

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

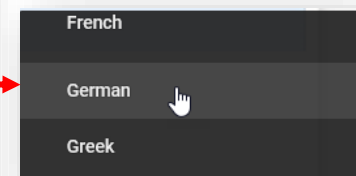
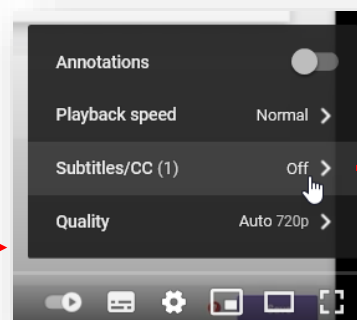
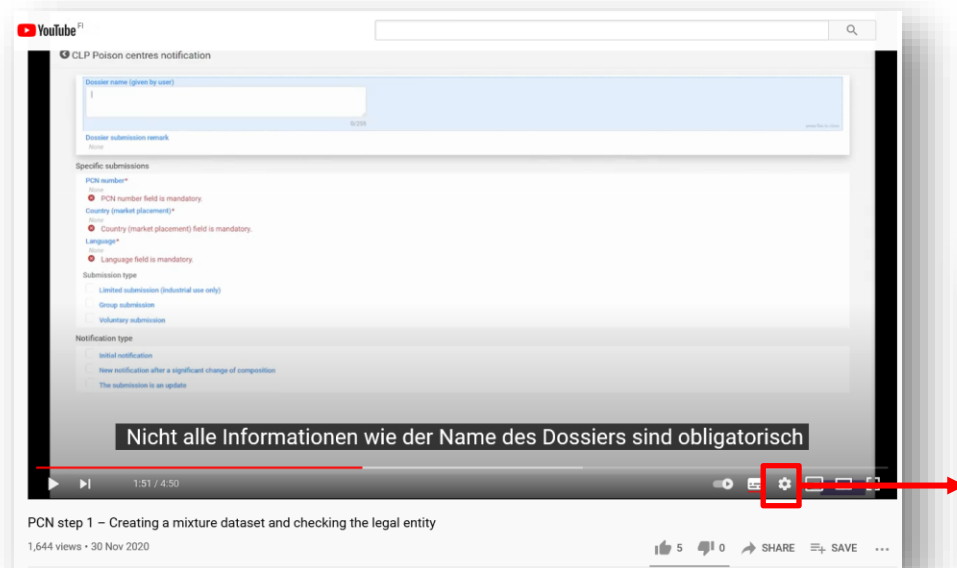
Questions

- Join Q&A at: slido.com
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
changes and functionalities

24 November 2021

Heidi RASIKARI
European Chemicals Agency





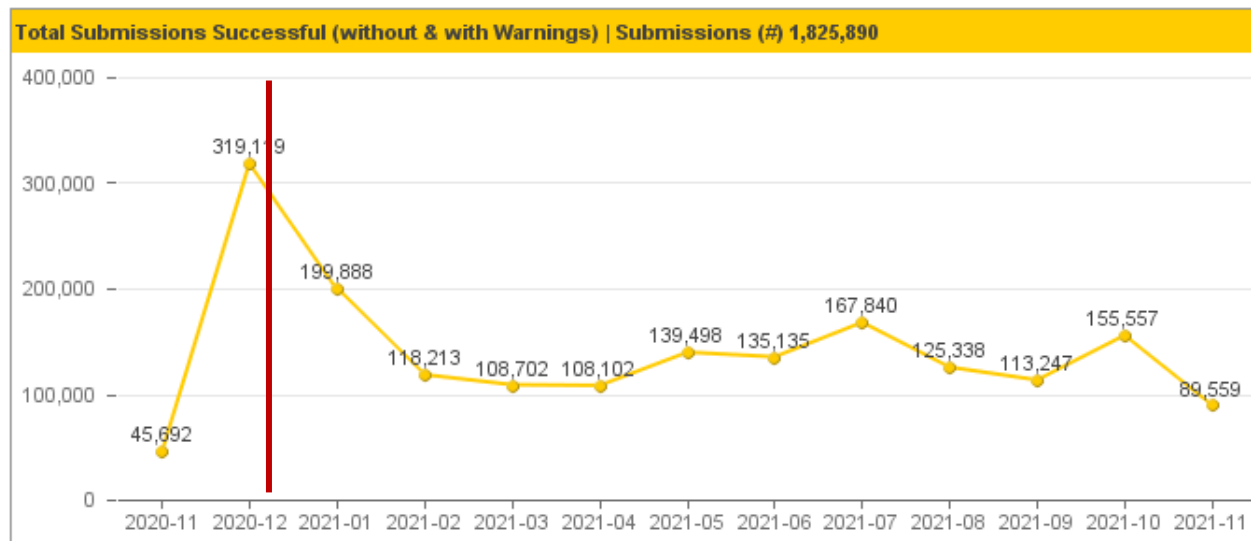
Outline

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

Submission numbers

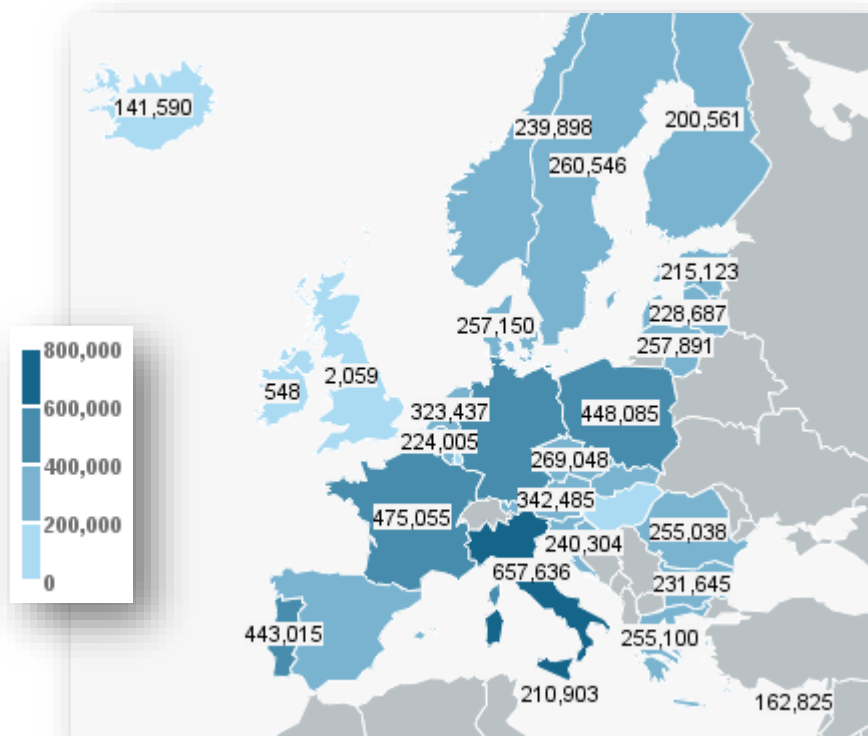
20 November to 21 October

- 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

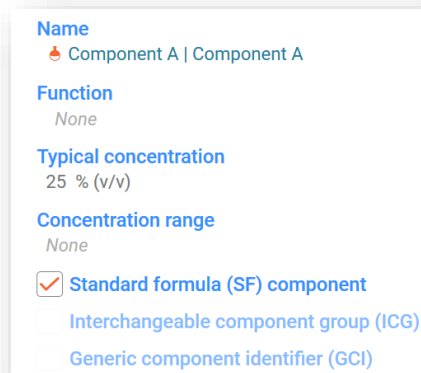
- PCN IT solution moving to maintenance mode
 - Hosts all features that support you to be compliant
 - Less resources allocated to future improvements
 - Continue to improve but only major feedback addressed

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

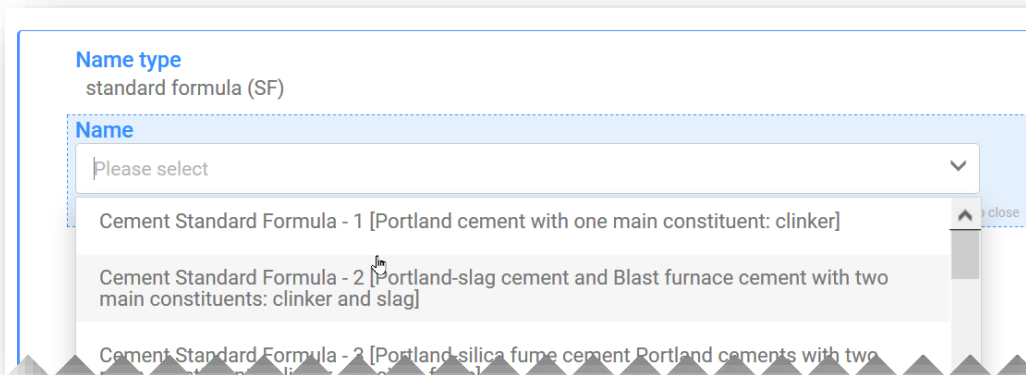


The screenshot shows a form for declaring a component. It includes fields for Name, Function, Typical concentration, and Concentration range. The 'Standard formula (SF) component' checkbox is checked, while 'Interchangeable component group (ICG)' and 'Generic component identifier (GCI)' are unchecked.

Name	Component A Component A
Function	None
Typical concentration	25 % (v/v)
Concentration range	None
<input checked="" type="checkbox"/> Standard formula (SF) component	
<input type="checkbox"/> Interchangeable component group (ICG)	
<input type="checkbox"/> 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 a section titled "Name type" containing the text "standard formula (SF)". Below this is a "Name" dropdown menu. The dropdown is open, showing a list of options. The first option is "Please select". The second option is "Cement Standard Formula - 1 [Portland cement with one main constituent: clinker]". The third option is "Cement Standard Formula - 2 [Portland-slag cement and Blast furnace cement with two main constituents: clinker and slag]". The fourth option is "Cement Standard Formula - 2 [Portland-silica fume cement Portland cements with two main constituents: clinker and slag]". A "close" button is visible on the right side of the dropdown menu.

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:

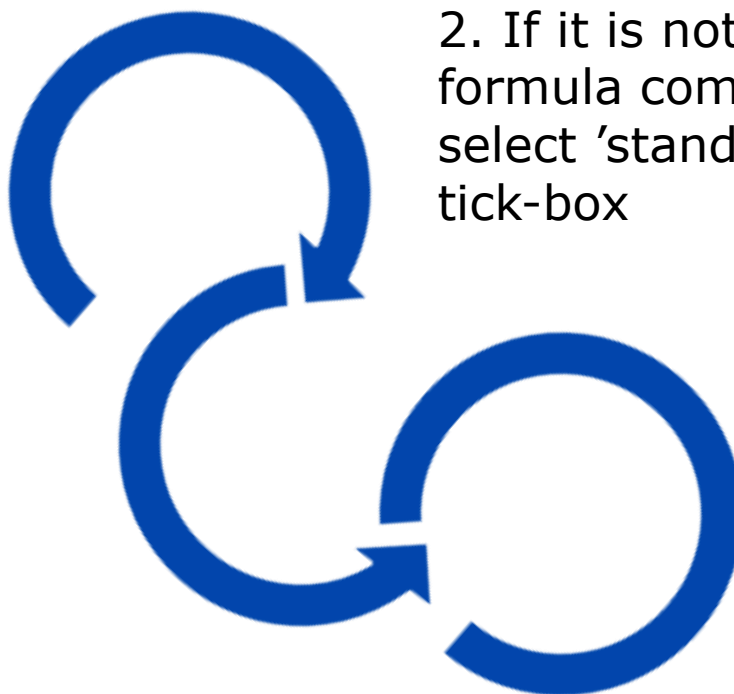
1. Use of standard formula 3/3

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

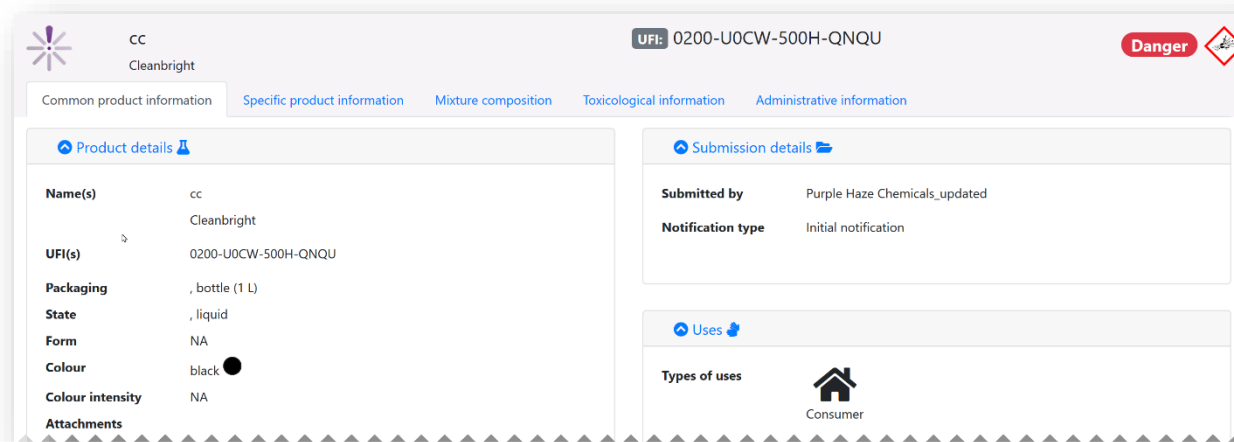
QLT869*

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' and 'Cleanbright' are shown, along with the UFI '0200-U0CW-500H-QNQU' and a 'Danger' hazard symbol. The interface is divided into several tabs: 'Common product information', 'Specific product information', 'Mixture composition', 'Toxicological information', and 'Administrative information'. The 'Common product information' tab is active, showing 'Product details' and 'Submission details'. The 'Product details' section includes fields for Name(s), UFI(s), Packaging, State, Form, Colour, Colour intensity, and Attachments. The 'Submission details' section includes fields for Submitted by and Notification type. The 'Uses' section shows 'Types of uses' with a 'Consumer' icon.

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

Submission details	
Submitted by	Purple Haze Chemicals_updated
Notification type	Initial notification

Uses	
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

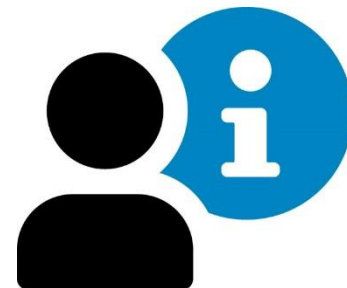


When is the dossier received?

- 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



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 **#UFI mattersEU**
poisoncentres.echa.europa.eu/ufi-matters-social-media-campaign



Upcoming changes – Cease product vs. Disable submission

Webinar: Poison centre
notifications: explaining new
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

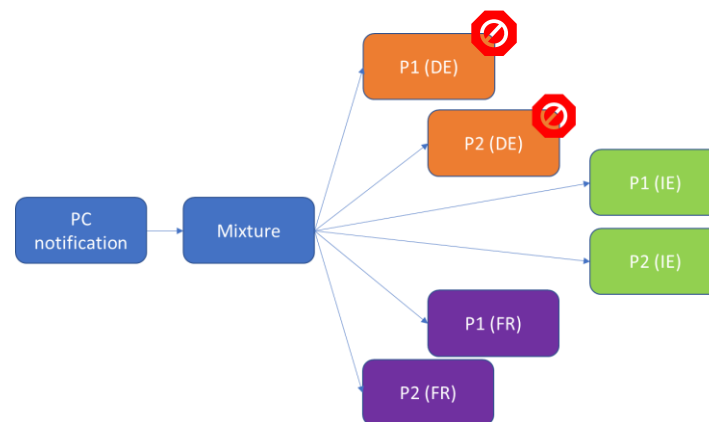
Business requirements:

- 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

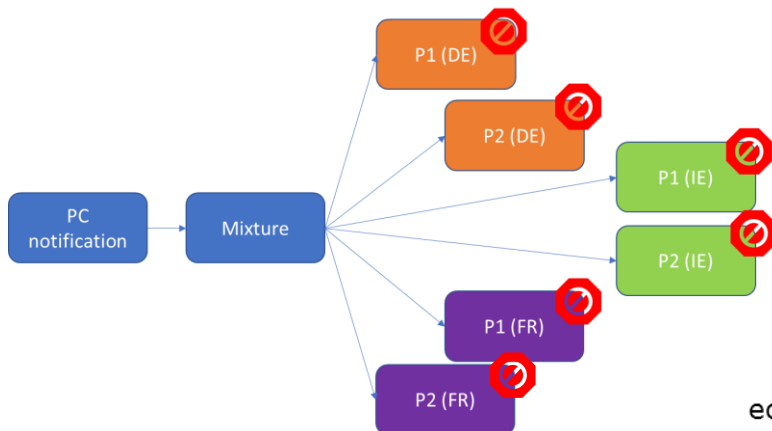
Granularity of the information

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

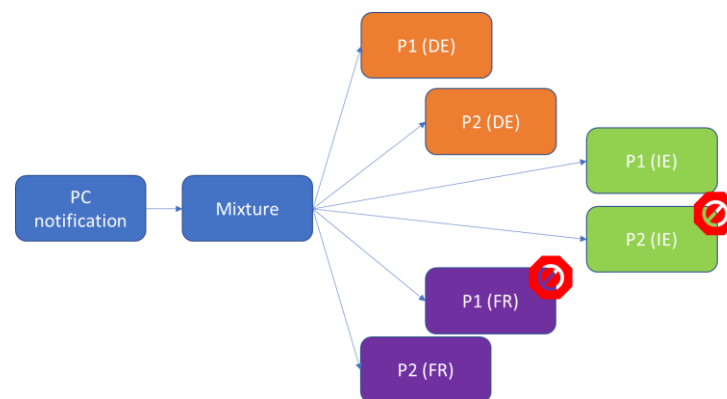
Scenario 1 – Cease all products from one market



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

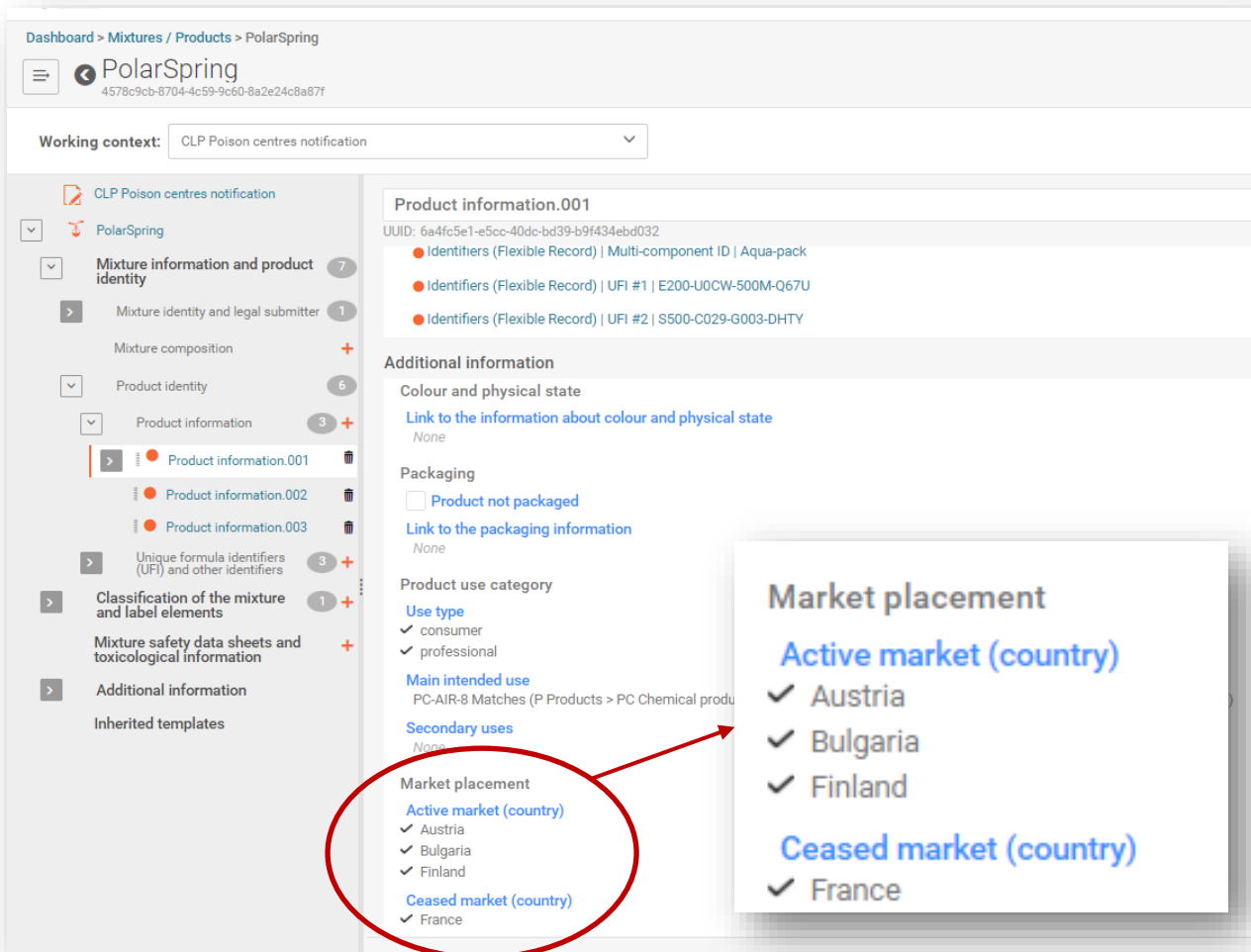
Part of the PCN v.4
format (submission of a
new dossier required)

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)



Dashboard > Mixtures / Products > PolarSpring

PolarSpring
4578c9cb-8704-4c59-9c60-8a2e24c8a87f

Working context: CLP Poison centres notification

CLP Poison centres notification

PolarSpring

Mixture information and product identity

Mixture identity and legal submitter

Mixture composition

Product identity

Product information

Product information.001

Product information.002

Product information.003

Unique formula identifiers (UFI) and other identifiers

Classification of the mixture and label elements

Mixture safety data sheets and toxicological information

Additional information

Inherited templates

Product information.001

UUID: 6a4fc5e1-e5cc-40dc-bd39-b9f434ebd032

- Identifiers (Flexible Record) | Multi-component ID | Aqua-pack
- Identifiers (Flexible Record) | UFI #1 | E200-U0CW-500M-Q67U
- Identifiers (Flexible Record) | UFI #2 | S500-C029-G003-DHTY

Additional information

Colour and physical state

[Link to the information about colour and physical state](#)

None

Packaging

☐ Product not packaged

[Link to the packaging information](#)

None

Product use category

[Use type](#)

- ✓ consumer
- ✓ professional

[Main intended use](#)

PC-AIR-8 Matches (P Products > PC Chemical produ

[Secondary uses](#)

None

Market placement

[Active market \(country\)](#)

- ✓ Austria
- ✓ Bulgaria
- ✓ Finland

[Ceased market \(country\)](#)

- ✓ France

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

Adapt dossier header

UUID: 24/d8a30-3cbe-4edc-9812-237798c130e7

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

- Possible to indicate both justifications in the same dossier

Notification type



The submission is an update

Reason for updating

Justification

+ New item

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

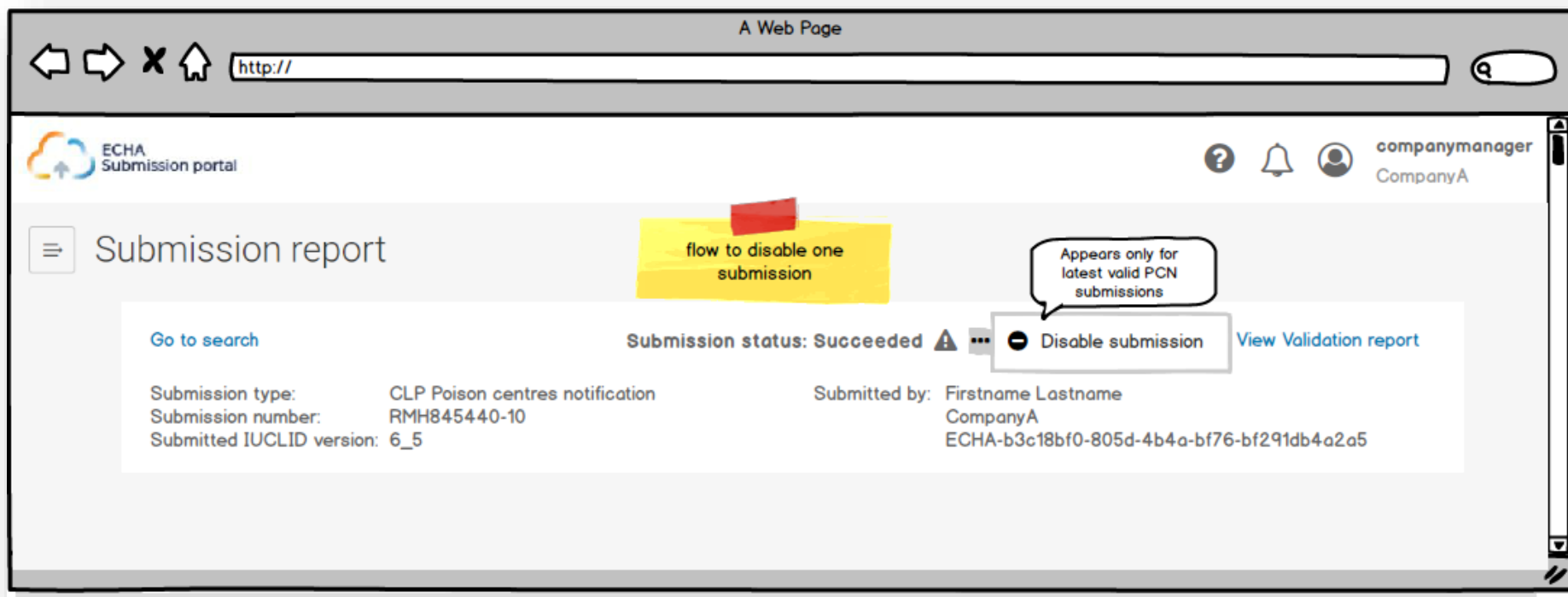
Condition #2

- 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



Reasons for disabling

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.

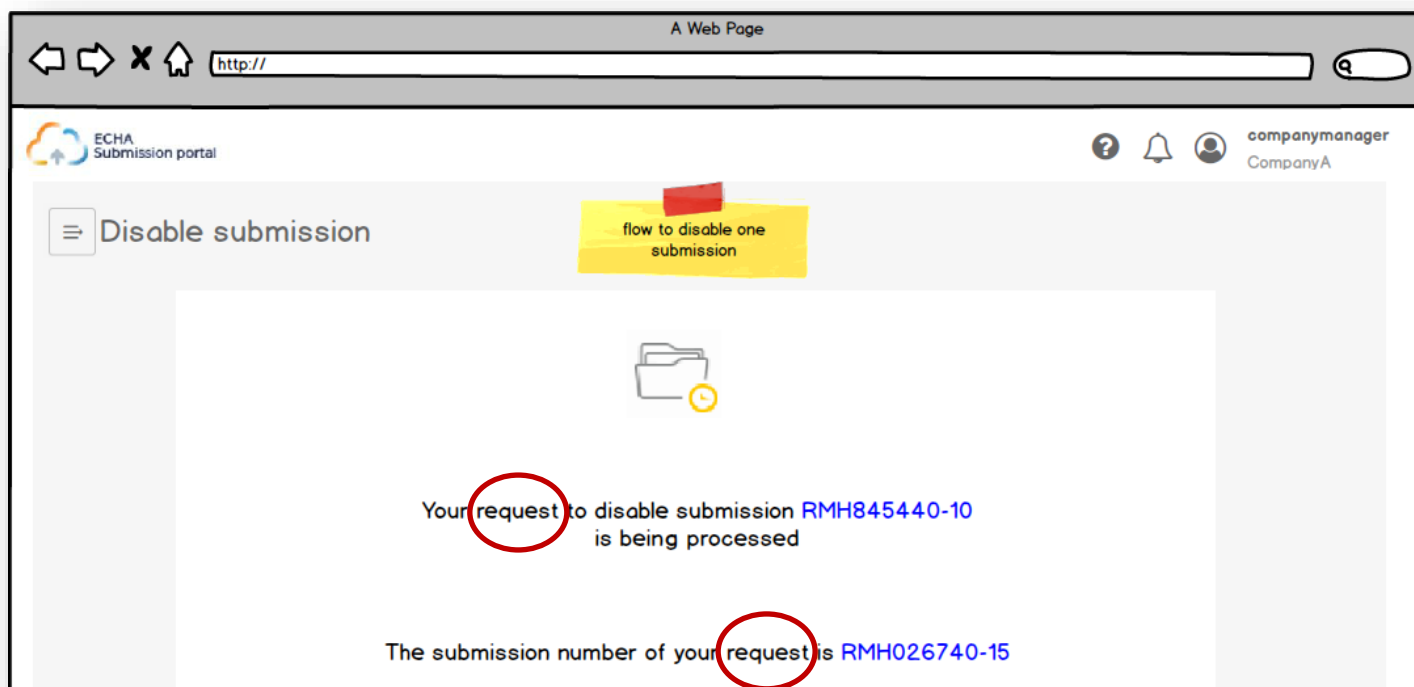
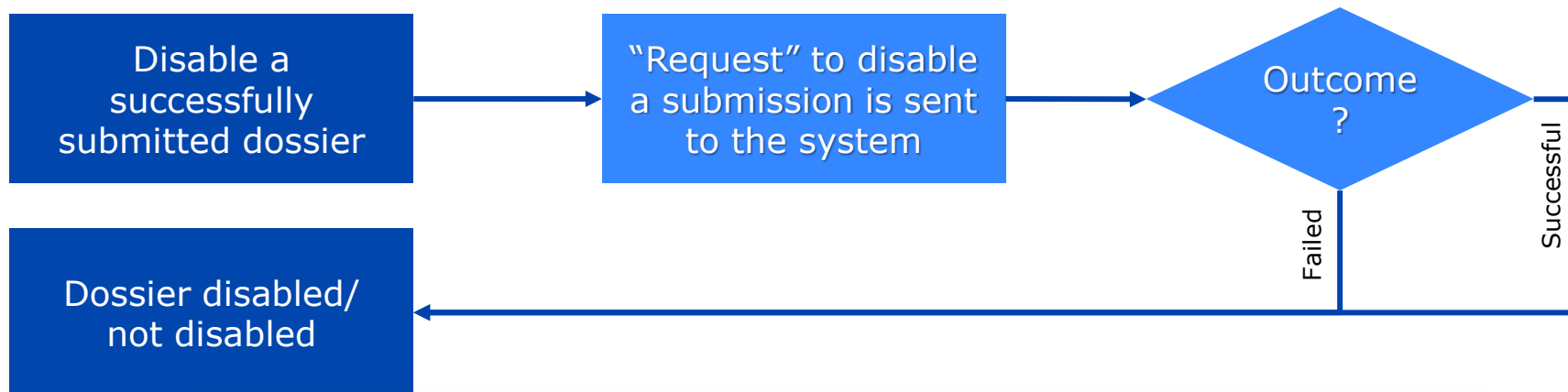
For more information see the appropriate section in [the Terms and Conditions here.](#)

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
CompanyA

Submission report

submission report for the "Disabled submission"

Indication that the submission has been disabled

Submission status: Succeeded **Disabled** View Validation report

Go to search

Submission type: CLP Poison centres notification
Submission number: RMH845440-10
Submitted IUCLID version: 6_5

Submitted by: Firstname Lastname
CompanyA
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
Type of submission: change in mixture classification
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

Submission report

Submission status: Succeeded

Go to search

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
Referenced submission: RMH845440-10
Reason for submission: Request to disable the Referenced submission
Reason for disable: Submission made unintentionally

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
f403b075-fad8-4faf-8484-7e1ba9a0cd57

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

Disabled submission

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

A Web Page

ECHA Submission portal

companymanager
CompanyA

Search

disable - search page

Search criteria

Submission number:

Dossier type:

Dossier UUID:

PCN number:

UFI:

Names:

Submission status:

Submission date: from to

Submission reason:

Disabled submissions:

Search

Clear

Export to Excel

Page 1 of 6 results

Sort by:

Request to disable one submission - new icon

Status of the request (as-is)

Some PCN number as the submission disabled

The submission number disabled

Disabled submission icon

Disabled submission

Submission number	PCN number	Names	Dossier UUID	UFI(s)	Dossier UUID	Submission date
RMH220672-25	d66c23e4-2cf7-4432-9e8d-65a73fab8f12	Dossier 4 Poly(oxy-1,2-ethanediy), o-(non...	3094131f-4f0e-40a0-8964-4e8954d70ab0	CX1M-5E71-V116-CN6C	305513aa-f70e-54a0-8943-4e8954d92cc3	21/12/2020 14:05
RMH45440-10	d66c23e4-2cf7-4432-9e8d-65a73fab8f12	Dossier 4 Poly(oxy-1,2-ethanediy), o-(non...	3094131f-4f0e-40a0-8964-4e8954d70ab0	CX1M-5E71-V116-CN6C	305513aa-f70e-54a0-8943-4e8954d92cc3	13/10/2020 10:25
RMH458463-04	d66c23e4-2cf7-4432-9e8d-65a73fab8f12	Dossier 4 Poly(oxy-1,2-ethanediy), o-(non...	305513aa-f70e-54a0-8943-4e8954d92cc3	CX1M-5E71-V116-CN6C	305513aa-f70e-54a0-8943-4e8954d92cc3	13/10/2020 00:22
RMH250390-22	C&L Notification for Cadmium Oxide	Dossier UUID	55b5a51-e4e4-4914-8732-d4baf10f101a			20/05/2020 12:00
RMH057867-06	7dc03a81-8b0d-4736-96cf-e9559413bea5	Test mixture, Forest Fresh	61cc0a82-abb0-4bcf-8459-f4274c8adb07	CX1M-5E71-V116-CN6C		06/04/2020 21:01
RMH229680-06	cd8fd11-dfe4-a9d-94f1-710ec17c0765	Test mixture, Forest Fresh	74155b09-873d-4bce-8a6d-b8474d8e2555	P9MD-C1E4-6X5A-19YC		07/04/2020 15:48

1 Items/Page 10

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
UFI's**

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	Na	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

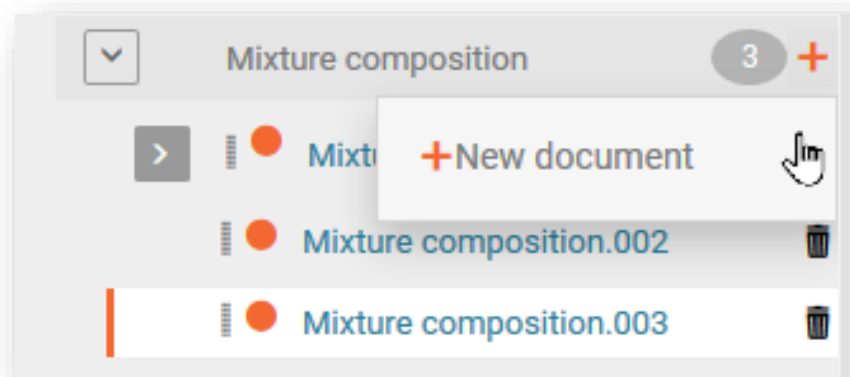
☐ Limited submission (industrial use only)

☒ Group submission

☐ Voluntary submission

Group Submission preparation

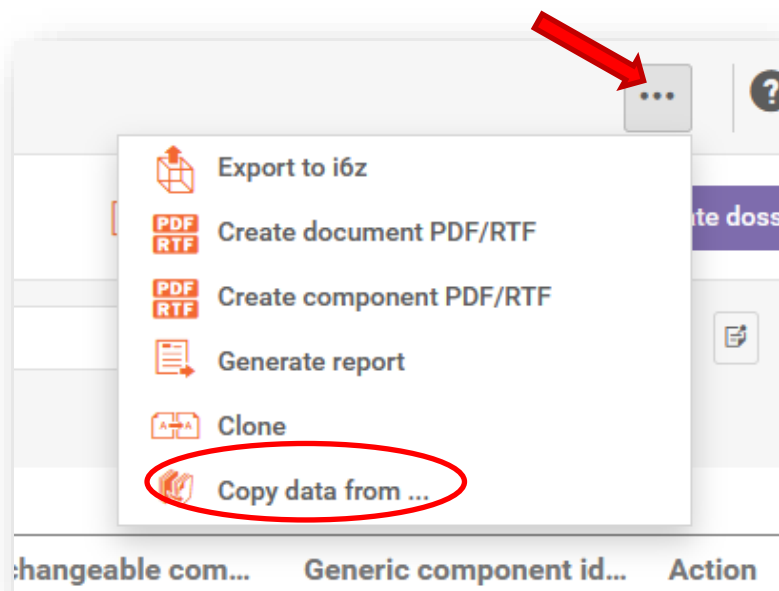
2. Enter individual mixture compositions



Practical way forward:

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

Group Submission preparation



Copy data from: Document Selection

- ☒ CLP Poison centres notification
- ☒ Mixture information and product identity
- ☒ Mixture composition
- ☒ Mixture composition.001

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

Name
Lavender oil | Lavender oil

Function
perfume

Typical concentration
None

Concentration range
>= 2.9 <= 3.1 % (w/w)

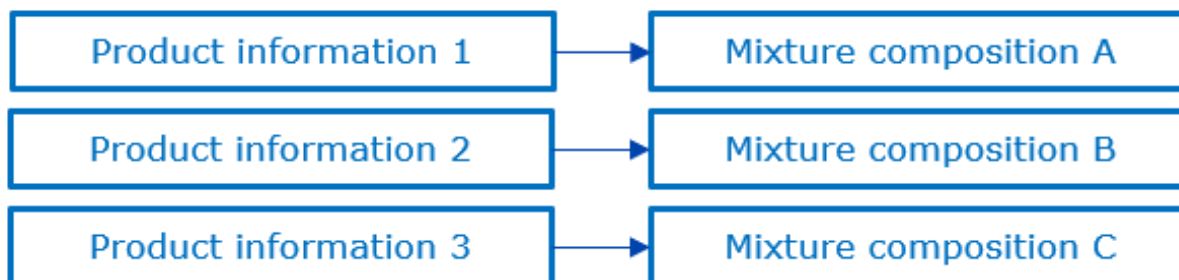
☐ Standard formula (SF) component

☐ Interchangeable component group (ICG)

☐ Generic component identifier (GCI)

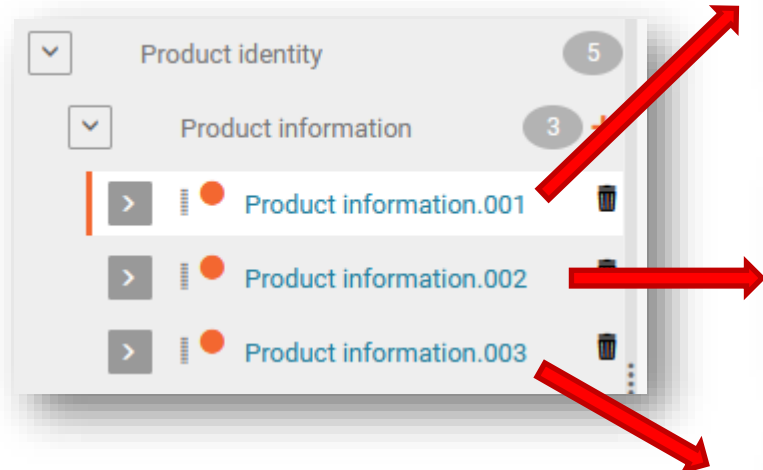
Group Submission preparation

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

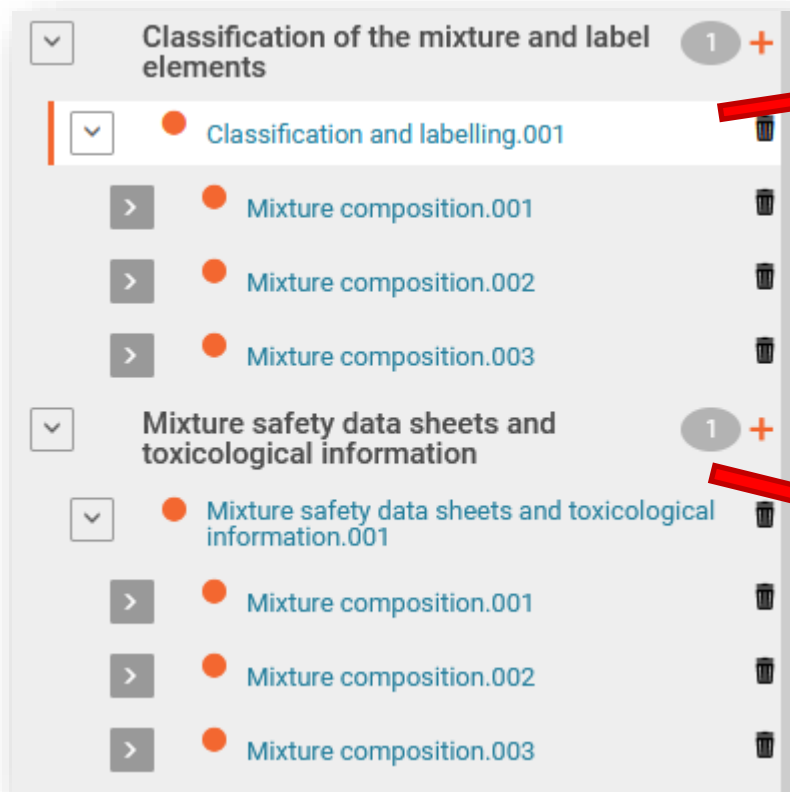
4. Enter C&L, toxicological information, pH documents for each mixture

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!

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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