

Welcome

Webinar: Poison centre
notifications - explaining new
changes and functionalities

24 November 2021

Poison Centres Team
Submission and Processing Unit
European Chemicals Agency





Agenda

- 11:00 **Introduction and latest developments**
Heidi Rasikari
- 11:15 **Upcoming changes – cease product vs. disable submissions**
Claudia Rimondo
- 11:35 **Making a group submission – what you need to know**
Daniele Ape
- 12:00 **Closing remarks**
Poison Centre Team
- 12:00 - 13.00 Webinar open for questions

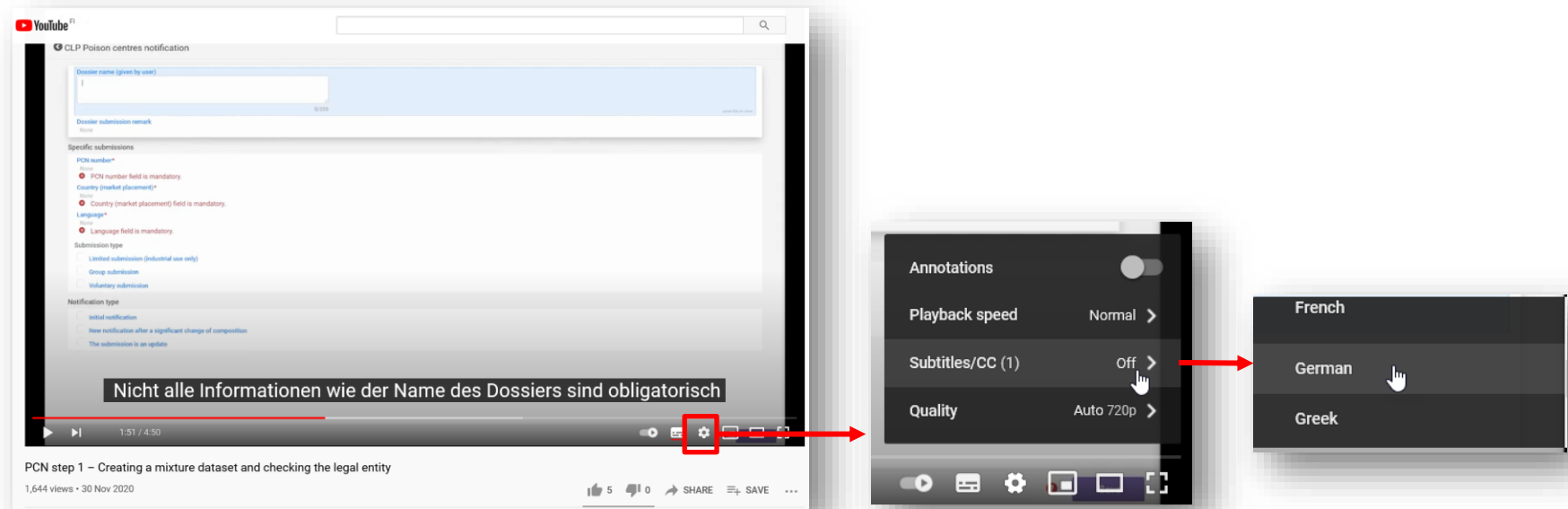
Questions

- Join Q&A at: [slido.com](https://www.slido.com)
Event code: **#pcentre21**
- Send questions **12:00 to 13:00 Helsinki time**
- Reply to questions within scope until 14:00
- Question not answered? Contact us:
echa.europa.eu/contact
- Video recording, presentations and Q&A:
echa.europa.eu/support/training-material/webinars



Poison centre videos

- [Recorded material](#) in YouTube - animations, tutorials...
- Try the auto-translate for subtitles – it may be helpful*



* Translation not officially endorsed by ECHA

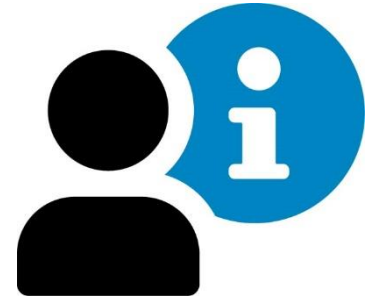
Latest developments

Webinar: Poison centre
notifications: explaining new
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24 November 2021

Heidi RASIKARI
European Chemicals Agency





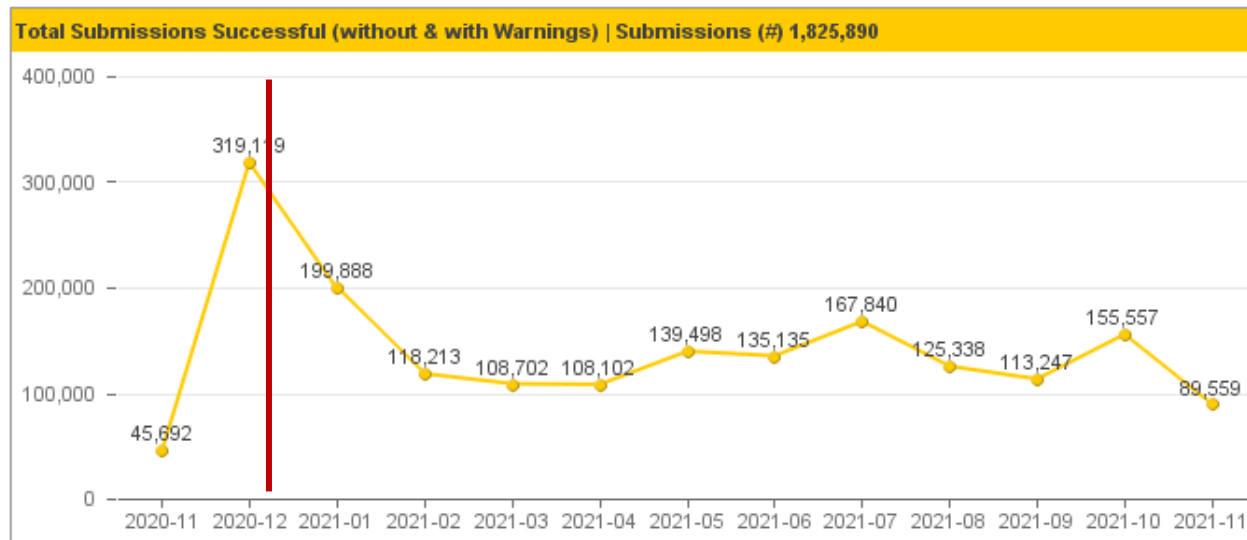
Outline

- Submission numbers update
- October release features
- Reported issues
- Update on Member States
- Helpdesk – what you need to know
- UFI campaign

Submission numbers

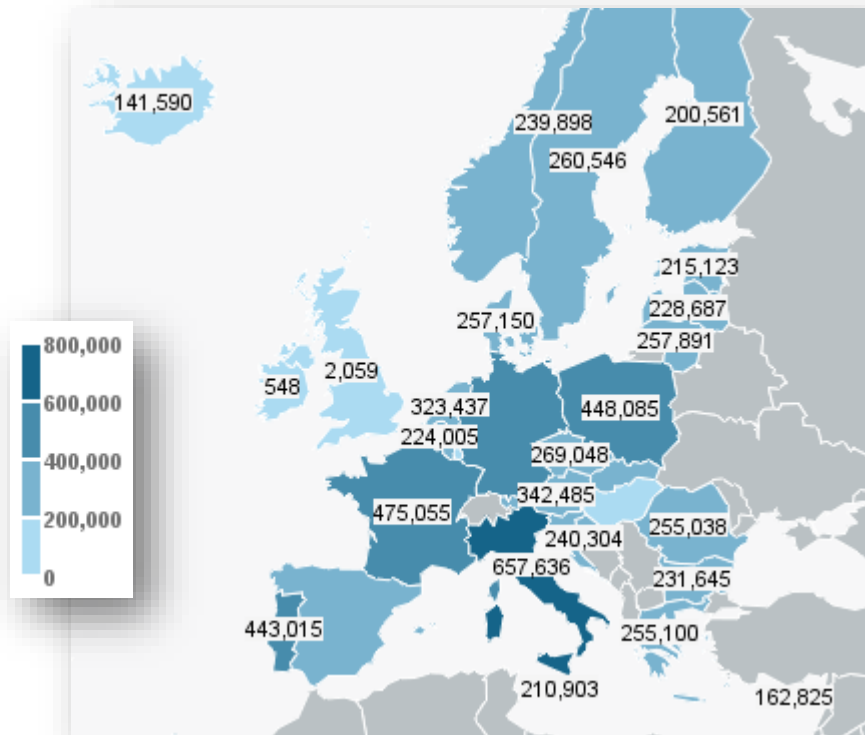
20 November to 21 October

- Close to 2 million successful submissions to date
- Peak before first compliance date
- Figure has stabilised ~100,000 (initial & updates) per month



1st compliance date

Market areas



Top 5

Market Area	Submissions (#)
Italy	657,636
Germany	596,128
France	475,055
Poland	448,085
Portugal	443,015

N.B.: Submissions can be multi-country

New features since October



Summary of October update

- Version 4.0 PCN format released 26 October 2021, main features include:

- *New update reasons e.g. 'Cease product from the market'*
- *Make a group submission*
- *Indicate a multicomponent product identifier*
- *Changes to the European Product Categorisation System*
- *New/modified Validation Rules*
- *HTML report replaced PDF report*

- [PCN practical guide](#) updated to support you
- For more details: refer to the information presented at our Safer Chemicals Conference:
 - Watch the [presentation](#)
 - Get the [slide set](#)



Future improvements

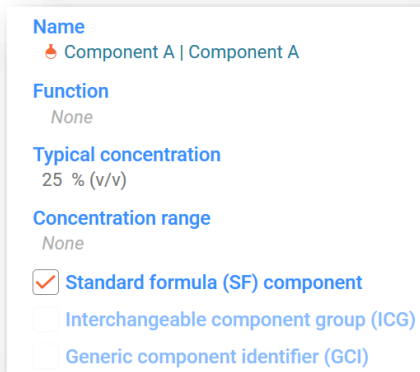
- PCN IT solution moving to maintenance mode
 - Hosts all features that support you to be compliant
 - Less resources allocated to future improvements
 - Continue to improve but only major feedback addressed

Identified issues



1. Use of standard formula 1/3

- 'Standard formula' tick-box is for specific components listed in Annex VIII for construction products or fuels
- **Previously:** Misunderstanding of the use of 'Standard formula' tick-box
- Tick-box waives certain validation rules
- [Declaring concentrations under Annex VIII](#) must be in line with Tables 1 and 2 according to hazard class
- Incorrect use has allowed notifiers to mistakenly report concentrations outside allowable limit

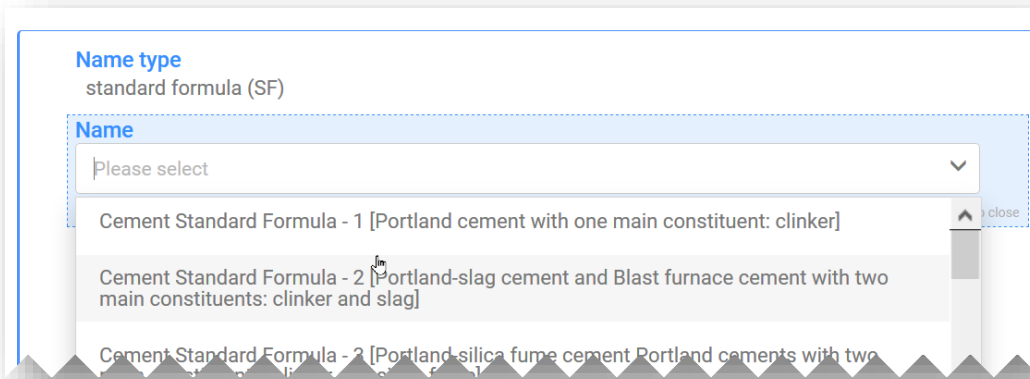


The screenshot shows a form for configuring a component. It includes the following fields and options:

- Name:** Component A | Component A
- Function:** None
- Typical concentration:** 25 % (v/v)
- Concentration range:** None
- Standard formula (SF) component
- Interchangeable component group (ICG)
- Generic component identifier (GCI)

1. Use of standard formula 2/3

Now: New validation rule checks if 'Standard formula' tick-box marked. Need to specify standard formula name you are referring to:



The screenshot shows a web form with the following elements:

- Name type:** standard formula (SF)
- Name:** A dropdown menu with the text "Please select" and a downward arrow. Below the dropdown, a list of options is visible, including "Cement Standard Formula - 1 [Portland cement with one main constituent: clinker]", "Cement Standard Formula - 2 [Portland-slag cement and Blast furnace cement with two main constituents: clinker and slag]", and "Cement Standard Formula - 2 [Portland-silica fume cement Portland cements with two".

Issue? Update notifications failing if previously used standard formula

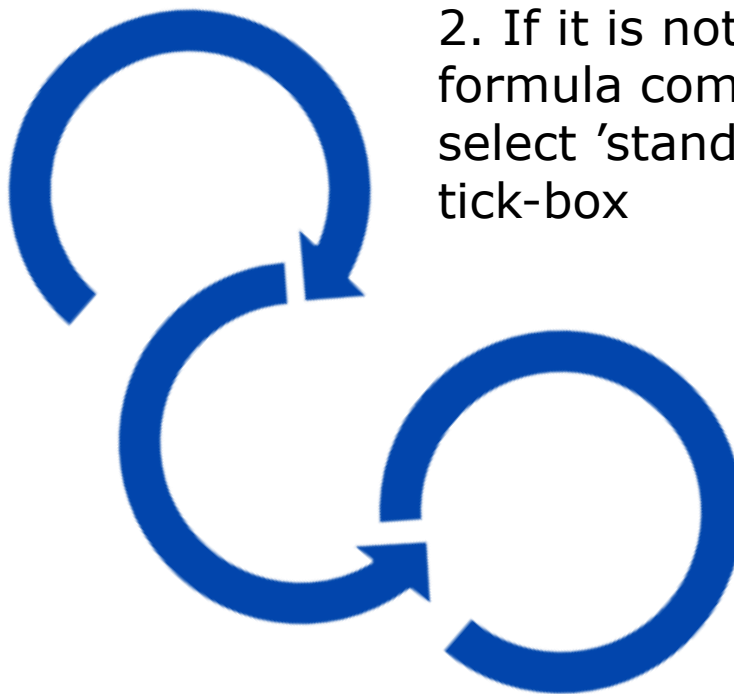
BR580*

If 'Component' is indicated to be 'SF (Standard formula)' then name of the standard formula or fuel must be provided:

1. Use of standard formula 3/3

How to fix it?

1. Is it really a standard formula component? If so, add the correct name



2. If it is not a standard formula component, de-select 'standard formula' tick-box

3. Check compositional data – ensure it is in allowed range. Wider concentrations can be made narrower without failure.

2. Mixture in mixture supplier

- New QLT checks that MiM supplier is EU-based

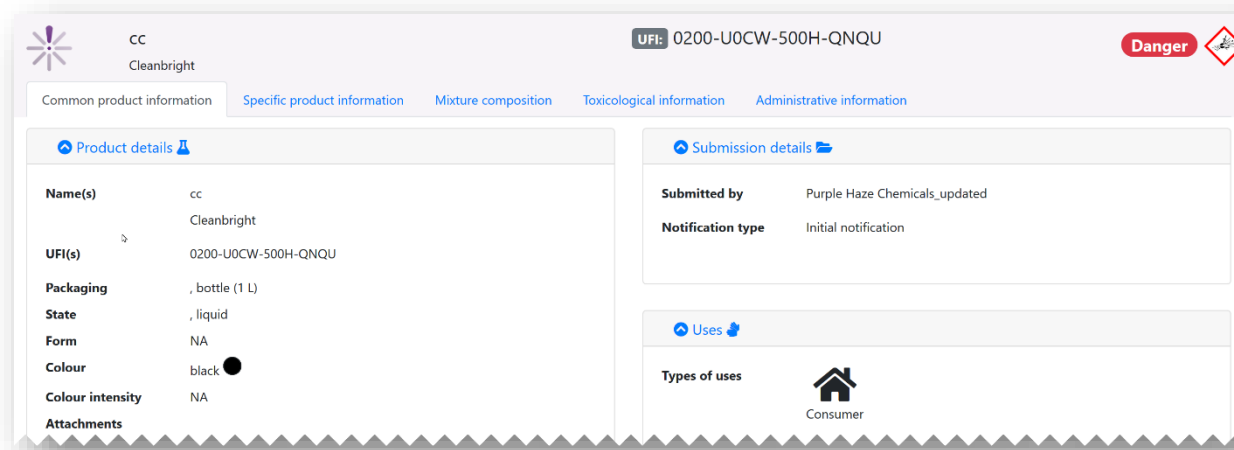
QLT869*

If the MiM does not have UFI and is instead identified with providing the available component(s) of the composition, then the legal entity in the 'Suppliers' record should be from EU country. Please note that the responsibility for mixtures imported into the EU remains on the importer.

- Why? To assist authorities in case of further follow up on composition
- If you are an EU importer of a MiM (mixture for further formulation), you need:
 - to notify the imported mixture (i.e. MiM) plus,
 - your own final product

3. HTML report 1/2

- PDF report obsolete replaced by HTML report




The screenshot displays the ECHA HTML report interface for a chemical product. At the top, the product name 'cc Cleanbright' is shown next to a star icon, and the UFI '0200-U0CW-500H-QNQU' is displayed. A red 'Danger' warning icon is present in the top right corner. Below the header, there are navigation tabs for 'Common product information', 'Specific product information', 'Mixture composition', 'Toxicological information', and 'Administrative information'. The 'Product details' section is expanded, showing the following information:

Name(s)	cc Cleanbright
UFI(s)	0200-U0CW-500H-QNQU
Packaging	, bottle (1 L)
State	, liquid
Form	NA
Colour	black ●
Colour intensity	NA
Attachments	

The 'Submission details' section shows:

Submitted by	Purple Haze Chemicals_updated
Notification type	Initial notification

The 'Uses' section shows:

Types of uses	 Consumer
---------------	---

- Why? Maintaining two reporting tools not efficient. Same report used by authorities and proven to be less error prone



3. HTML report 2/2

- Improved reporting format – reports all provided information
- Enhanced visual representation and organisation of information
- Possible to download whole file as PDF
- Save sections using browser settings e.g. to omit sections for confidentiality reasons

Member States overview



Member States overview

		Duty holders must continue to notify their mixtures according to national systems until further notice.
Belgium		
Bulgaria		
Iceland		
Liechtenstein		
Luxembourg		
Slovakia		

- Expect all Member States to use ECHA's systems
- Currently, six Member States remaining and either:
 - On-boarded but not ready to accept
 - In the process of onboarding
- Need to submit a harmonised submission through national channels. Contact appointed body for more details or visit their website
- Belgian Appointed Body (also representing Luxembourg) onboarded and aim to be accepting January 2022



When is the dossier received?

- Event “*Dossier received by [country code]*” generated when dossier available to appointed body
- Event ‘*Dossier received*’ may be generated in different moments:
 - Usually instantaneous
 - Up to 24 hours - system processing submission during peak volumes can cause delays
 - >24 hours – possible technical issue, contact ECHA Helpdesk
- Note it is possible to see ‘*Dossier received*’ even though appointed body may not be accepting
- Check the Member States [overview table](#) to see when you can place on the market

ECHA Helpdesk





Changes

1. National Helpdesks - First point of contact for **EU & non-EU**

- For regulatory questions (some technical support)
- Answer in national language
echa.europa.eu/support/helpdesks

2. ECHA Helpdesk - For technical support

- Redirect regulatory questions to National helpdesks
echa.europa.eu/contact/clp

3. National appointed bodies

- For information referring to national procedures e.g. onboarding or information about fees
poisoncentres.echa.europa.eu/appointed-bodies

UFI campaign for consumers



Why the UFI matters

- Poison centres have mere minutes to identify the exact product, assess the information & provide a rapid response
- The UFI supports this process
- Our goal is to educate consumers about the UFI
 - Why it exists
 - Which products contain it
 - Where to find it
- Consumer site created
- Educational information in all EU languages, UFI animation, example label

» WHY UFI MATTERS

If you have an accident involving everyday chemical products, use the UFI code to get faster medical advice.

UFI: H563-L905-R783-J823

WARNING
KEEP OUT OF REACH OF CHILDREN
USES SERIOUS EYE IRRITATION

The 16-character UFI code can be found on certain products that may harm your health if not used correctly.

Check if you already find the UFI on products you have at home.

» The best way to avoid accidents is to keep chemical products out of children's reach! «

#UFImattersEU

ECHA
EUROPEAN CHEMICALS AGENCY

poisoncentres.echa.europa.eu/why-the-ufi-matters-for-everybody

But we need to reach further!

- Social media campaign - 'challenge' finding UFI on products at home to 10 Dec.
- Work with stakeholders, Member States, as well as institutional and national influencers
- Aim to spread the message and share on social media
- All materials translated - visit our campaign page
- Join us in **#UFImattersEU**
poisoncentres.echa.europa.eu/ufi-matters-social-media-campaign



Upcoming changes – Cease product vs. Disable submission

Webinar: Poison centre
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changes and functionalities

24 November 2021

Claudia RIMONDO
European Chemicals Agency



Topics covered

- Business requirements about ceasing a product from the market
- Business requirements about disabling a submitted dossier
- IT solutions to address those requirements

Ceasing a product from the market

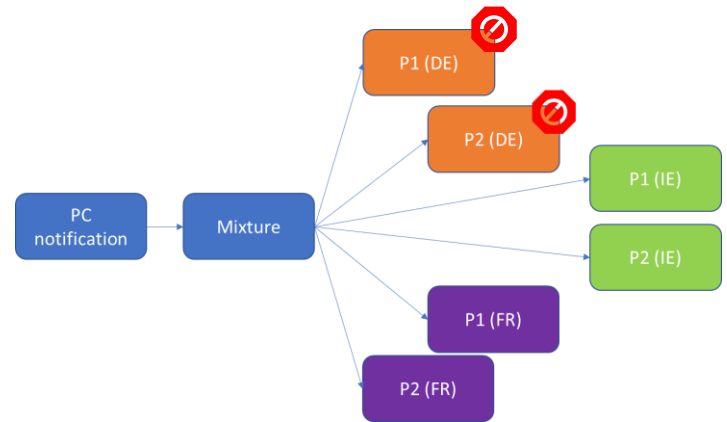
Business requirements:

- Industry wants to indicate that a mixture is no longer marketed in a certain area
- Poison centres need to access information about ceased products as those can still be used and cause poisonings after they have been ceased
- Appointed Bodies need information on ceased products to perform toxicovigilance activities
- Ceasing a product from the market as voluntary option, no legal requirement

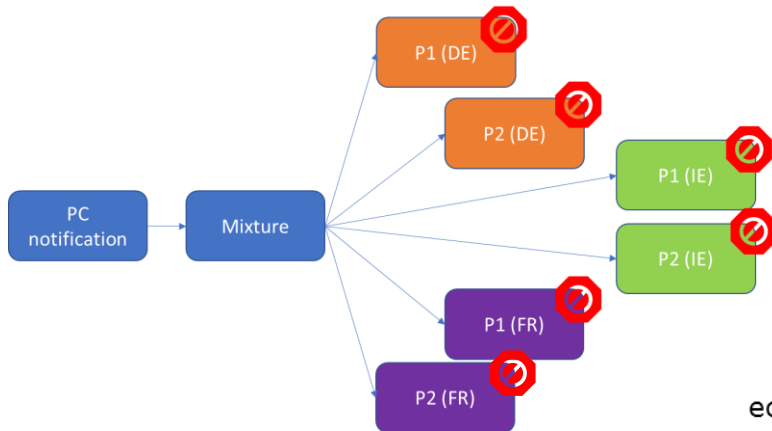
Granularity of the information

- Industry needs to indicate which exact product is no longer placed in a certain market area

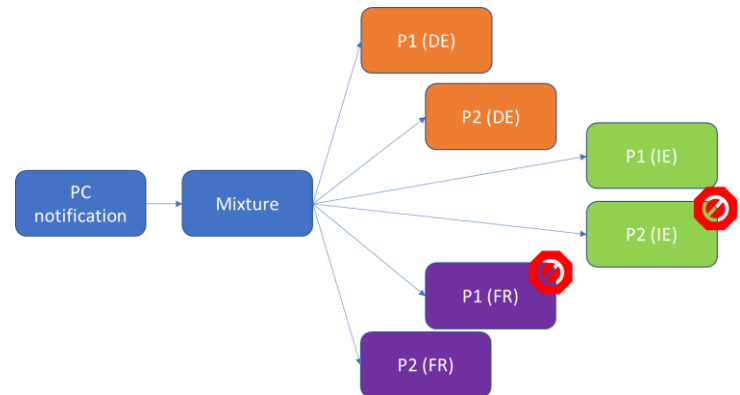
Scenario 1 – Cease all products from one market



Scenario 2 – Cease all products from all the markets



Scenario 3 – Cease some products from some markets



Disabling a submitted dossier (1/2)

Disabling a submitted dossier may be needed because:

- Industry notifies a wrong UFI and the UFI cannot be deleted or fully replaced due to existing validation rules for updates
- Industry has notified to one market area by mistake and needs to disable this submission to avoid paying fees
- Industry wants to provide more accurate information or correct the already notified mixture composition, but this is not possible due to the existing validation rules enforcing same components and allowable ranges for changes in the existing concentration
- Industry has submitted a "new notification for significant change of composition" instead of an update of an existing notification having the same composition
- Industry has submitted by mistake a test dossier in the production environment.

Disabling a submitted dossier (2/2)

Business requirements:

- Industry needs to be able to disable succeeded submissions and this information should be propagated to the downstream systems consuming the information from the ECHA Submission portal
- Industry must be able to keep track of their disabled submissions
- Appointed Bodies and Poison Centres need to be able to identify the disabled submissions so these are not taken into consideration in their day-to-day tasks
- Disabling a submitted dossier as voluntary action, no legal requirement

Different requirements → Different solutions

Ceasing a product
from the market

≠

Disabling a
submitted dossier

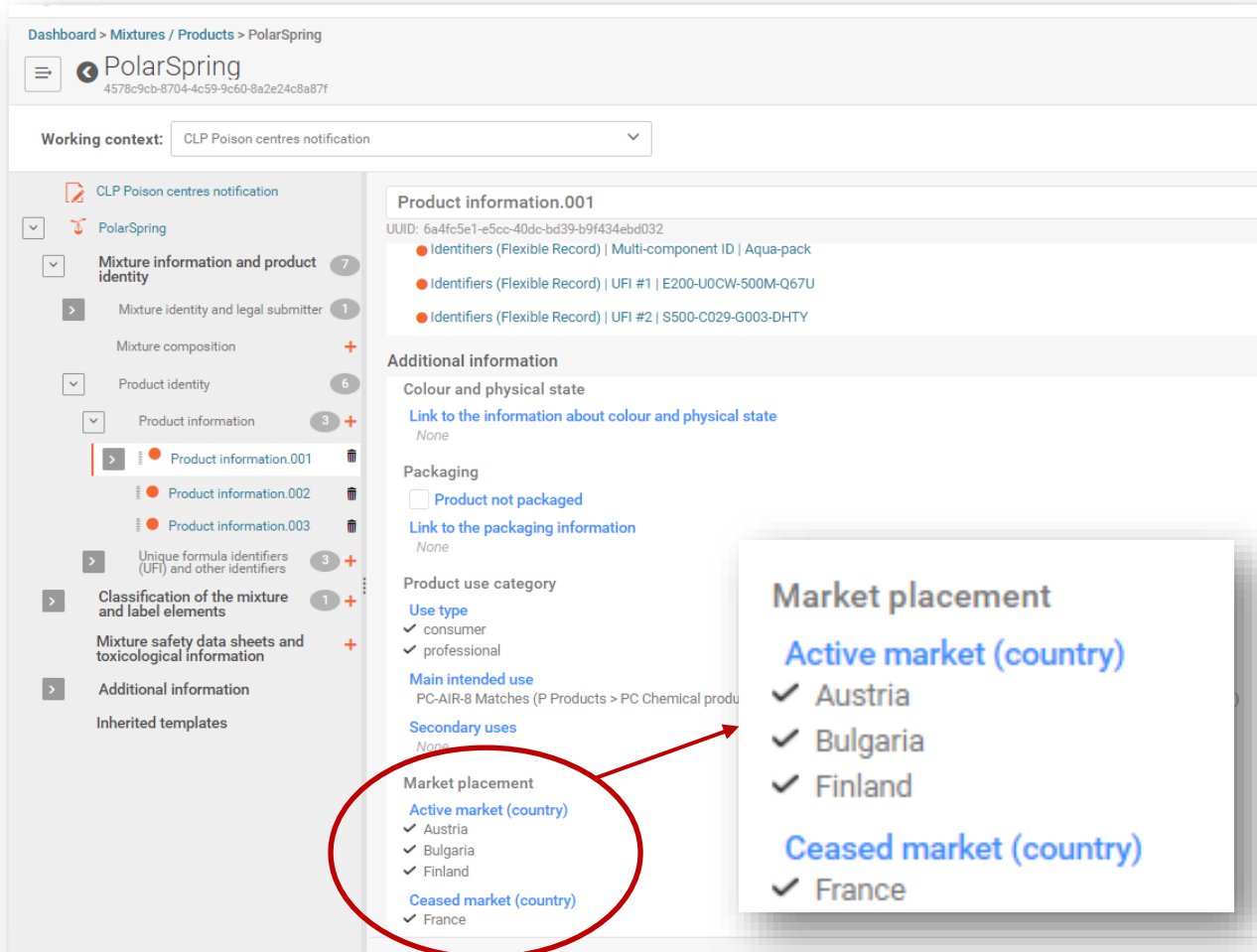
Part of the PCN v.4
format (submission of a
new dossier required)

Feature in ECHA
Submission portal
(submission of a new
dossier NOT required)

How to indicate in the PCN dossier that a product has been ceased from the market?



Manage market areas in Product record(s)



The screenshot shows the ECHA CLP Poison centres notification interface. The main content area displays 'Product information.001' with a UUID and three identifiers. Below this, the 'Additional information' section includes 'Colour and physical state', 'Packaging', 'Product use category', and 'Secondary uses'. The 'Market placement' section is highlighted with a red circle and contains a list of countries under 'Active market (country)' and 'Ceased market (country)'. A red arrow points from this section to a larger, semi-transparent window titled 'Market placement' which shows a detailed view of the market placement options, including checked boxes for Austria, Bulgaria, and Finland under 'Active market (country)', and a checked box for France under 'Ceased market (country)'.

- 2 lists now available
- Select the market areas from the relevant lists
- Repeat for all the relevant product records

Adapt dossier header

UUID: 947d8a30-3cbe-4edc-9812-937798c130e7

Country (market placement)*

- ✓ Austria
- ✓ Bulgaria
- ✓ Finland
- ✓ France

Language*

- ✓ Bulgarian
- ✓ Finnish
- ✓ French
- ✓ German
- ✓ Swedish

Sum of
Countries in "Active market" list
+
Countries in "Ceased market" list

Notification type

The submission is an update

Reason for updating

Justification + New item

- Possible to indicate both justifications in the same dossier

Reason for updating

Justification + New item

1 Justification
cease product from market
Remarks
None

Reason for updating

Justification + New item

1 Justification
re-place product on market
Remarks
None

Information to end users

- PCN dossier made available to Appointed Bodies and Poison Centres
- Full set of information accessible
 - Product details
 - Reason for updating

How to disable a successfully submitted PCN dossier?



Conditions for disabling a submitted dossier

Condition #1

- Disabling only succeeded submissions is possible; failed submissions are not dispatched and do not have any impact on the downstream systems

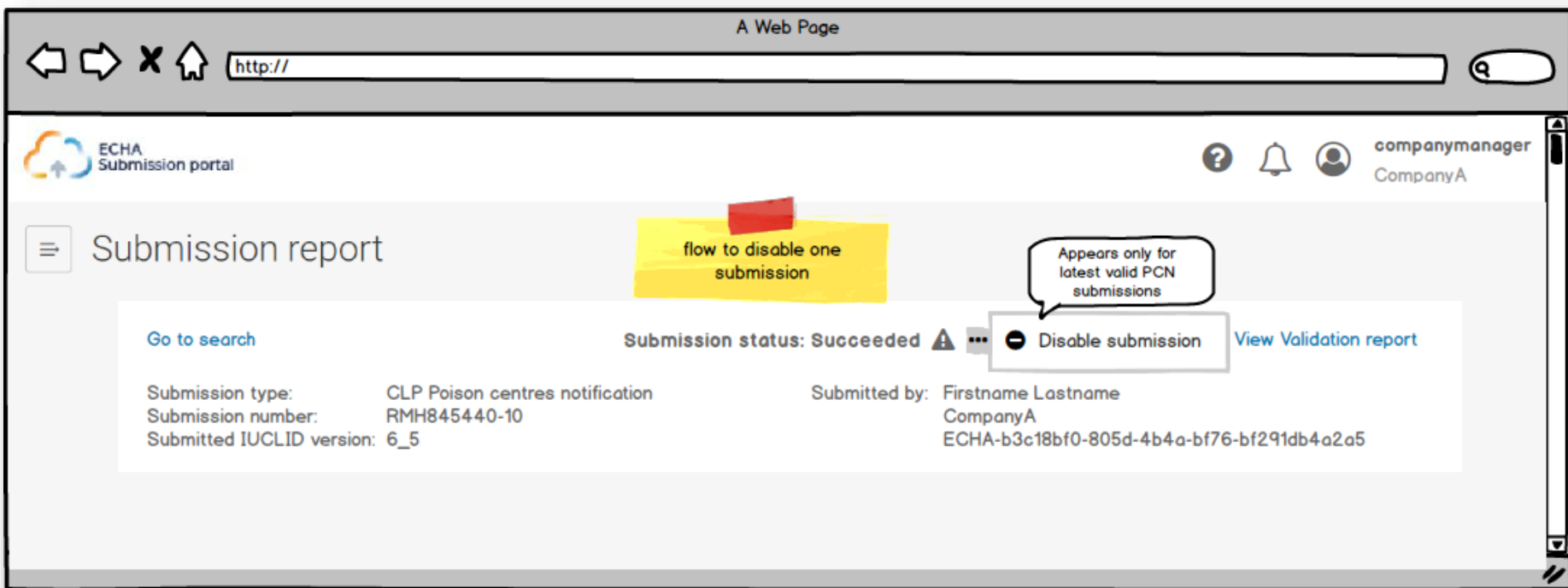
Condition #2

- Disabling only the latest submission is possible

Condition #3

- Disabling only own Legal Entity's submissions is possible

Disabling a submission from the ECHA Submission portal



A Web Page

http://

ECHA Submission portal



companymanager
CompanyA

Submission report

flow to disable one submission

Appears only for latest valid PCN submissions

Go to search

Submission status: Succeeded   **Disable submission** [View Validation report](#)

Submission type: CLP Poison centres notification
Submitted by: Firstname Lastname
Submission number: RMH845440-10
CompanyA
Submitted IUCLID version: 6_5
ECHA-b3c18bf0-805d-4b4a-bf76-bf291db4a2a5

Submission number

A Web Page

http://

ECHA Submission portal

companymanager
CompanyA

Disable submission

flow to disable one submission

Are you sure you want to disable submission RMH845440-10?
This action cannot be reverted.

If yes, select a reason for doing it:

- Submission made unintentionally
- Submitted dossier contains test data
- Submission made by a wrong company
- Submitted dossier contains wrong information

By selecting "Disable" you will indicate that your submission is not relevant for any regulatory compliance purposes. Your dossier will still remain accessible. Choosing to disable your submission may have negative regulatory consequences.

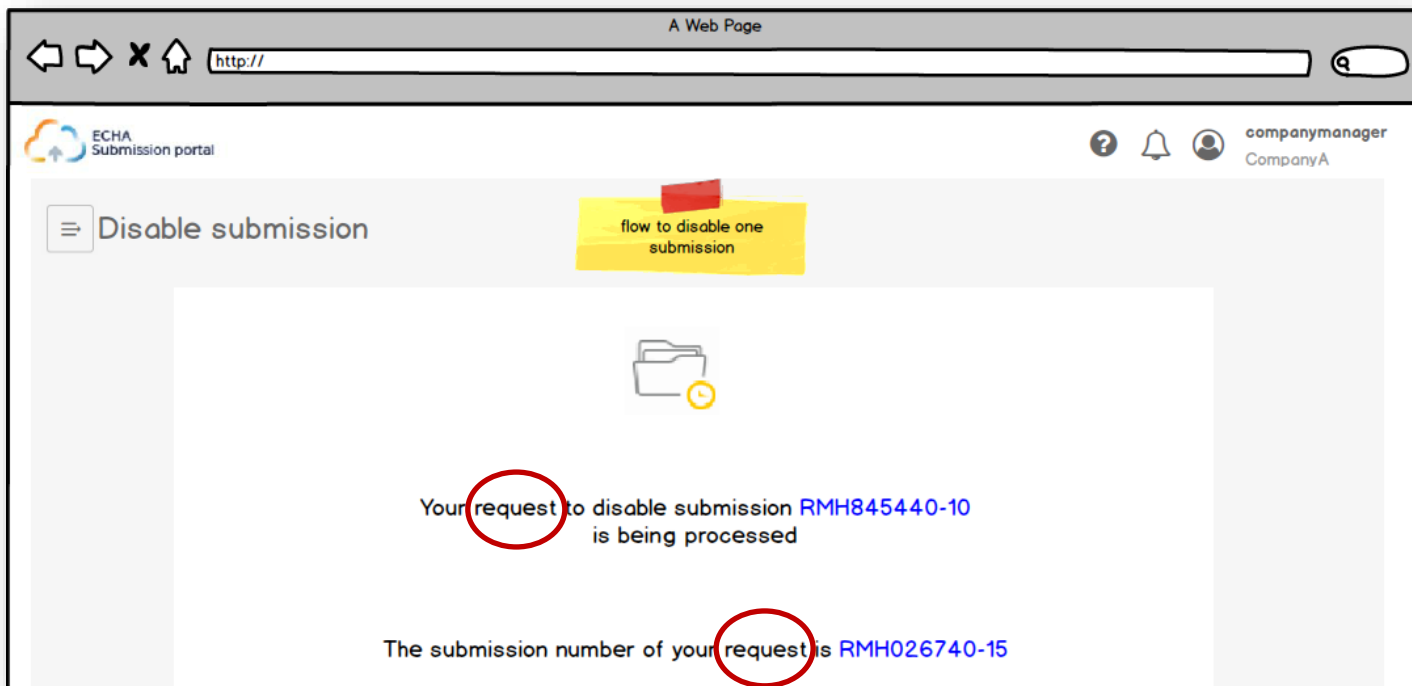
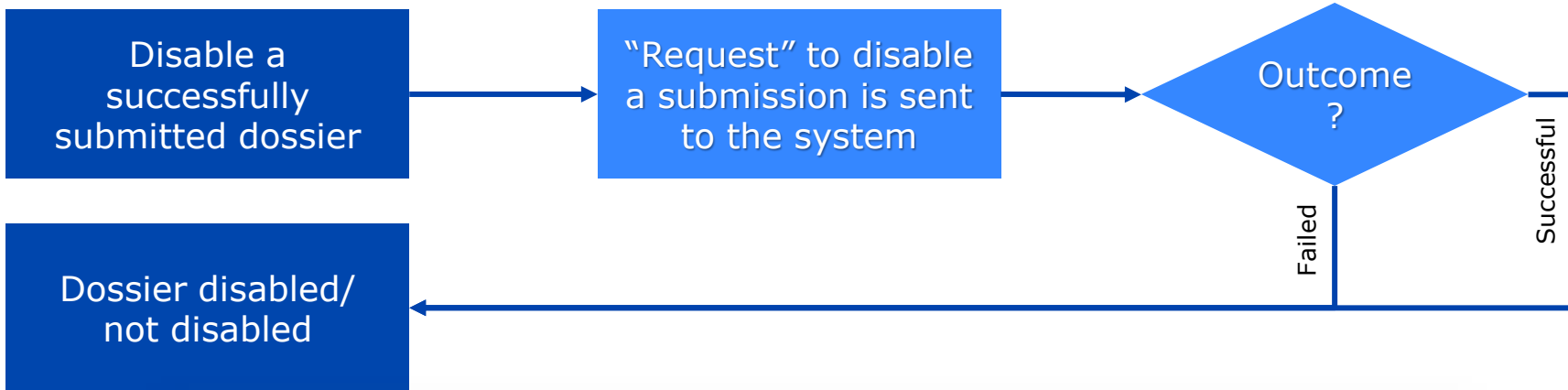
For more information see the appropriate section in [the Terms and Conditions here](#).

Returns to the submission report

Cancel

Gets enabled when the reason is indicated and disclaimer is acknowledged

Disable



Submission report of the *Disabled* submission

A Web Page

ECHA Submission portal

companymanager
Company A

Submission report

submission report for the "Disabled submission"

Indication that the submission has been disabled

Go to search Submission status: Succeeded **Disabled** [View Validation report](#)

Submission type: CLP Poison centres notification Submitted by: Firstname Lastname
 Submission number: RMH845440-10 Company A
 Submitted IUCLID version: 6_5 ECHA-b3c18bf0-805d-4b4a-bf76-bf291db4a2a5

Submission information

PCN number: [d66c23e4-2cf7-4432-9e8d-65a73fab8f12](#)
 Mixture name: Test mixture
 Dossier name: Notification after change in composition (same ...
 Dossier UUID: e085f25d-345b-4bb2-be12-19570f88accd
 File name: e085f25d-345b-4bb2-be12-19570f88accd.i6z
 Reason for submission: The submission is an initial notification
 The submission is a new notification after a chan ...
 Reason for updating: The submission is an update
 change in mixture classification
 Type of submission: Limited submission

Product information

Use type: Consumer, Professional, Industrial
 Name(s): Forest Fresh
 Forest Clean
 Identifier(s): P9MD-C1E4-6X5A-19YC
 P8FD-D3E4-6XRF-YD34

Recipients (Member States - market placement)

Belgium
 Finland
 Greece
 Italy

Submission events

13/10/2020 10:25 Dossier submitted
 13/10/2020 10:25 Dossier passed validation checks
 13/10/2020 10:30 Dossier received by FI
 13/10/2020 10:31 Dossier received by GR
 13/10/2020 10:32 Dossier received by IT
 21/12/2020 14:05 Submission disabled

New event to indicate this submission is now disabled

Submission graph

SCIP number
 d66c23e4-2cf7-4432-9e8d-65a73fab8f12

13/10/2020 00:22	RMH458463-04		Disabled submission
13/10/2020 10:25	RMH845440-10		
21/12/2020 14:05	RMH220672-25		

Submission history

For PCN number d66c23e4-2cf7-4432-9e8d-65a73fab8f12

Showing 1 to 3 of 3 submissions

Submission date	Submission number	Submission status
13/10/2020 00:22	RMH458463-04	
13/10/2020 10:25	RMH845440-10	
21/12/2020 14:05	RMH220672-25	

Request for disable Submissions/page 20

Disabled submission - same as graph

Submission report of the Request

A Web Page

ECHA Submission portal

companymanager CompanyA

Submission report

submission report for the "Request to disable"

Go to search

Submission status: Succeeded

Submission type: CLP Poison centres notification
 Submission number: RMH220672-25
 Submitted IUCLID version: N/A

Submitted by: companymanager CompanyA
 ECHA-b3c18bf0-805d-4b4a-bf76-bf291db4a2a5

Submission information

PCN number: [d66c23e4-2cf7-4432-9e8d-65a73fab8f12](#) Belgium

Referenced submission: [RMH845440-10](#) land
 Greece
 Italy

Reason for submission: Request to disable the Referenced submission

Reason for disable: Submission made unintentionally

Reason for disable should appear

Recipients (Member States - market placement)

Submission events

- 06/04/2020 19:21 Dossier submitted
- 06/04/2020 19:21 Dossier passed validation checks
- 07/04/2020 16:25 Dossier disabled in FI
- 07/04/2020 16:25 Dossier disabled in GR
- 07/04/2020 16:25 Dossier disabled in IT

Submission graph

PCN number: 1403b075-fad8-4faf-8484-7e1ba9a0cd57

Disabled submission

- 13/10/2020 00:22 [RMH458463-04](#) ✓
- 13/10/2020 10:25 [RMH845440-10](#) ✓
- 21/12/2020 14:05 [RMH220672-25](#) ✓

Submission history

For PCN number [d66c23e4-2cf7-4432-9e8d-65a73fab8f12](#)

Showing 1 to 3 of 3 submissions


Submission date	Submission number	Submission status
13/10/2020 00:22	RMH458463-04	✓
13/10/2020 10:25	RMH845440-10	✓
21/12/2020 14:05	RMH220672-25	✓

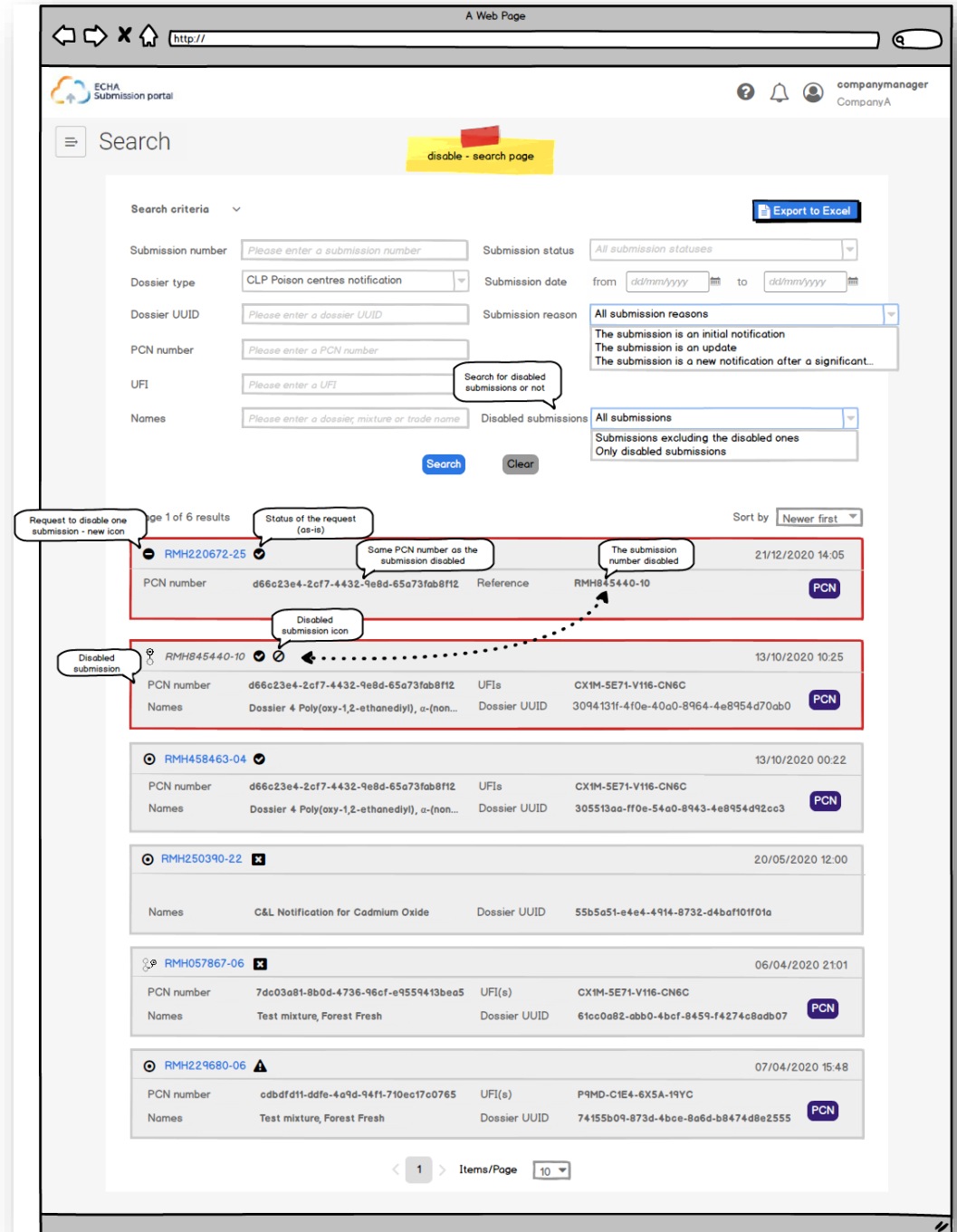
Request for disable

Submissions/page 20

- Recipients retrieved from the submission to be disabled
- Request itself does not define any recipients

Search page

- Search criteria adapted to filter in/out disabled submissions
- Requests included in search results 



The screenshot shows the ECHA Submission portal search interface. At the top, there is a search bar and a 'disable - search page' button. Below the search bar, there are several search criteria fields: Submission number, Dossier type (set to 'CLP Poison centres notification'), Dossier UUID, PCN number, UFI, and Names. There are also dropdown menus for Submission status, Submission date, Submission reason, and Disabled submissions. A 'Search' button and a 'Clear' button are located below the criteria. To the right, there is an 'Export to Excel' button and a dropdown menu for 'Disabled submissions' with options: 'All submissions', 'Submissions excluding the disabled ones', and 'Only disabled submissions'. Below the search criteria, there is a table of search results. The table has columns for 'Request to disable one submission - new icon', 'Status of the request (as-is)', 'PCN number', 'Reference', and 'Submission date'. The first row is highlighted in red and has several callout boxes: 'Request to disable one submission - new icon' pointing to a minus sign icon, 'Status of the request (as-is)' pointing to a checkmark, 'Some PCN number as the submission disabled' pointing to the PCN number, and 'The submission number disabled' pointing to the reference. The second row is also highlighted in red and has a callout box: 'Disabled submission icon' pointing to a disabled icon. Below the table, there is a pagination bar showing '1' items per page.

Information to end users

- Disabled dossiers remain visible and accessible by Appointed Bodies and Poison Centres BUT they are marked as "*Disabled*" (not valid)
- Dossier marked as "*Disabled*"
 - In the HTML report from the PCN database (12/2021)
 - In the eDelivery/Secure folder package (12/2021)
 - New search criteria in PCN database (2022)

Availability of the “Disable submission” feature

- ECHA Submission portal users: December 2021
- S2S users: Summer 2022
 - Update of the Application Programming Interface (API) required (V.4)
 - Possibility to disable submissions only after companies have adapted to API V.4
 - If a submission gets disabled from the submission portal manually, no information can be communicated via S2S before API V.4 is in place

What you need to know when making a group submission

Webinar: Poison centre notifications: explaining new changes and functionalities

24 November 2021

Daniele APE
European Chemicals Agency



Topics covered

- What is Group Submission
- When can be an option and which information requirements apply
- Preparation of Group Submission
- Validation of Group Submission

What is a Group Submission and when can be an option?



Group Submission option

What for? Allow single submission covering multiple mixture compositions when the differences are (very) limited but they cannot be considered as the same.

Nothing new from a legal perspective: provisions included in the first version of Annex VIII

But functionality available in the Submission Portal since October 2021

Group Submission criteria (I)

Same composition except for certain components used only as *perfumes*

Same concentrations/ranges for all common components

Same classification for health and physical hazards

All mixtures placed on the market by the same submitter

Group Submission criteria (II)

The components which differ (i.e. not present in all the mixtures of the group) can constitute not more than 5% of each composition

Common perfumes (if any) are not counted in the 5% limit

It must be clear which perfume(s) are present in which mixture(s)

Group Submission information required

Information in Part B of Annex VIII to be provided for each mixture

A GS may therefore cover mixtures placed on the market(s) with different:

- Trade names
- Packaging information
- Uses (and EuPCS)
- Physical states and characteristics
- Toxicological information (?)
- Environmental classification (?)

**One or
multiple
UFIs**

Group Submission information required

Common and not common components can be either substance or MiMs and must be identified following standard rules

Components can be identified with a Generic Component Identifier ("*Perfumes*" or "*Colouring agents*") if criteria apply

Note: perfumes not classified or classified for certain classes only do not need to have concentration

Group Submission

Common components	Concentrations
Surfactant 123	5-6%
Soap xyz	2-5%
Sodium carbonate	7-10%
Processing aid xxx	1-2%
Water	66-76.4%

Must constitute at least 95% of each actual mixture

Mixture A		Mixture B		Mixture C	
<i>Perfume components</i>	<i>Conc. %</i>	<i>Perfume components</i>	<i>Conc. %</i>	<i>Perfume components</i>	<i>Conc. %</i>
Perfume MiM X	<i>Na</i>	Perfumes (GCI)	0.6 - 1.6	Perfume MiM Z	0.5 - 0.9
Perfume MiM Y	0.5 - 1.5			Perfumes (GCI)	0.1 - 1.1

Can constitute max 5% of each actual mixture

How to prepare a Group Submission?



Group Submission preparation

1. Establish the correct submission type

Working context: CLP Poison centres notification

CLP Poison centres notification

Group submission - candles

Mixture information and product identity 1

Classification of the mixture and label elements +

Mixture safety data sheets and toxicological information +

Additional information

Inherited templates

UUID: 5c30be51-77c8-49d3-8b79-c39339e3e784

Dossier name (given by user)
None

Dossier submission remark
None

Specific submissions

PCN number*
00353c61-c924-406b-b406-27b017a67d38

Country (market placement)*
✓ Austria

Language*
✓ German

Submission type

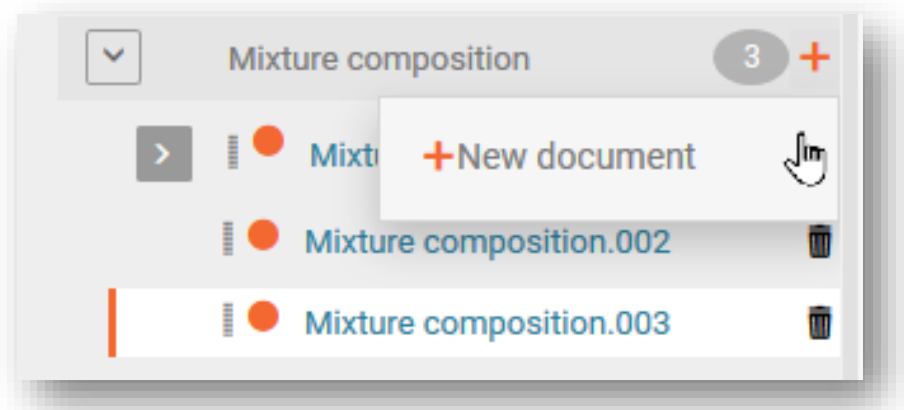
Limited submission (industrial use only)

Group submission

Voluntary submission

Group Submission preparation

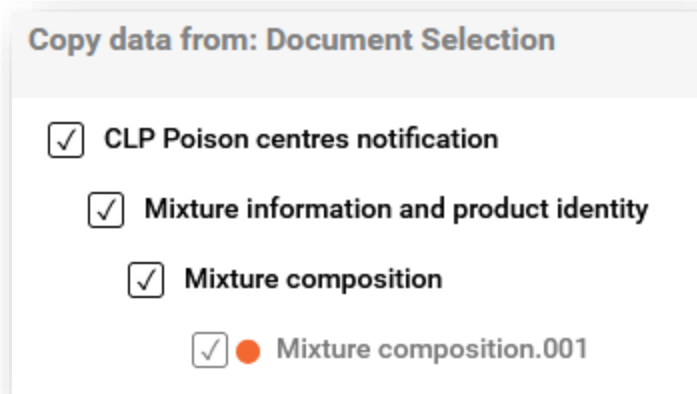
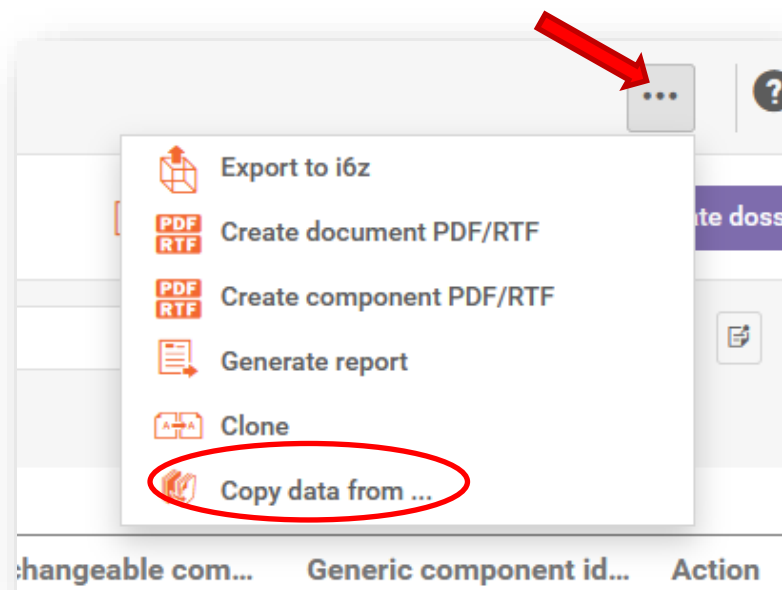
2. Enter individual mixture compositions



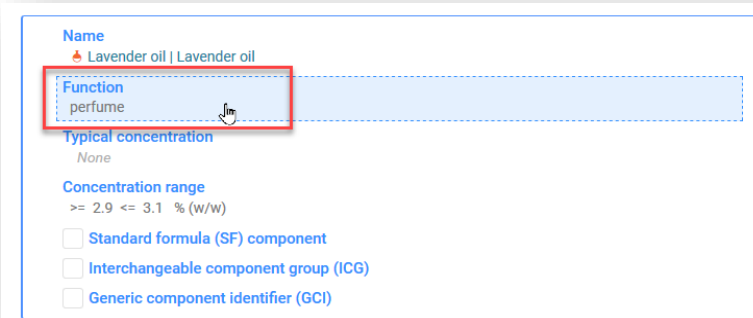
Practical way forward:

- a) enter the common composition once
- b) create clones
- c) add specific perfume component(s) to each clone

Group Submission preparation

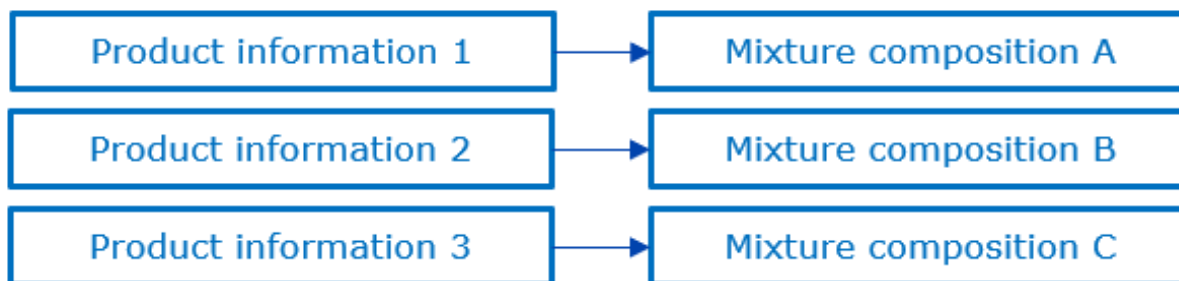


N.B.: indicate function as "*Perfumes*" to relevant component



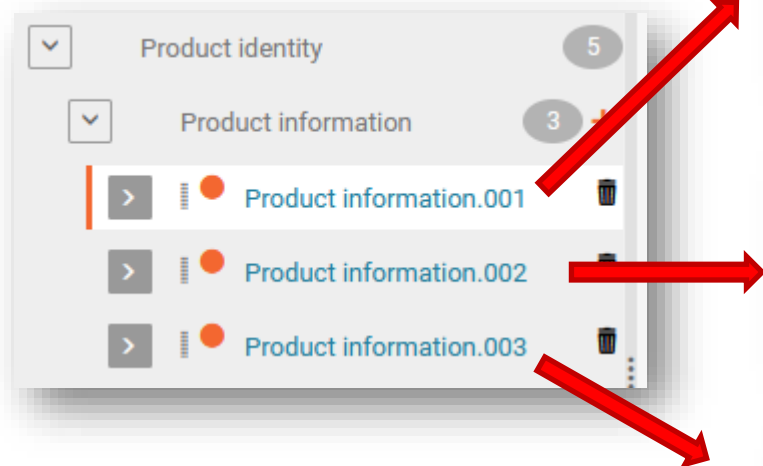
Group Submission preparation

3. Enter Product information for each mixture individually



- More than one product record can be linked to each mixture
- Each product record can be linked to one mixture only

Group Submission preparation



Group submission

For a group submission, specify to which mixture it applies.

● MixtureComposition (Flexible Record) | Mixture composition.001

Group submission

For a group submission, specify to which mixture it applies.

● MixtureComposition (Flexible Record) | Mixture composition.001

Group submission

For a group submission, specify to which mixture it applies:

● MixtureComposition (Flexible Record) | Mixture composition.002

Group Submission preparation

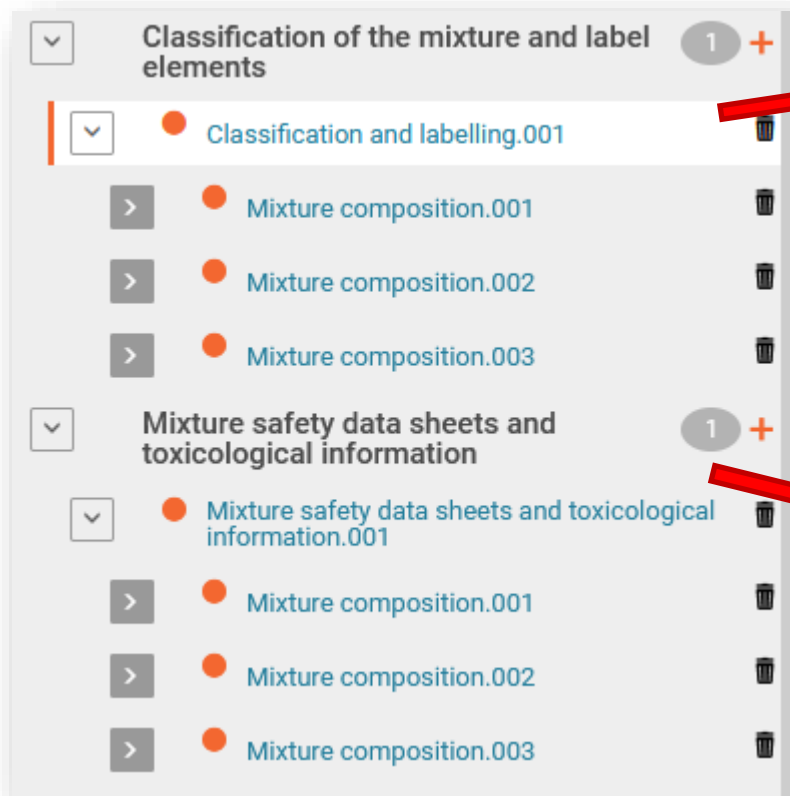
4. Enter C&L, toxicological information, pH documents for each mixture

The same record can be linked to multiple mixtures

Or

A different record can be linked to each mixture composition (e.g. differences in environmental classification require different C&L records)

Group Submission preparation



Classification of the mixture and label elements 1 +

- Classification and labelling.001
- Mixture composition.001
- Mixture composition.002
- Mixture composition.003

Mixture safety data sheets and toxicological information 1 +

- Mixture safety data sheets and toxicological information.001
- Mixture composition.001
- Mixture composition.002
- Mixture composition.003

Group submission

For a group submission, specify to which mixture it applies:

- MixtureComposition (Flexible Record) | Mixture composition.003
- MixtureComposition (Flexible Record) | Mixture composition.002
- MixtureComposition (Flexible Record) | Mixture composition.001

Group submission

For a group submission, specify to which mixture it applies:

- MixtureComposition (Flexible Record) | Mixture composition.003
- MixtureComposition (Flexible Record) | Mixture composition.002
- MixtureComposition (Flexible Record) | Mixture composition.001

How does the validation work?



Group Submission validation

Specific set of rules associated to submission type “Group submission”, to check:

- Same information as required for standard submissions on the dossier as such (e.g. info in dossier header), on the individual mixtures (e.g. allowed concentration ranges) and product information (e.g. packaging info)
- Specific GS-requirements (e.g. minimum common composition, differing components must be *perfumes*)

Group Submission validation

Group submission	Standard submission
At least one pH record exists (and all are linked to a mixture composition)	Exactly one pH record exists
At least one Tox info record (and all are linked to a mixture composition)	Exactly one Tox info record exists
At least two mixture compositions exist	Exactly one mixture composition exists
All components except specific <i>Perfumes</i> components must have concertation	All components must have concertation
At least one C&L record exists (and a link to each mixture exists)	Exactly one C&L record exists

Update Group submissions

- Changes not affecting mixture compositions
- Changes concerning perfumes only
- Addition/deletion mixture composition(s)

Notification type

The submission is an update

Reason for updating

Justification + New item

1

Justification

change in mixture composition without requiring a new UFI

- Changes affecting mixture compositions (Part B.4 of Annex VIII)

Notification type

New notification after a significant change of composition

+ New UFI

Grouping existing submissions

Mixtures notified via standard submissions before last format update may qualify for GS

No update option exists to “merge” standard submissions

Way forward is to wait for “disabling” functionality and re-submit a new Group submission

Closing remarks

Webinar: Poison centre
notifications: explaining new
changes and functionalities

24 November 2021

Poison Centres Team
European Chemicals Agency



Take home messages

- If your dossier has not been received, we ask for your patience, but you can always contact us and we will investigate.
- Check our support material first – more often than not, the answer is provided there.
- If you need more specific advice consider who you should contact first.
- Join our UFI challenge on social media to help spread the message.

Take home messages

- Consider the different business meaning of “*ceasing a product from the market*” and “*disabling a successfully submitted dossier*”.
- Use the proper IT solution according to your business need.
- Remember: a disabled submission still remains accessible by Appointed Bodies and Poison Centres but it is marked as “*Disabled*”.
- Be aware of the legal consequences of disabling a successfully submitted dossier.
- Consider the availability of the disabling submission feature in Summer 2022 for S2S users.

Take home messages

- Consider legal criteria when preparing a GS: only the submitter knows the actual common/not common composition
- Consider if the use of a Generic Component Identifier in a standard submission is a (more) suitable option
- Consider the possible future business plans before choosing the submission option

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