Gas used as fuel]

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%)

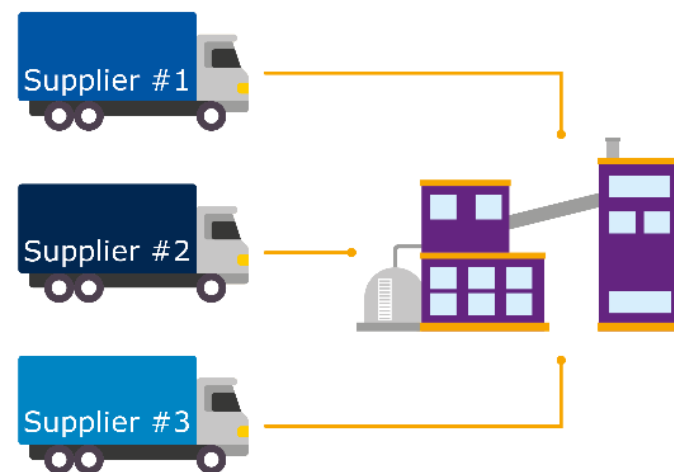


Cross sector use - interchangeable component groups

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

4 November 2020

Webinar Poison centres – closing in on
the first compliance date

Claudia RIMONDO

Poison Centres Team

Submission and Processing Unit

European Chemicals Agency

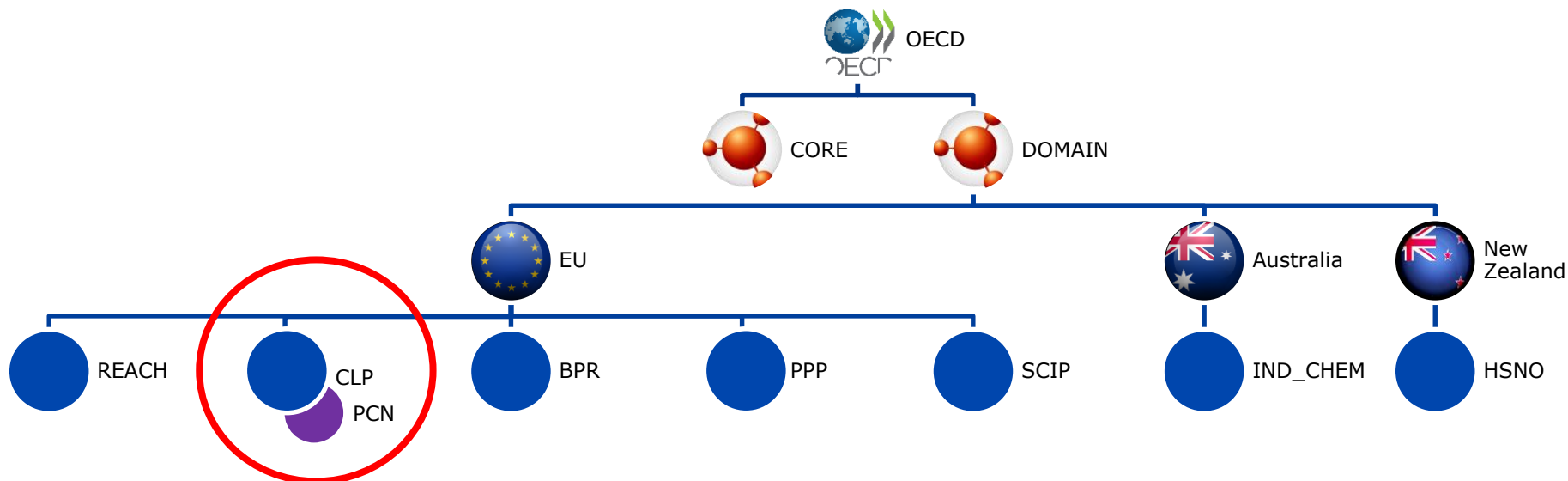


2020 release timeline



- 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

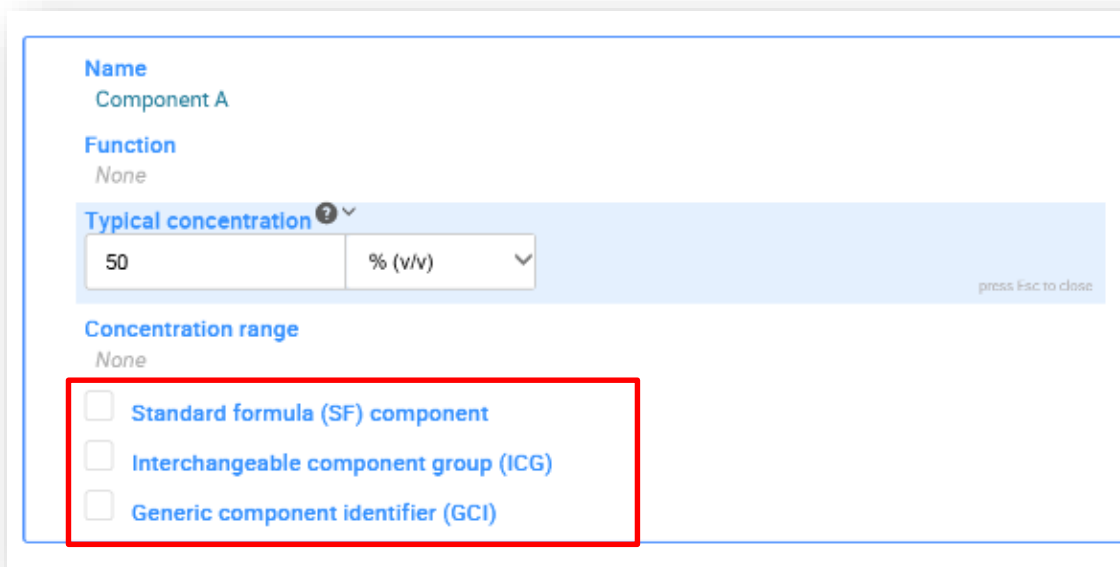
10. New BR related to ICG and SFs + latest amendment of the Annex VIII

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'



The screenshot shows a web form for configuring a component. The form is titled 'Name' and contains the following fields and options:

- Name:** Component A
- Function:** None
- Typical concentration:** A dropdown menu with a value of '50' and a unit dropdown menu set to '% (v/v)'. A small question mark icon is next to the label. A 'press Esc to close' hint is visible on the right side of the dropdown area.
- Concentration range:** None
- Component type options (highlighted with a red box):**
 - Standard formula (SF) component
 - Interchangeable component group (ICG)
 - Generic component identifier (GCI)

Indicating Standard Formula in a notification

CLP Poison centres notification

Hard-Cement-1000

Mixture information and product identity (4)

- Mixture identity and legal submitter (1)
- Mixture composition (1) +
- Mixture composition.001**
 - Portland cement clinker
 - SF MiM - Cement
- Product identity (2)
- Classification of the mixture and label elements (1) +
- Mixture safety data sheets and toxicological information (1) +
- Additional information (3)

Hard-Cement-1000
UUID: fac49dda-e6dc-4b3e-b2...

Mixture name*
Hard-Cement-1000

Legal entity owner*
ClaRim | Helsinki | Finland

Other identifiers + New item

#...	Name type	Name	Country
1	Standard formula (SF)	Cement Standard Formula - 1 [Portland cement with one main constituent: clinker]	None

1. Indicate the SF name & description (picklist)

Reporting Standard Formula components

2. In Mixture composition document, add each components:

- identity
- &
- concentration

... as given in Part D Annex VIII

Components

+ New item

#	Name	Function	Concentration range	Standard formula (SF...)	Interchar
1	Tin(II) sulfate Tin(II) sulfate	None	>= 0 < 0.1 % (w/w)	<input checked="" type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/>
2	Iron(II) sulfate Iron(II) sulfate	None	>= 0 < 1 % (w/w)	<input checked="" type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/>
3	Flue dust Inorganic mineral materials	None	>= 0 < 5 % (w/w)	<input checked="" type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/>
4	Calcium sulfate Calcium sulfate	None	>= 0 < 8 % (w/w)	<input checked="" type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/>
				<input checked="" type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/>

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

Standard Formula datasets available

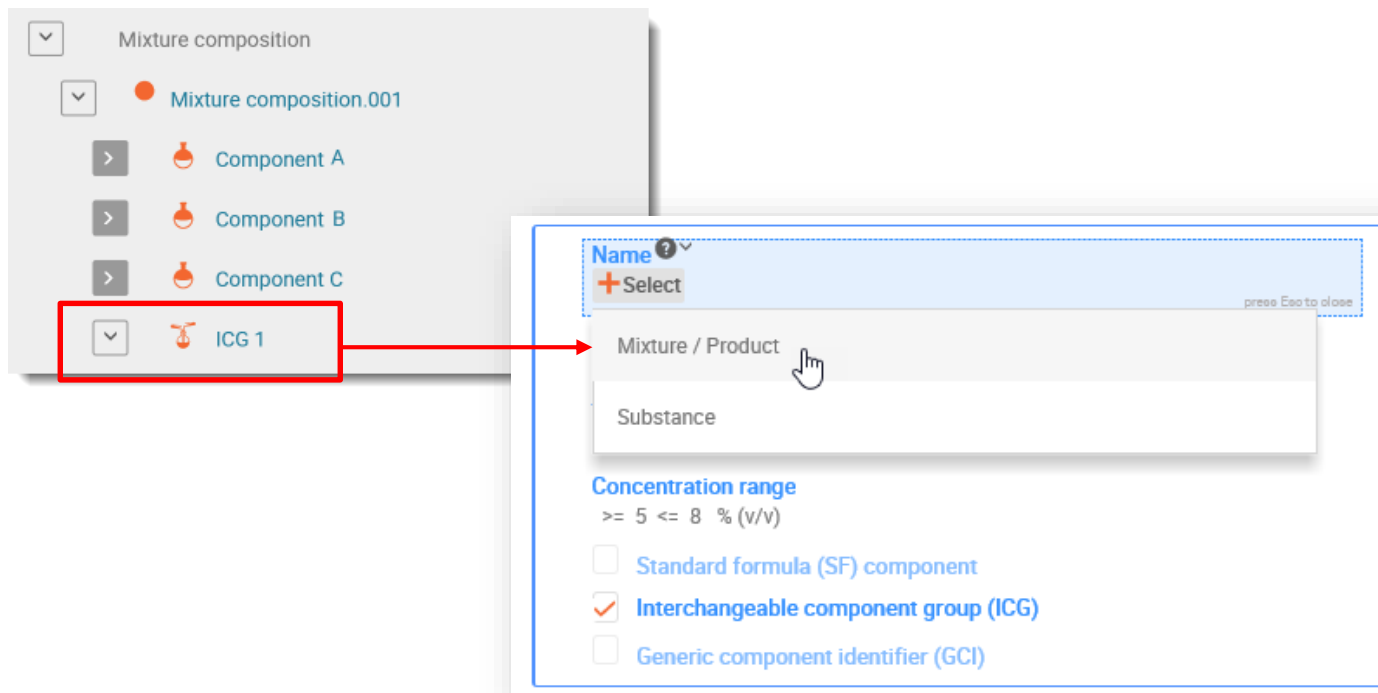
- ECHA has prepared Standard Formula datasets in cooperation with CEMBUREAU
- Standard Formula datasets available from <https://poisoncentres.echa.europa.eu/poison-centres-notification-format>
- *Use of the Standard Formula datasets remains under the sole responsibility of the user. ECHA does not give 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.*



- Component A
- Component B
- Component C
- Interchangeable component group

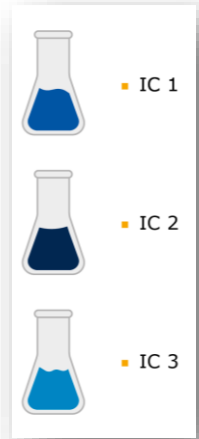
Indicating ICGs

- 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.



The screenshot shows a 'Mixture composition' panel with a list of components: Component A, Component B, Component C, and ICG 1. ICG 1 is highlighted with a red box. A red arrow points from ICG 1 to a configuration window. The configuration window has a 'Name' field with a '+ Select' button and a 'press Esc to close' hint. Below the name field, there are two options: 'Mixture / Product' (selected with a mouse cursor) and 'Substance'. Underneath, the 'Concentration range' is set to '>= 5 <= 8 % (v/v)'. At the bottom, there are three checkboxes: 'Standard formula (SF) component' (unchecked), 'Interchangeable component group (ICG)' (checked), and 'Generic component identifier (GCI)' (unchecked).

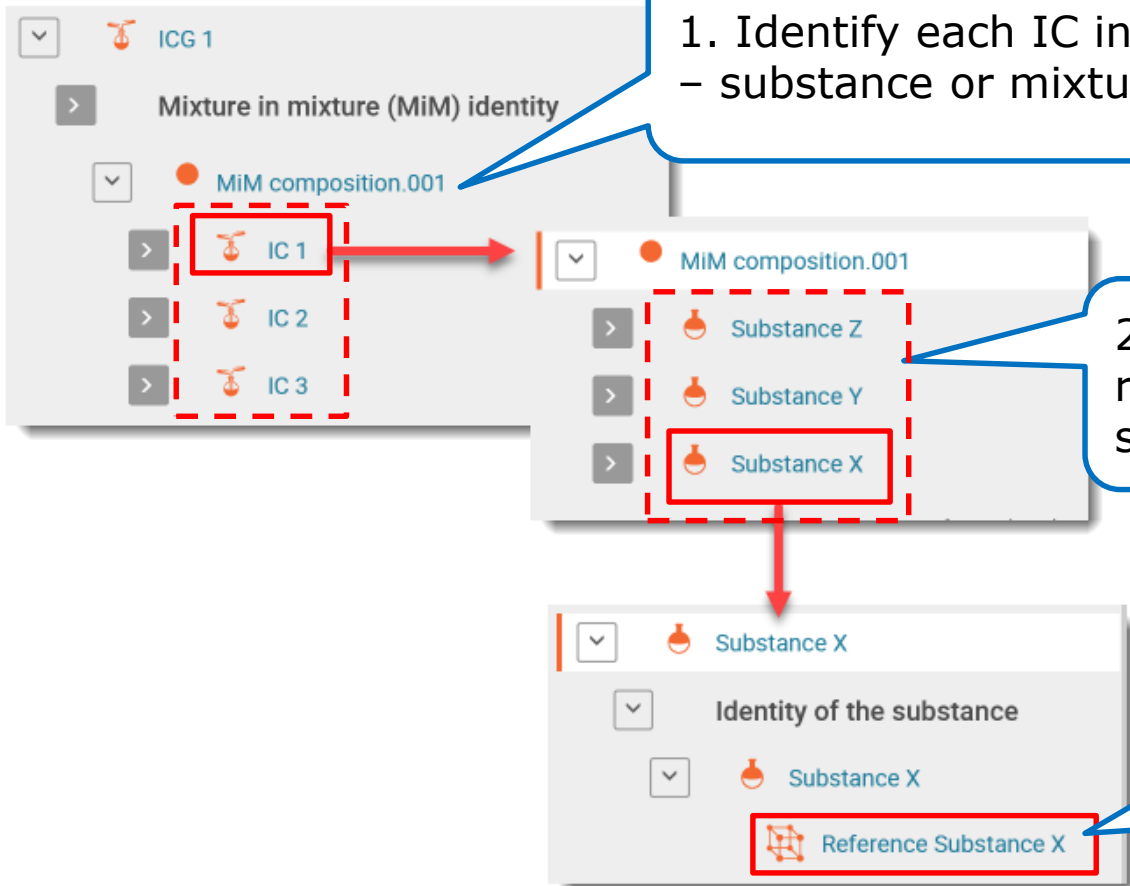
Reporting the composition of ICs



1. Identify each IC in the group – substance or mixture

2. Within each IC MiM, report details of each substance

3. Link each substance to a reference substance



List of justifications when pH is not available

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

pH is not available

Justification

Please select ▼

- pH is above 15
- pH is below -3
- substance/mixture is a gas
- substance/mixture is non-polar/aprotic
- substance/mixture is non-soluble (in water)
- substance/mixture not stable
- substance/mixture reacts with water

New reasons for update

- New update justifications included in the list

Notification type

The submission is an update

Reason for updating

Justification + New item

Other update reason

None

Click to select

- Click to add text
- Free text field
- Multilingual field

change in the mixture classification

change in the product identifier

correction of error

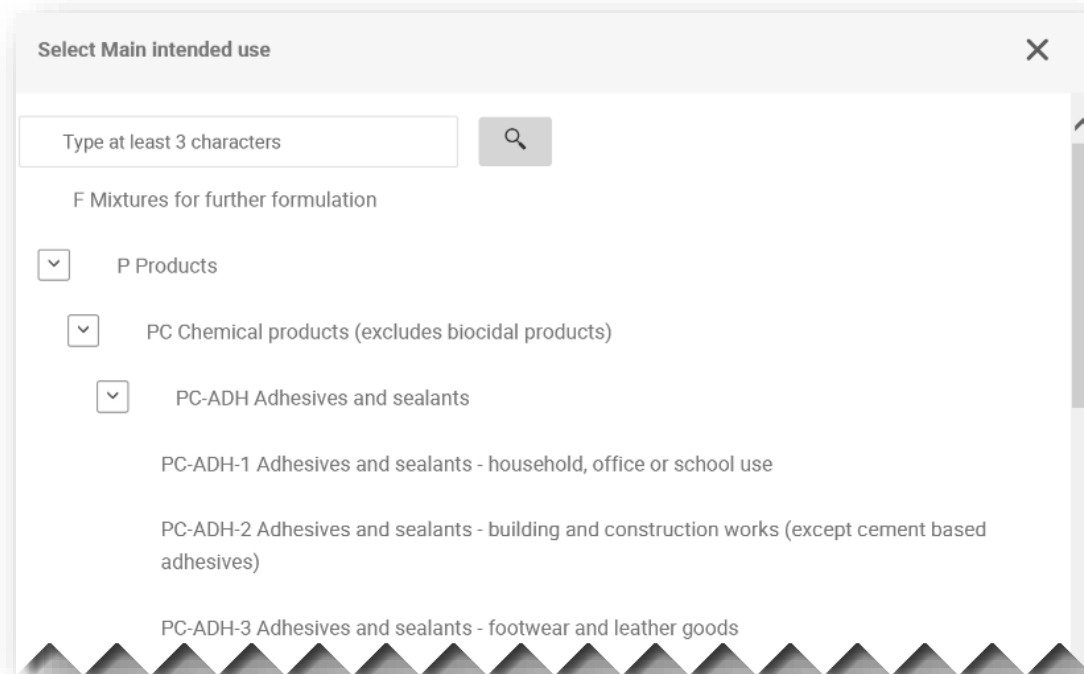
correction/deletion of trade name

expansion of market area

new toxicological information available

EuPCS version 2 included

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



Select Main intended use

Type at least 3 characters

F Mixtures for further formulation

P Products

PC Chemical products (excludes biocidal products)

PC-ADH Adhesives and sealants

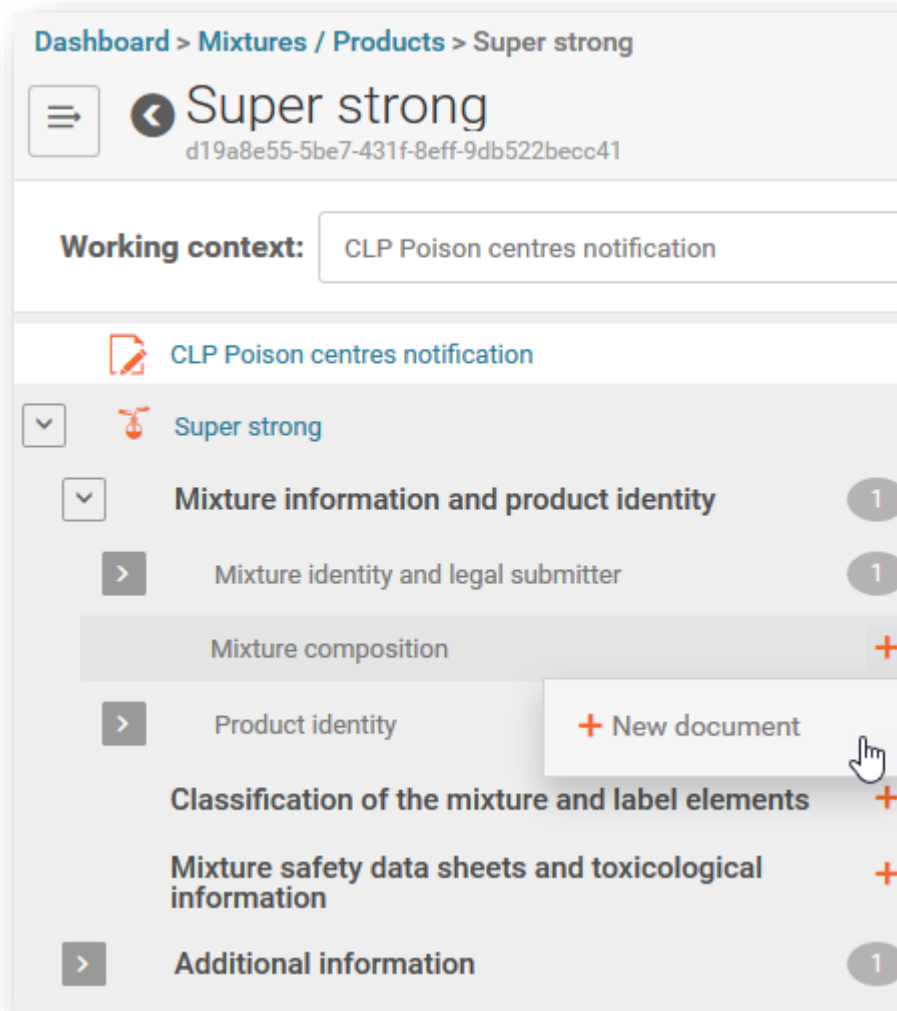
PC-ADH-1 Adhesives and sealants - household, office or school use

PC-ADH-2 Adhesives and sealants - building and construction works (except cement based adhesives)

PC-ADH-3 Adhesives and sealants - footwear and leather goods

Improvements to navigation tree

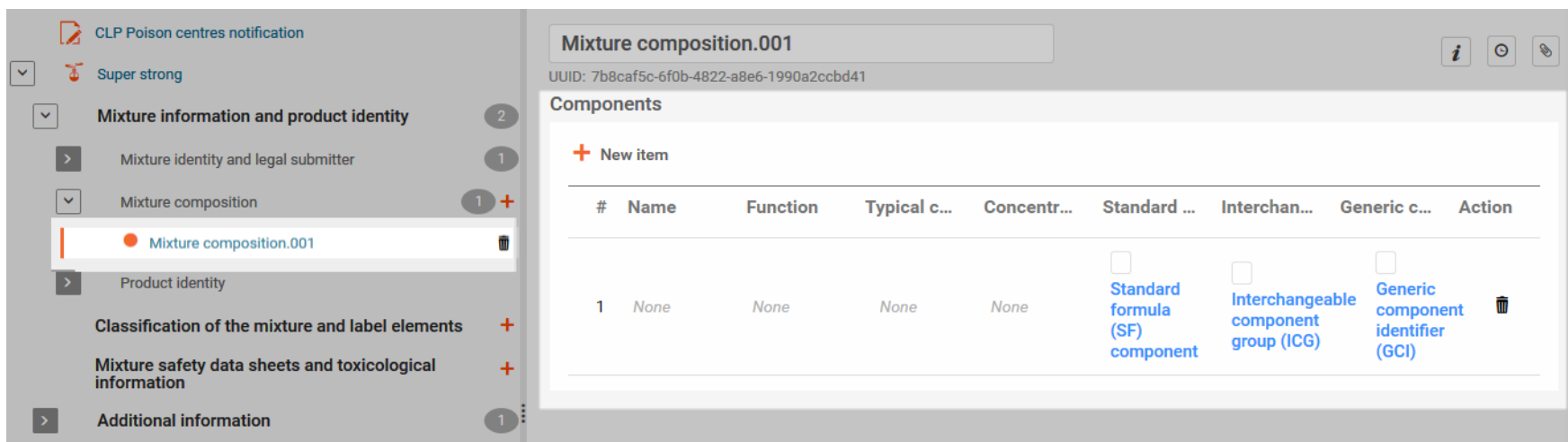
- Easily move from dossier header to other areas of the notification
- Expand & collapse
- Also possible to create or delete documents from the navigation tree



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



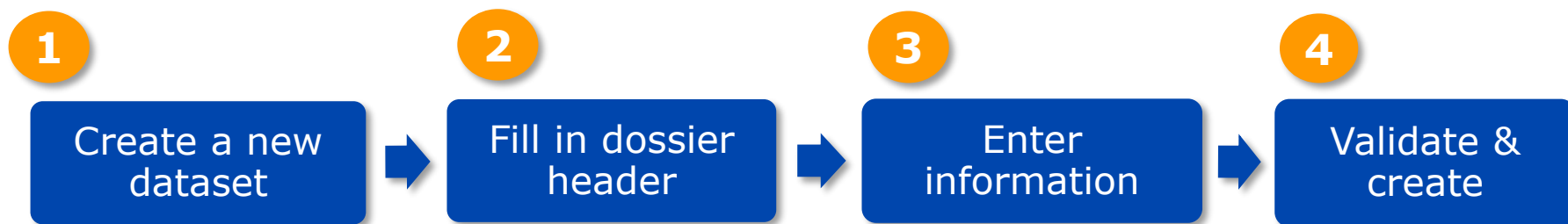
The screenshot shows the ECHA notification interface. On the left is a navigation menu with sections like 'CLP Poison centres notification', 'Super strong', 'Mixture information and product identity', 'Mixture composition', 'Product identity', 'Classification of the mixture and label elements', 'Mixture safety data sheets and toxicological information', and 'Additional information'. The 'Mixture composition' section is expanded, showing a sub-item 'Mixture composition.001'. The main content area displays the details for 'Mixture composition.001' with a UUID: 7b8caf5c-6f0b-4822-a8e6-1990a2ccbd41. Below this is a 'Components' table with a 'New item' button and a table with columns: #, Name, Function, Typical c..., Concentr..., Standard ..., Interchan..., Generic c..., and Action. The table contains one row with the following data:

#	Name	Function	Typical c...	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)	

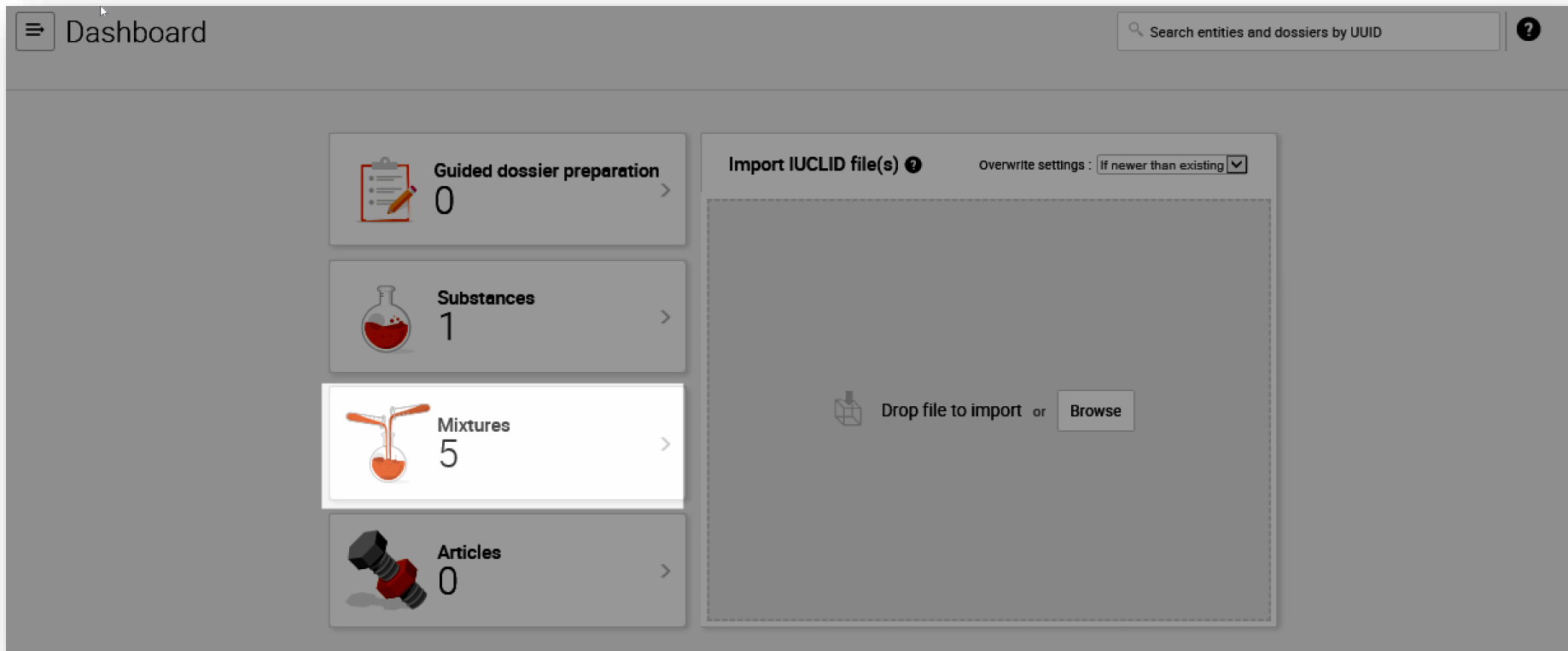
Decommissioning of Guided Dossier tool

- 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



The screenshot shows the IUCLID dashboard interface. At the top left, there is a "Dashboard" label with a hamburger menu icon. At the top right, there is a search bar with the text "Search entities and dossiers by UUID" and a help icon. The main content area is divided into two columns. The left column contains four summary cards: "Guided dossier preparation" with 0 items, "Substances" with 1 item, "Mixtures" with 5 items (highlighted in white), and "Articles" with 0 items. The right column is titled "Import IUCLID file(s)" and includes an "Overwrite settings" dropdown menu set to "if newer than existing". Below this is a large dashed box for file import, with a "Drop file to import" instruction and a "Browse" button.

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

Select Mixture / Product

+ Create

×

Dashboard > Mixtures / Products > Hard-Cement-1000

☰ Hard-Cement-1000
fac49dda-e6dc-4b3e-b23a-ec5d52ad7469

Working context: CLP Poison centres notification

Draft dossier header

Validate Create dossier

CLP Poison centres notification

- Mixture information and product identity 4
- Classification of the mixture and label elements 1
- Mixture safety data sheets and toxicological information 1
- Additional information 3

Mixture / Product information [View Dossiers](#)

Mixture / Product name	Hard-Cement-1000		
Legal entity	ClaRim	UUID	fac49dda-e6dc-4b3e-b23a-ec5d52ad7469

Templates

Mixture information and product identity 4

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)

← CLP Poison centres notification

Dossier name (given by user)
None

Dossier submission remark
None

Specific submissions

PCN number*
None
✘ PCN number field is mandatory.

Country (market placement)*
None
✘ Country (market placement) field is mandatory.

Language*
None
✘ Language field is mandatory.

Submission type

Limited submission (industrial use only)

Group submission

Voluntary submission

Notification type

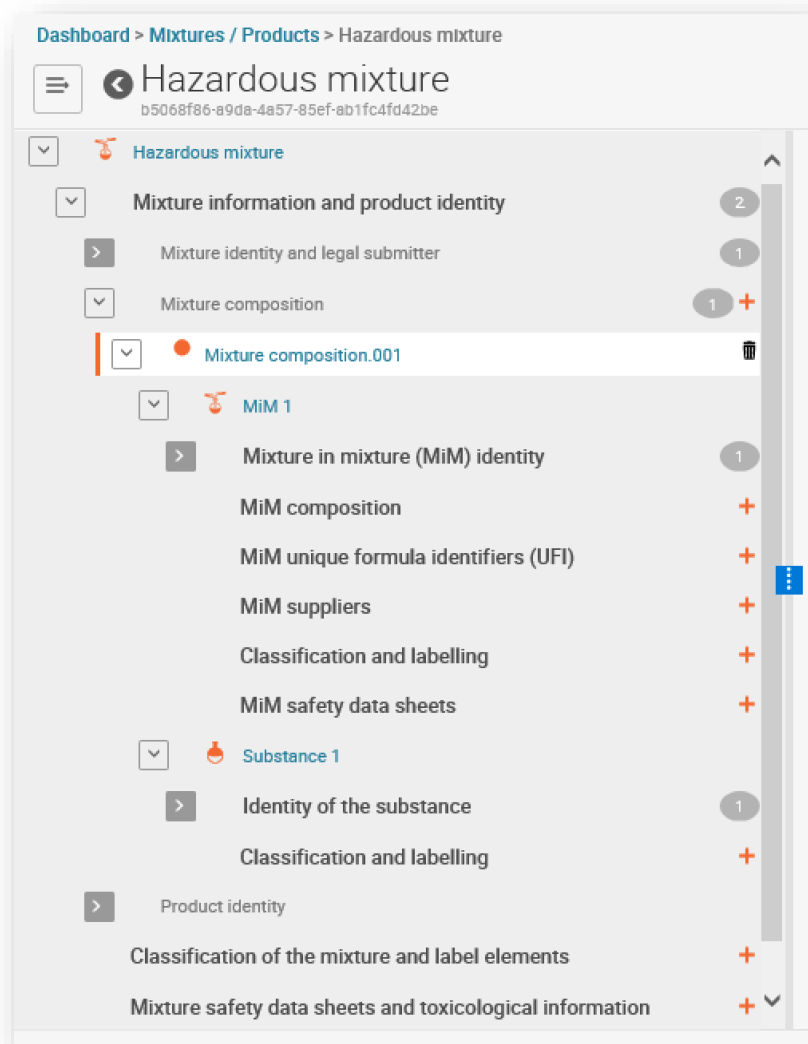
Initial notification

New notification after a significant change of composition

The submission is an update

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



The screenshot displays the ECHA dashboard interface for a 'Hazardous mixture' dossier. The breadcrumb trail at the top reads 'Dashboard > Mixtures / Products > Hazardous mixture'. The main title is 'Hazardous mixture' with a unique identifier 'b5068f86-a9da-4a57-85ef-ab1fc4fd42be'. The navigation tree on the left is organized as follows:

- Hazardous mixture** (2 documents)
 - Mixture information and product identity** (1 document)
 - Mixture identity and legal submitter (1 document)
 - Mixture composition (1 document, with a '+' icon for creating new)
 - Mixture composition.001** (selected)
 - MiM 1** (1 document)
 - Mixture in mixture (MiM) identity (1 document)
 - MiM composition (+)
 - MiM unique formula identifiers (UFI) (+)
 - MiM suppliers (+)
 - Classification and labelling (+)
 - MiM safety data sheets (+)
 - Substance 1** (1 document)
 - Identity of the substance (1 document)
 - Classification and labelling (+)
 - Product identity (+)
 - Classification of the mixture and label elements (+)
 - Mixture safety data sheets and toxicological information (+)

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

Dashboard > Mixtures / Products > Hazardous mixture

Hazardous mixture
b5068f86-a9da-4a57-85ef-ab1fc4fd42be

Hazardous mixture

Mixture information and product identity (2)

Mixture identity and legal submitter (1)

Mixture composition (1) +

Mixture composition.001

Product identity

Classification of the mixture and label elements +

Mixture safety data sheets and toxicological information +

Additional information

Mixture composition.001
undefined: 0390eb34-7c48-470d-8914-0e383b34769f

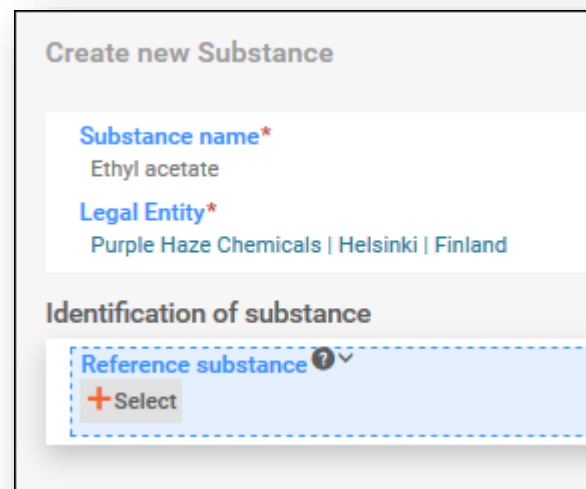
Components

+ New Item

#.	Name	Function	Typical con...	Concentrati...	Standard fo...	Interchange...	Generic co...	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)	

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



Create new Substance

Substance name*
Ethyl acetate

Legal Entity*
Purple Haze Chemicals | Helsinki | Finland

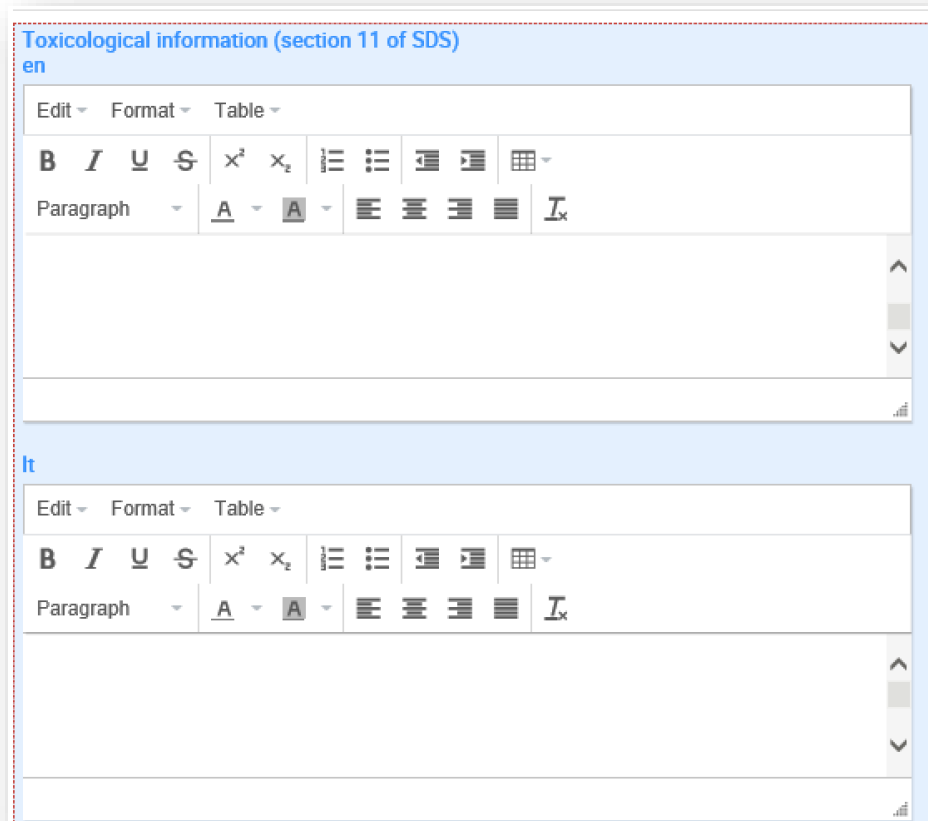
Identification of substance

Reference substance ?
+ Select

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

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



Toxicological information (section 11 of SDS)
en

Edit - Format - Table -

B *I* U ~~S~~ x² x₂ [List Icons] [Table Icon]

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

it

Edit - Format - Table -

B *I* U ~~S~~ x² x₂ [List Icons] [Table Icon]

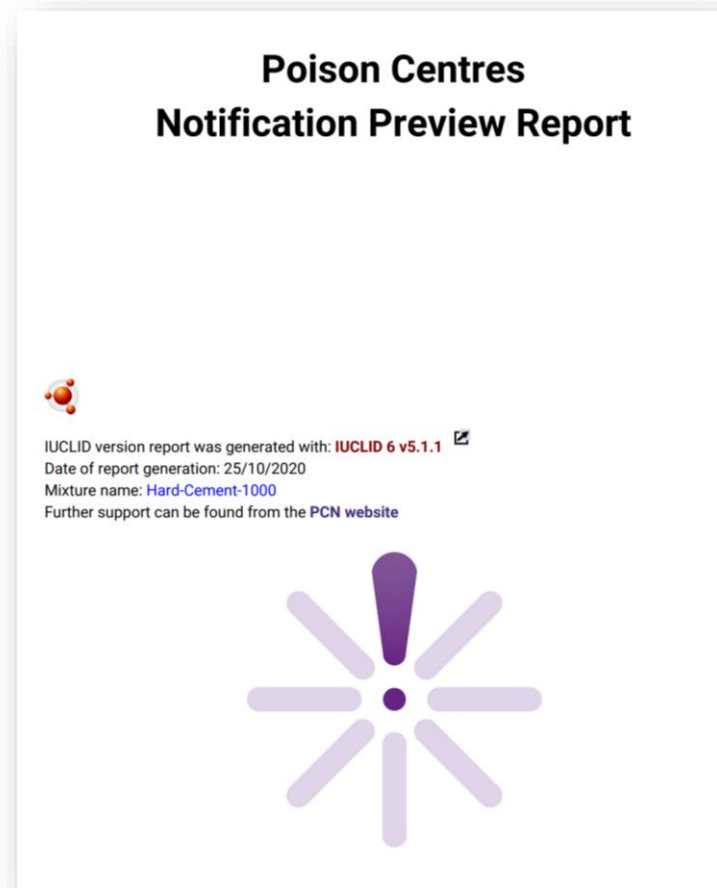
Paragraph - A - A - [List Icons] [Table Icon]

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)

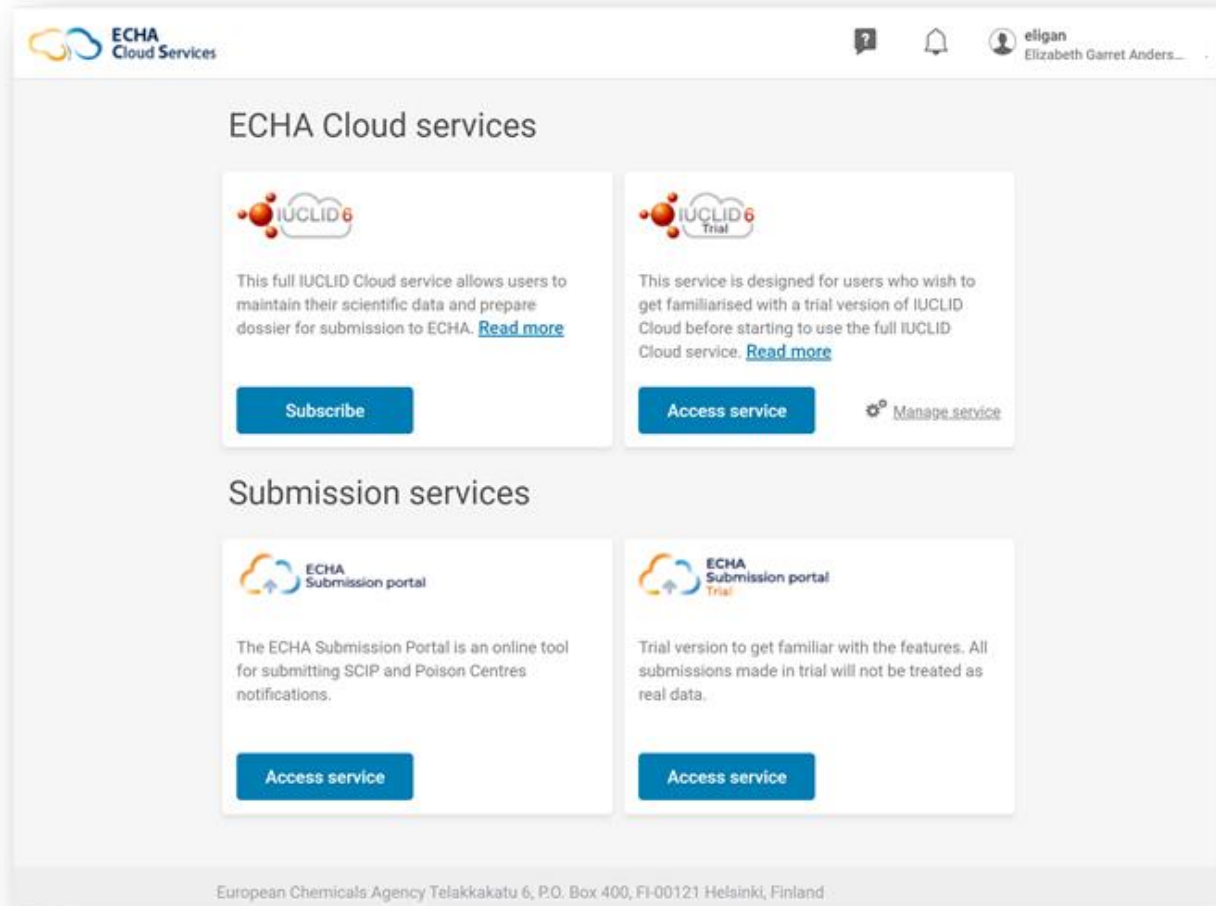


October release new features (II)

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



The screenshot shows the ECHA Cloud Services landing page. At the top left is the ECHA Cloud Services logo. At the top right, there are icons for help, notifications, and a user profile for 'eligan Elizabeth Garret Anders...'. The main content is divided into two sections: 'ECHA Cloud services' and 'Submission services'. Each section contains two service cards. The 'ECHA Cloud services' section features 'IUCLID 6' (full service) and 'IUCLID 6 Trial'. The 'Submission services' section features 'ECHA Submission portal' (full service) and 'ECHA Submission portal Trial'. Each card includes a description, a 'Read more' link, and an 'Access service' button. The 'IUCLID 6' card also has a 'Subscribe' button, and the 'IUCLID 6 Trial' card has a 'Manage service' button. At the bottom, the address 'European Chemicals Agency Telakkakatu 6, P.O. Box 400, FI-00121 Helsinki, Finland' is displayed.

ECHA Cloud Services

ECHA Cloud services

IUCLID 6

This full IUCLID Cloud service allows users to maintain their scientific data and prepare dossier for submission to ECHA. [Read more](#)

Subscribe

IUCLID 6 Trial

This service is designed for users who wish to get familiarised with a trial version of IUCLID Cloud before starting to use the full IUCLID Cloud service. [Read more](#)

Access service [Manage service](#)

Submission services

ECHA Submission portal

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

Access service

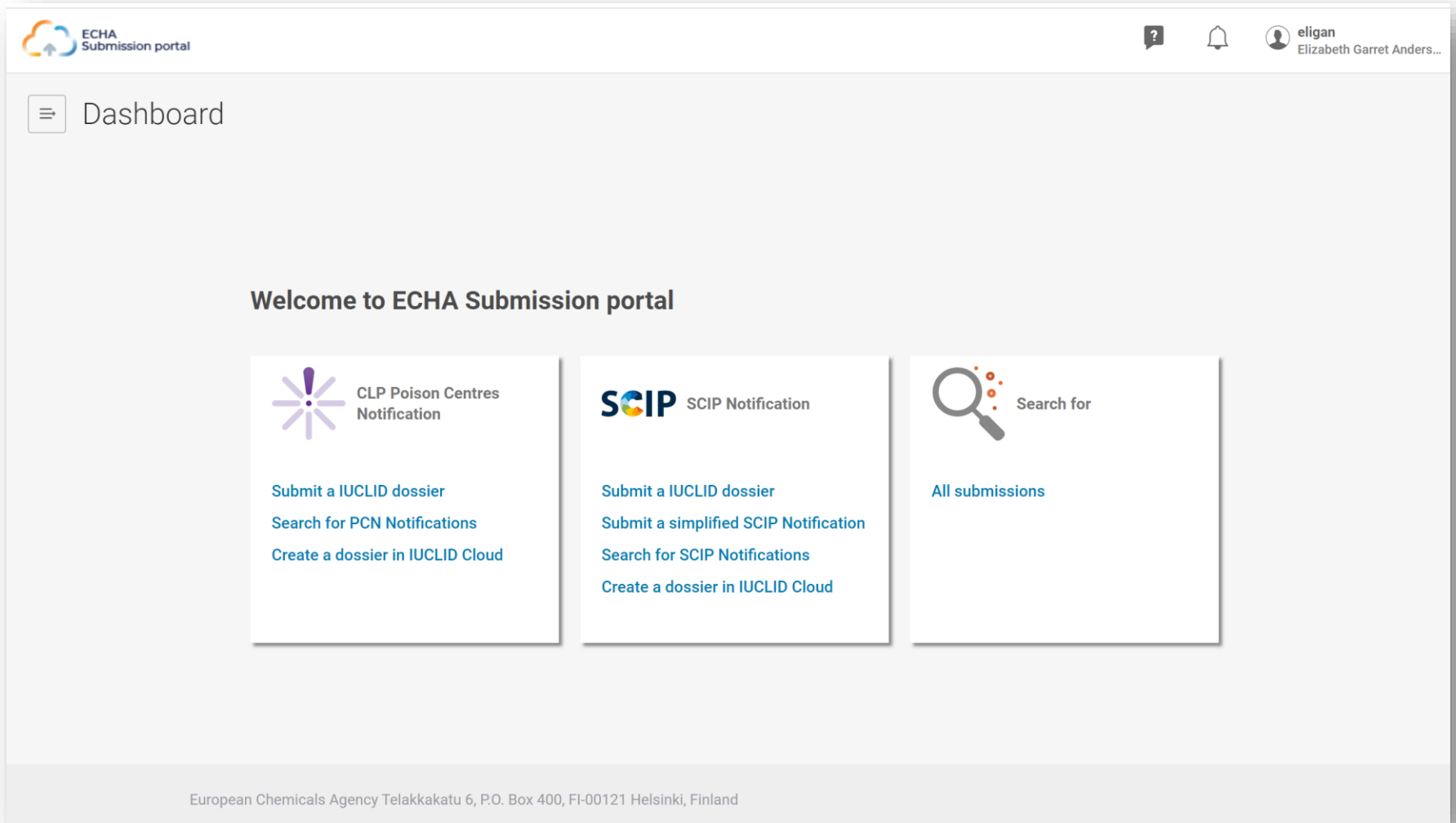
ECHA Submission portal Trial

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

Access service

European Chemicals Agency Telakkakatu 6, P.O. Box 400, FI-00121 Helsinki, Finland

New ECHA Submission portal user interface

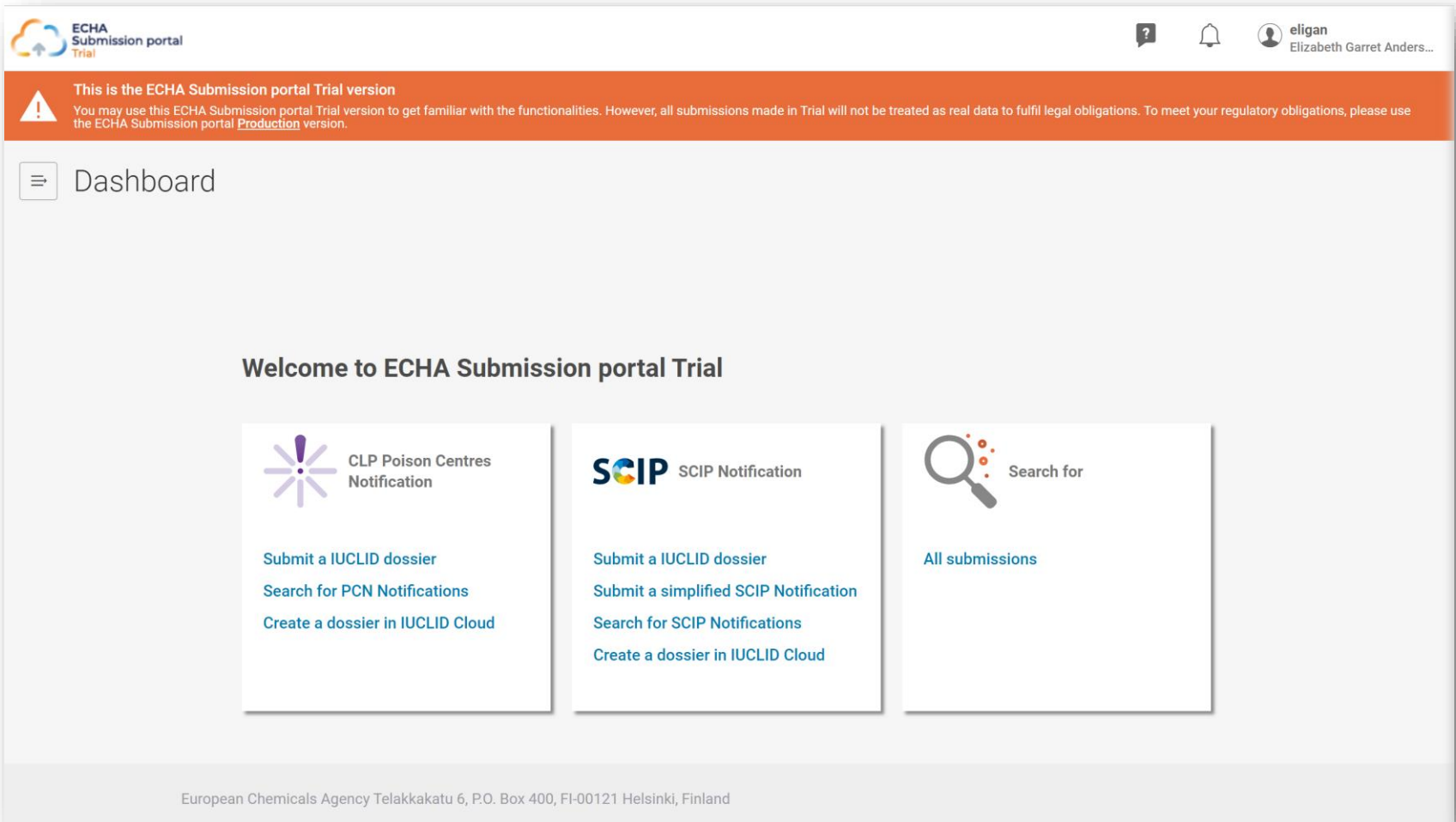


The screenshot shows the ECHA Submission portal user interface. At the top left, there is a logo for 'ECHA Submission portal'. At the top right, there are icons for help, notifications, and a user profile for 'eligan Elizabeth Garret Anders...'. Below the header, there is a 'Dashboard' link with a hamburger menu icon. The main content area is titled 'Welcome to ECHA Submission portal' and features three main action cards:

- CLP Poison Centres Notification** (indicated by a purple starburst icon):
 - Submit a IUCLID dossier
 - Search for PCN Notifications
 - Create a dossier in IUCLID Cloud
- SCIP Notification** (indicated by the SCIP logo):
 - Submit a IUCLID dossier
 - Submit a simplified SCIP Notification
 - Search for SCIP Notifications
 - Create a dossier in IUCLID Cloud
- Search for** (indicated by a magnifying glass icon):
 - All submissions

At the bottom of the page, the address 'European Chemicals Agency Telakkakatu 6, P.O. Box 400, FI-00121 Helsinki, Finland' is displayed.

ECHA Submission portal TRIAL version



The screenshot shows the ECHA Submission portal TRIAL version dashboard. At the top left is the ECHA Submission portal TRIAL logo. On the top right, there are icons for help, notifications, and a user profile for 'eligan Elizabeth Garret Anders...'. A prominent orange banner contains a warning icon and the text: '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.' Below the banner is a 'Dashboard' menu item. The main content area is titled 'Welcome to ECHA Submission portal Trial' and features three main action cards: 1. 'CLP Poison Centres Notification' with a purple starburst icon, containing links for 'Submit a IUCLID dossier', 'Search for PCN Notifications', and 'Create a dossier in IUCLID Cloud'. 2. 'SCIP Notification' with the SCIP logo, containing links for 'Submit a IUCLID dossier', 'Submit a simplified SCIP Notification', 'Search for SCIP Notifications', and 'Create a dossier in IUCLID Cloud'. 3. 'Search for' with a magnifying glass icon, containing a link for 'All submissions'. The footer of the page states: 'European Chemicals Agency Telakkakatu 6, P.O. Box 400, FI-00121 Helsinki, Finland'.

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



Contact - CLP

Your request

Request type *

Annex VIII – Poison Centres

Topic *

Feedback

Latest developments in system to system

4 November 2020

Webinar Poison centres – closing in on
the first compliance date

Stefen SUPANIC

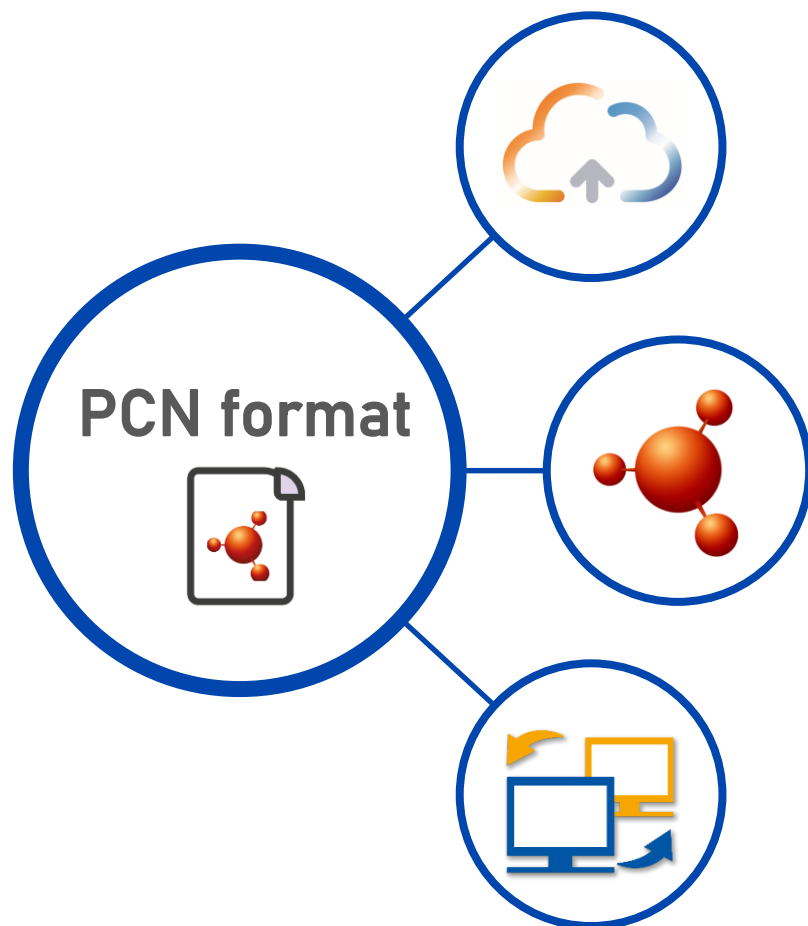
Poison Centres Team

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>

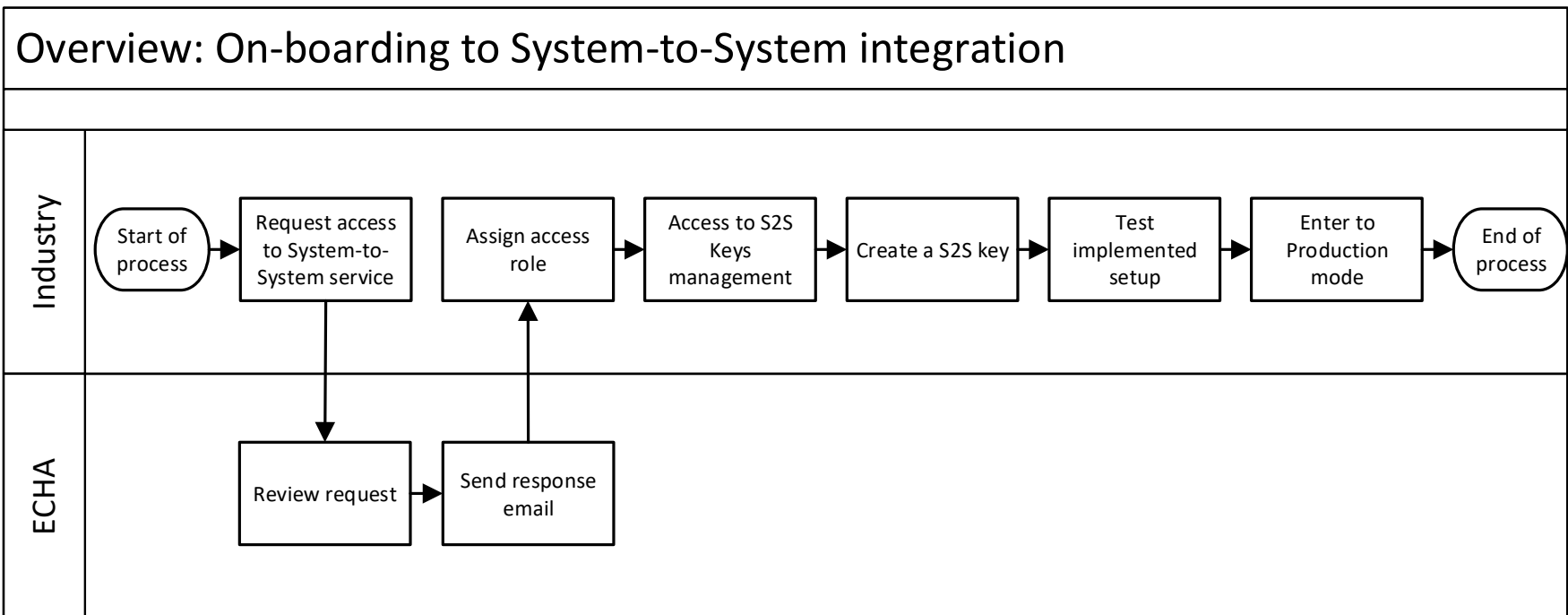
Offline in IUCLID 6

- 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 be dispatched to the Appointed Bodies.
- See technical documentation for further information

Documentation

▼ How to join ECHA's system-to-system service

- [How to join ECHA's system-to-system integration service](#) [EN] [PDF]
- [ECHA submission portal terms and conditions](#) [EN] [PDF]

▼ API specific documentation

- [System-to-system integration for industry](#) [EN] [PDF]
- [API specification document](#) [EN] [ZIP]
- [PCN Format](#)
- [SCIP Format](#)

<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 Position centres – closing in on the first compliance date

Saara SUMIALA
Data Quality team
Data Availability Unit
European Chemicals Agency



Covered today...

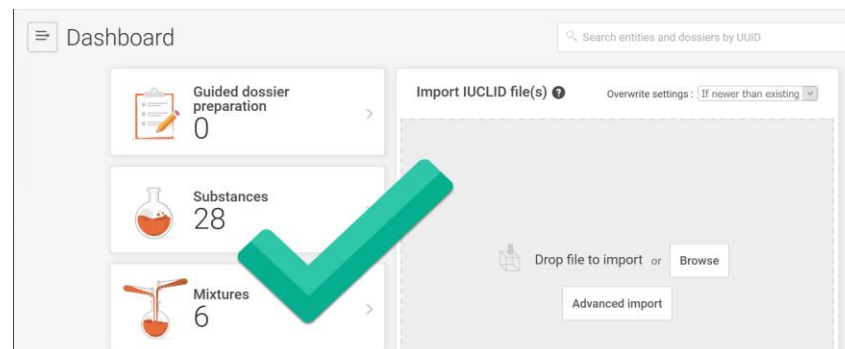
- Tips how to fix Validation rule failures
- Three most common questions in Helpdesk
- October 2020 changes
- Help

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 October 2020 (IUCLID 6.5)
 - '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

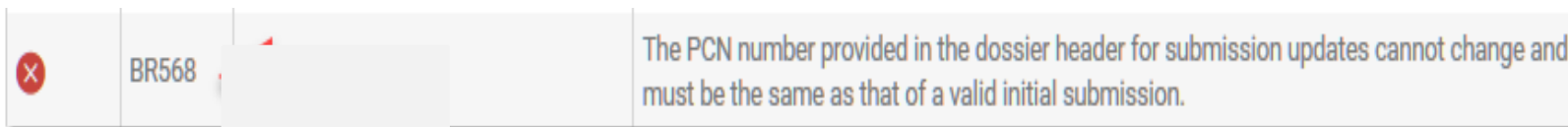
Validation rules - tips

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

3 most common topics in HelpDesk questions



[BR568]



Notification type

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

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.

The image shows two overlapping screenshots from the IUCLID 6 software. The background screenshot is a 'Validation assistant report' for 'Mixture safety data sheets and toxicological information.001'. It displays a red error icon and a message: 'Mixture information is incomplete. You must provide information on toxicological information (mixtures). This section must include information on toxicological information (section 11 of SDS). Toxicological information (section 11 of SDS). Information required for section 11 of the SDS is specified in Annex II of the CLP Regulation.' A red circle highlights the error message, with a red arrow pointing to the foreground screenshot.

The foreground screenshot is a detailed view of the 'Edit Mixture safety data sheets and toxicological information.001' window. It shows the 'Information on mixtures' section with the following fields:

- Name or trade name of mixture / product: None
- Safety data sheets of mixture / product: + New item

A table below lists the languages for which toxicological information must be provided:

#	Safety data sheet	Country	Language	Remarks	Action
1	Toxicological information (section 11 of SDS)	en			
2	Toxicological information (section 11 of SDS)	de			

Each language entry has a corresponding text editor with a red box highlighting the empty input area, indicating that this information must be filled in for each language.

[BR625]

'Qualifiers' must be provided for concentration range.

✖ **Mixture composition.001**
Mixture composition Components, (1)
Substance 1 do not have qualifier(s).

Business rule (BR625)

Components

+ New Item

None None

1 **Name**
Substance 1

Function
None

Typical concentration
None

Concentration range ? v

v	10	v	11	% (w/w)	v
---	----	---	----	---------	---

Remarks
None

press Esc to close

Latest changes




BR621 *new*

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

pH is not available

Justification

Please select 

✘ This field is mandatory, based on the information previously provided. pres

pH value
None

Solution concentration (%)
None

[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'

Specific submissions

PCN number*

Country (market placement)*

- ✓ United Kingdom of Great Britain and Northern Ireland 
- ✓ United Kingdom: Northern Ireland 

Language*

✓

Submission type

[QLT634] *new*

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

Reference substance information

IUPAC name

not available



CAS number

None

[QLT635] *new*

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

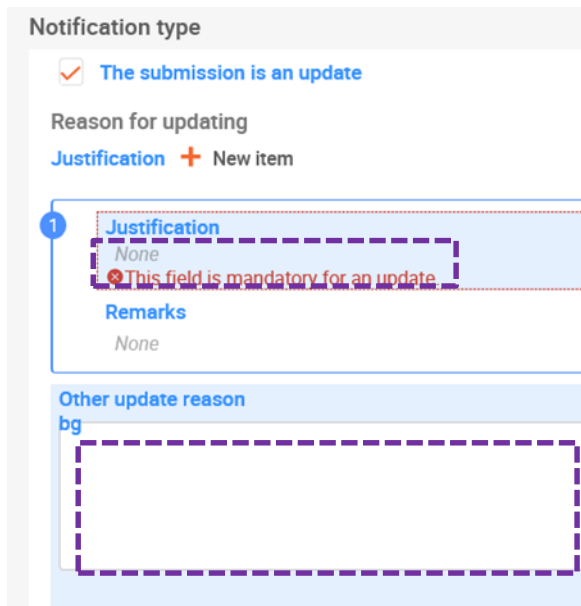
Substance name*

Proprietary substance



[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**'.



Notification type

The submission is an update

Reason for updating

Justification + New item

1 Justification

None

✖ This field is mandatory for an update.

Remarks

None

Other update reason

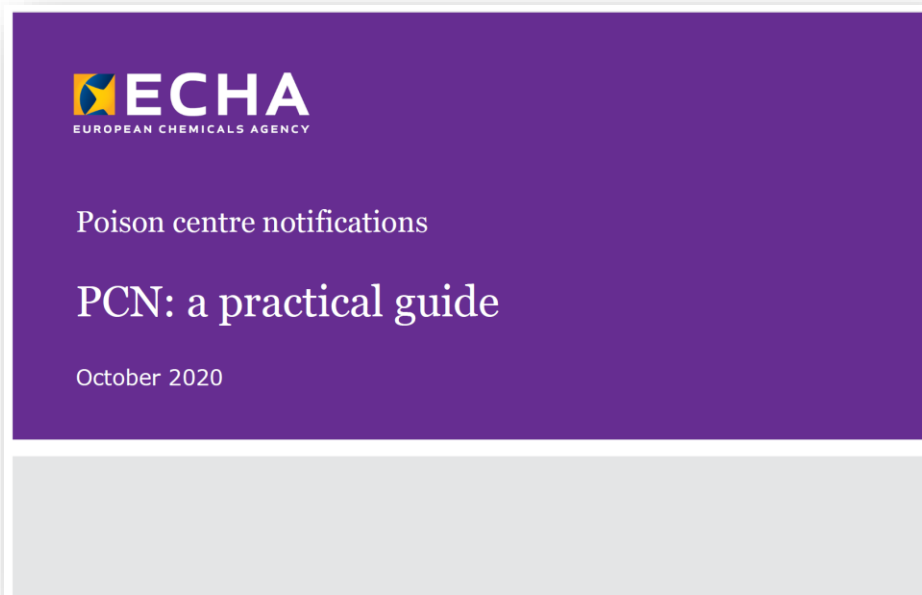
bg

Help



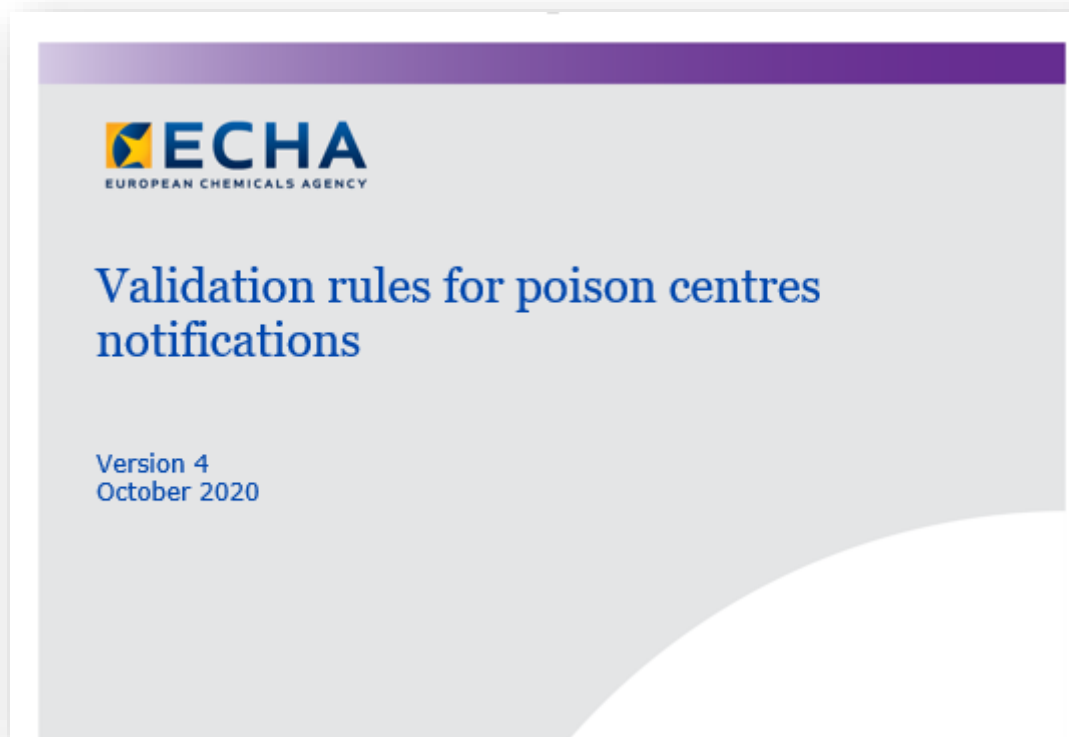
Help – ‘PCN: a practical guide’

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



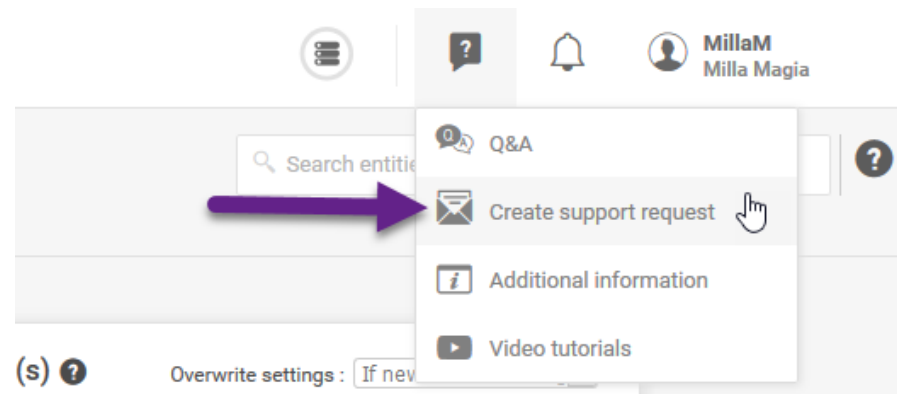
Help – List of Validation rules

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



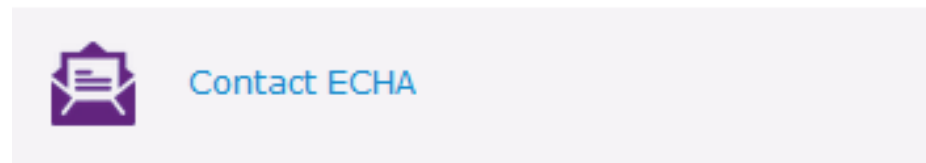
Help – HelpDesk

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

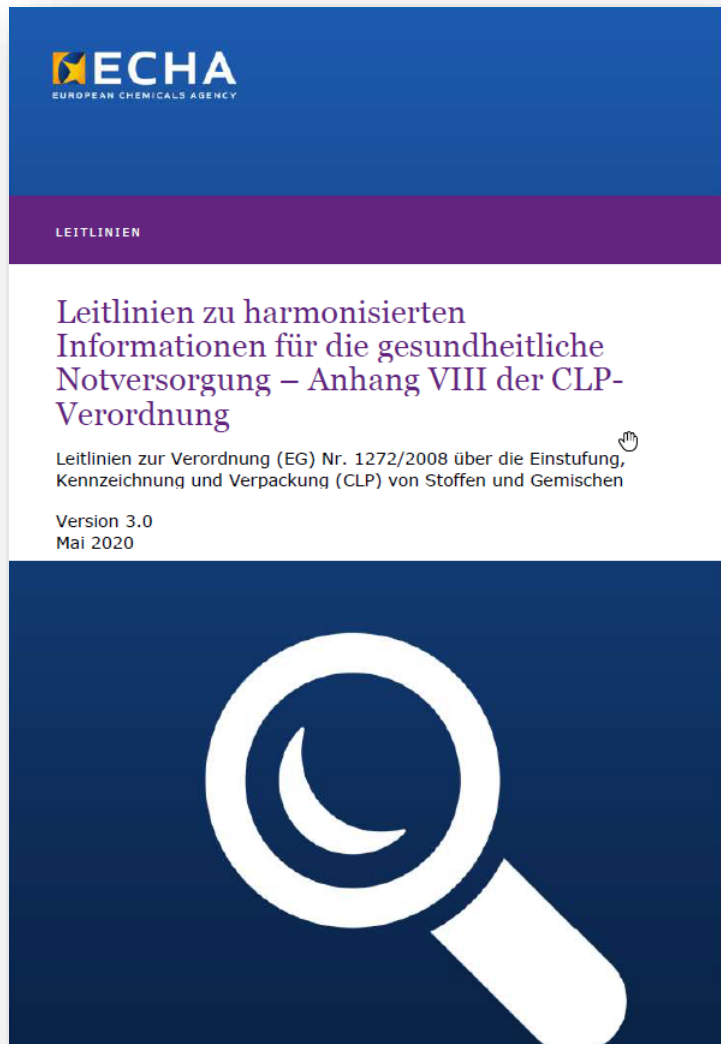
4 November 2020

Webinar Poison 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

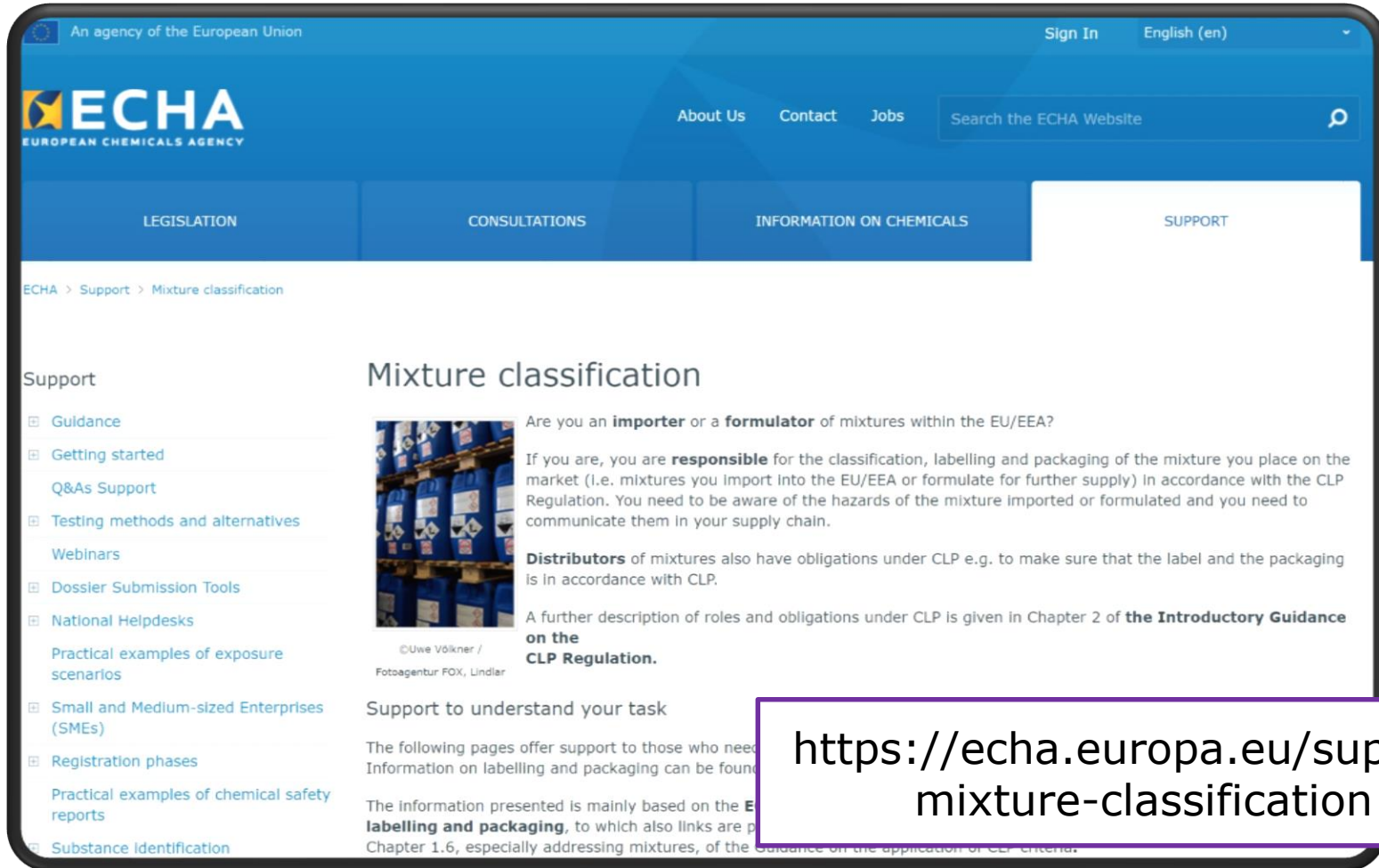
<https://echa.europa.eu/guidance-documents/guidance-on-clp>

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



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

ECHA
EUROPEAN CHEMICALS AGENCY

About Us Contact Jobs

LEGISLATION CONSULTATIONS INFORMATION ON CHEMICALS **SUPPORT**

ECHA > Support > Mixture classification

Support

- Guidance
- Getting started
 - Q&As Support
- Testing methods and alternatives
 - Webinars
- Dossier Submission Tools
- National Helpdesks
 - Practical examples of exposure scenarios
- Small and Medium-sized Enterprises (SMEs)
- Registration phases
 - Practical examples of chemical safety reports
- Substance Identification

Mixture classification

Are you an **importer** or a **formulator** of mixtures within the EU/EEA?

If you are, you are **responsible** for the classification, labelling and packaging of the mixture you place on the market (i.e. mixtures you import into the EU/EEA or formulate for further supply) in accordance with the CLP Regulation. You need to be aware of the hazards of the mixture imported or formulated and you need to communicate them in your supply chain.

Distributors of mixtures also have obligations under CLP e.g. to make sure that the label and the packaging is in accordance with CLP.

A further description of roles and obligations under CLP is given in Chapter 2 of **the Introductory Guidance on the CLP Regulation**.

©Uwe Völkner / Fotoagentur FOX, Lindlar

Support to understand your task

The following pages offer support to those who need information on labelling and packaging can be found here:

The information presented is mainly based on the **ECHA Introductory Guidance on the CLP Regulation**, to which also links are provided in Chapter 1.6, especially addressing mixtures, of the **Guidance on the application of CLP criteria**.

<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 ZAPOSILITEV 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 podjetja, 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

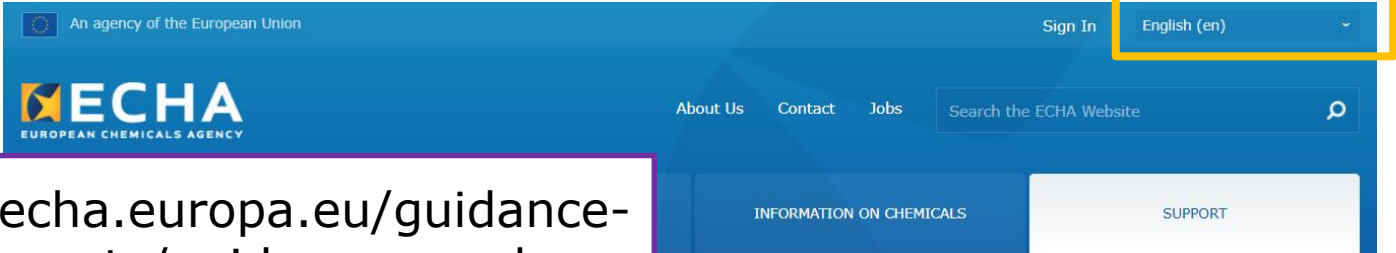


- Guidance on the compilation of safety data sheets
- Section 3: Composition
- Section 11: Toxicological information
- Under revision

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

- Guidance
- Identify your obligations
- Consultation Procedure
- Guidance Documents
- Guidance in a Nutshell
- Practical Guides
- Formats and templates

Guidance on CLP

[Guidance on REACH](#) [Guidance on CLP](#) [Guidance on BPR](#) [Guidance on PIC](#)

The list below contains all the **Guidance Documents** which are available, or will be available, on this website. These documents have been developed with the participation of many stakeholders: Industry, Member States and NGOs. The objective of these documents is to **facilitate the implementation of CLP** by describing good practice on how to fulfil the obligations.

Some of these documents have been or will be translated into official EU languages. You can access the translations from this webpage: use the language menu on the top right corner of the page.

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

Reference name:	Guidance on Annex VIII to CLP
Description:	This document provides guidance on the provisions of 45 and Annex VIII to CLP. These concern the obligation to submit certain information on hazardous mixtures placed on the market, for emergency response reasons.
	download full PDF document (18/05/2020)

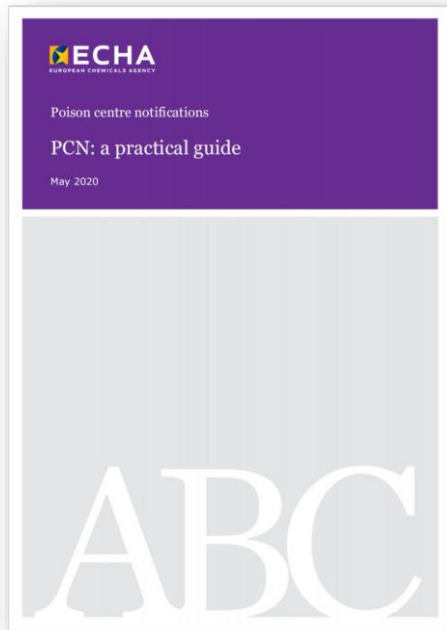
[Additional information on the ECHA website](#) [Read more](#)

Note: this guidance is currently being updated. For the latest draft, please see the [Consultation Procedure](#).

Link to other support material in our website

Link to consultation webpages (drafts)

Sources of information for IT tools

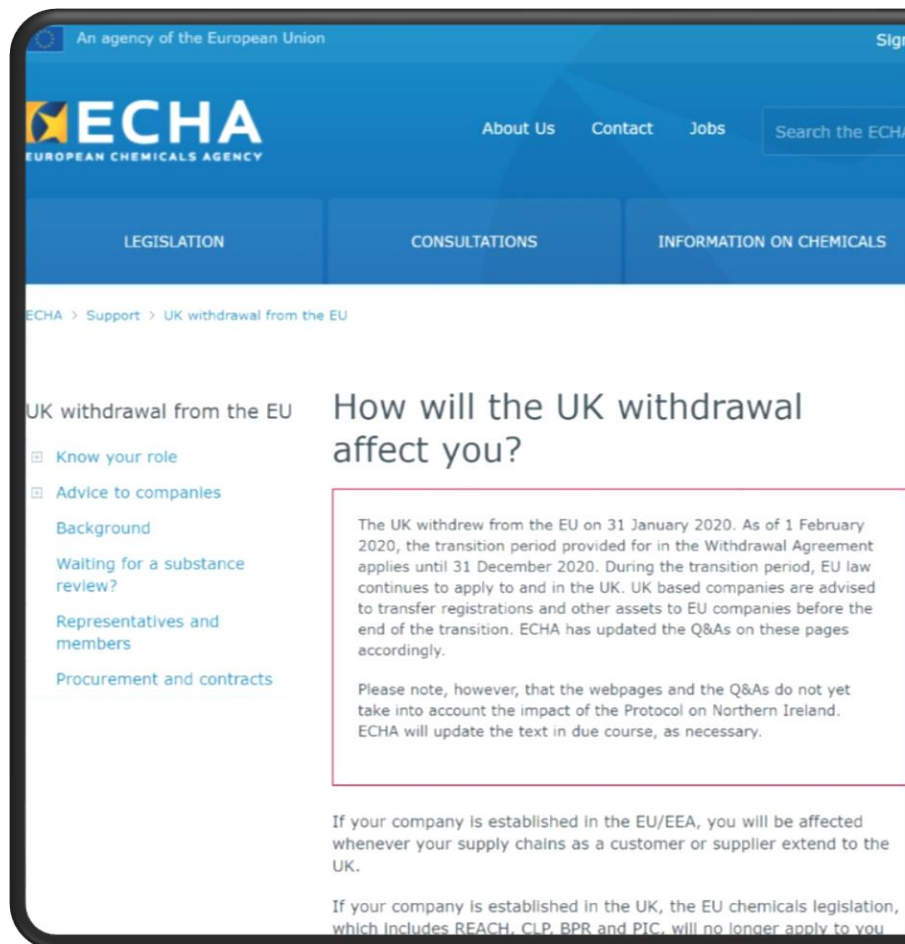


When using
IUCLID



Any account
with ECHA tools

UK withdrawal from the EU



Know your role

Start by identifying your role in the supply chain and your future connection to the EU and EEA market. Where and with whom you do business will determine how the withdrawal will affect you.

From the options below, select the role that describes your business and see how you can start preparing for the UK's withdrawal from the EU. If your situation does not fit any of these roles or you wish to know more, you can read all our Q&As under "Advice to companies / Q&As".

 <p>UK-based REACH registrant</p>	 <p>UK-based only representative</p>
 <p>UK-based manufacturer or supplier of substances under the BPR</p>	 <p>EU-based company</p>
 <p>UK-based authorisation holder under REACH</p>	 <p>EU downstream user of an authorised substance</p>
 <p>Manufacturer or formulator outside the EU/EEA</p>	

Hot topics - support and practical advice

4 November 2020

Webinar Poison 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.

Overview of Member States' decisions to include in implementation of Annex VIII in the CLP Regulation (in-house, Confidential - version 18.10.2018)

Member State	Readiness of Member States to accept notifications via ECHA submission system	Submission status	Notification language	Fees for notifications	Placing on the market allowed until the ECHA submission system	Member State
Austria	Green	Green	Green	Green	Green	Austria
Belgium	Green	Green	Green	Green	Green	Belgium
Bulgaria	Green	Green	Green	Green	Green	Bulgaria
Canada	Red	Red	Red	Red	Red	Canada
China	Red	Red	Red	Red	Red	China
Croatia	Green	Green	Green	Green	Green	Croatia
Czechia	Green	Green	Green	Green	Green	Czechia
Denmark	Green	Green	Green	Green	Green	Denmark
Egypt	Red	Red	Red	Red	Red	Egypt
France	Green	Green	Green	Green	Green	France
Germany	Green	Green	Green	Green	Green	Germany
Greece	Green	Green	Green	Green	Green	Greece
India	Red	Red	Red	Red	Red	India
Japan	Green	Green	Green	Green	Green	Japan
South Korea	Green	Green	Green	Green	Green	South Korea
USA	Red	Red	Red	Red	Red	USA

<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 \neq 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!

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- 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