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

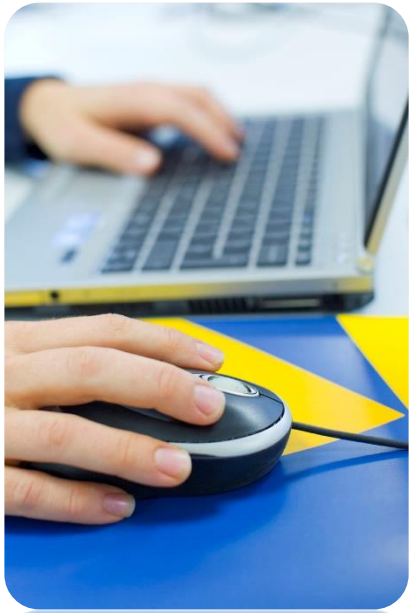
11:35 **Making a group submission – what you need to know**
Daniele Ape

12:00 **Closing remarks**
Poison Centre Team

12:00 - 13.00 Webinar open for questions

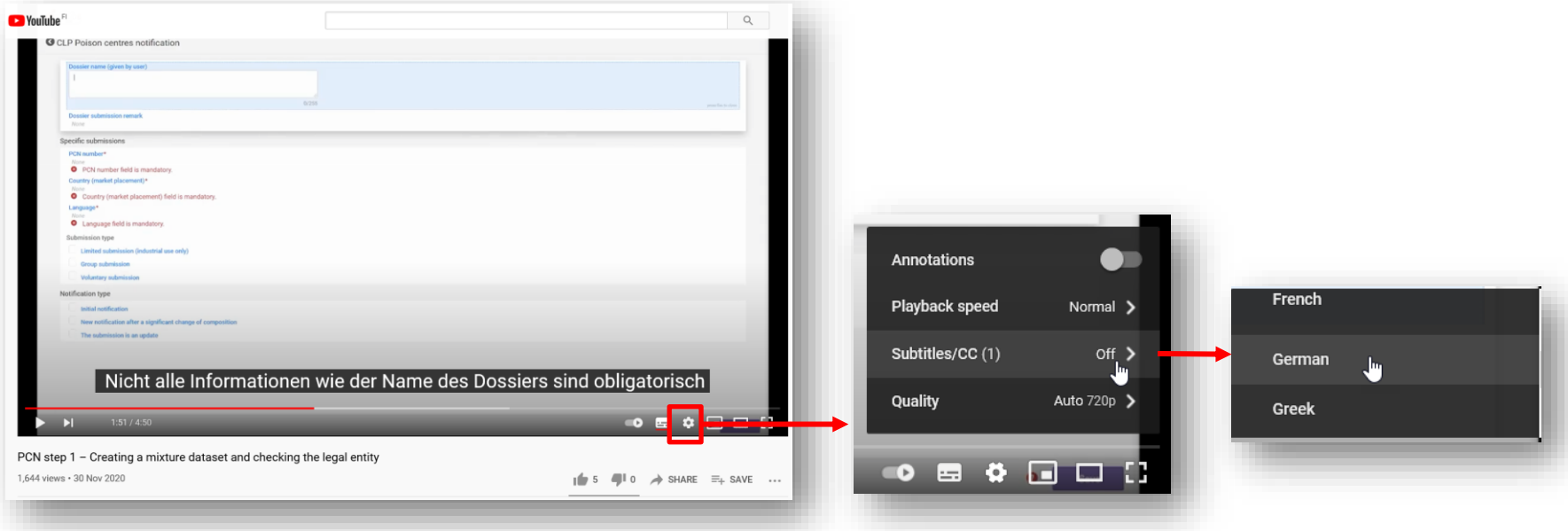
Questions

- 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

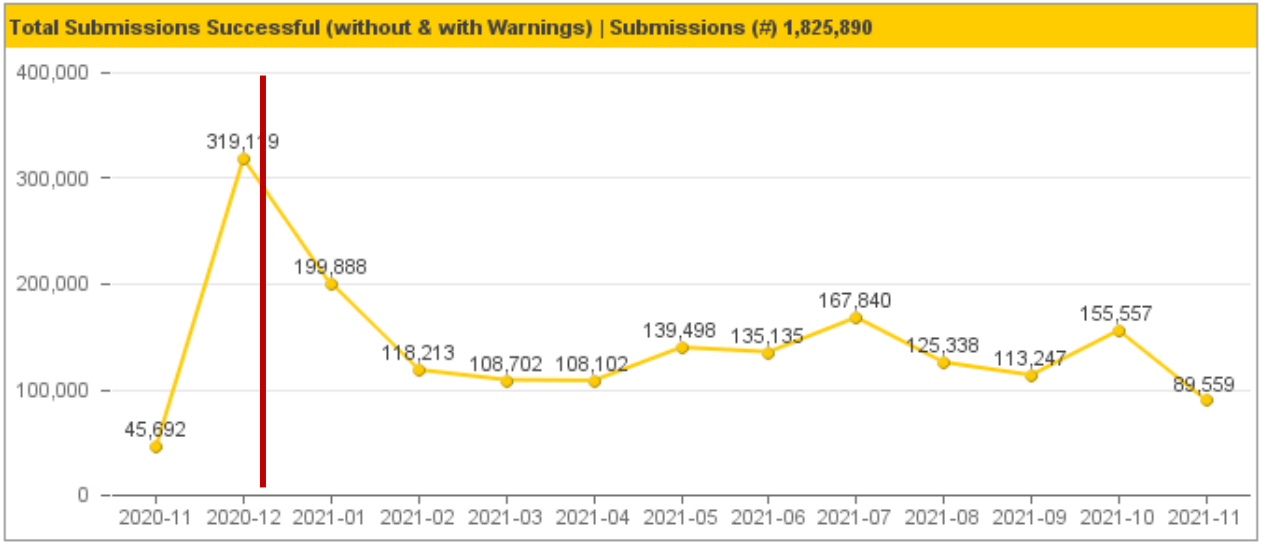
Outline

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

Submission numbers

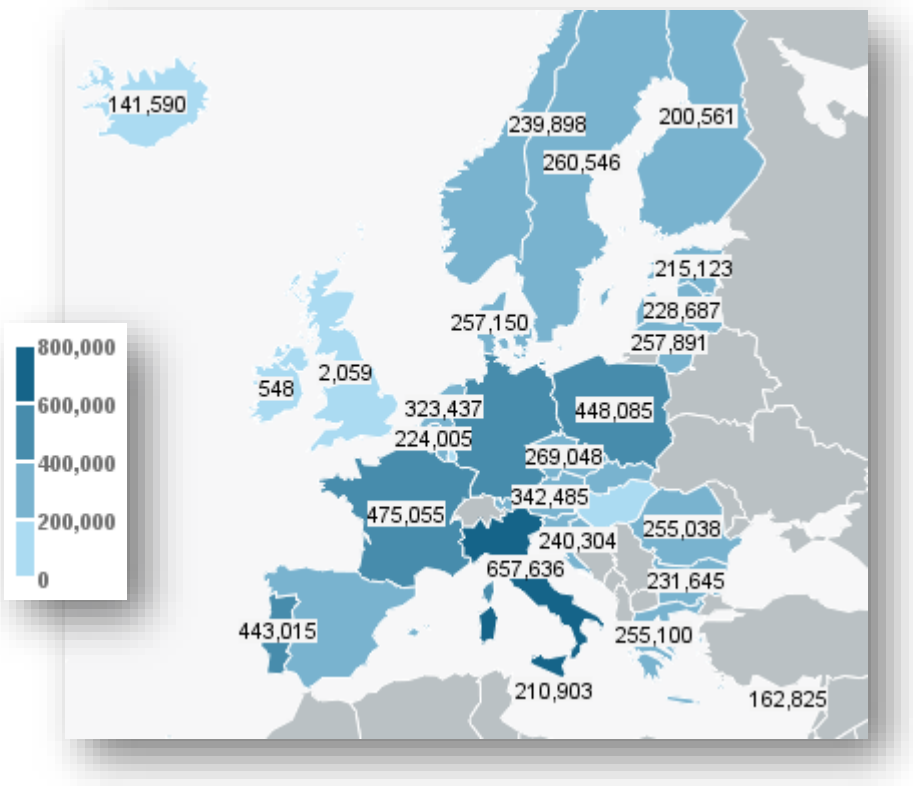
20 November to 21 October

- 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

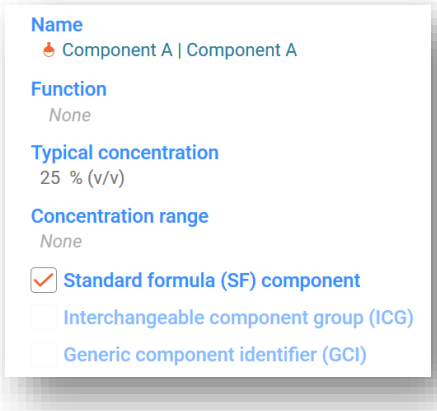
Future improvements

- 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

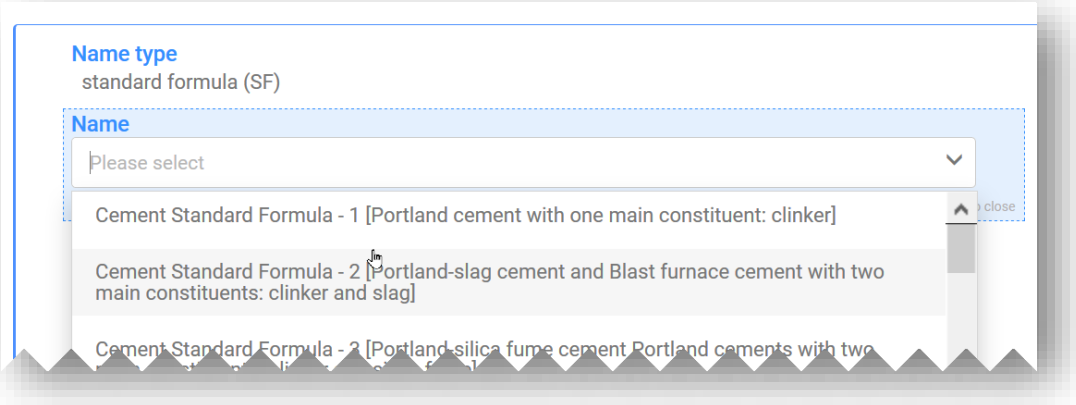
- ’Standard formula’ tick-box is for specific components listed in Annex VIII for construction products or fuels
- **Previously**: Misunderstanding of the use of ’Standard formula’ tick-box



- 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

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:



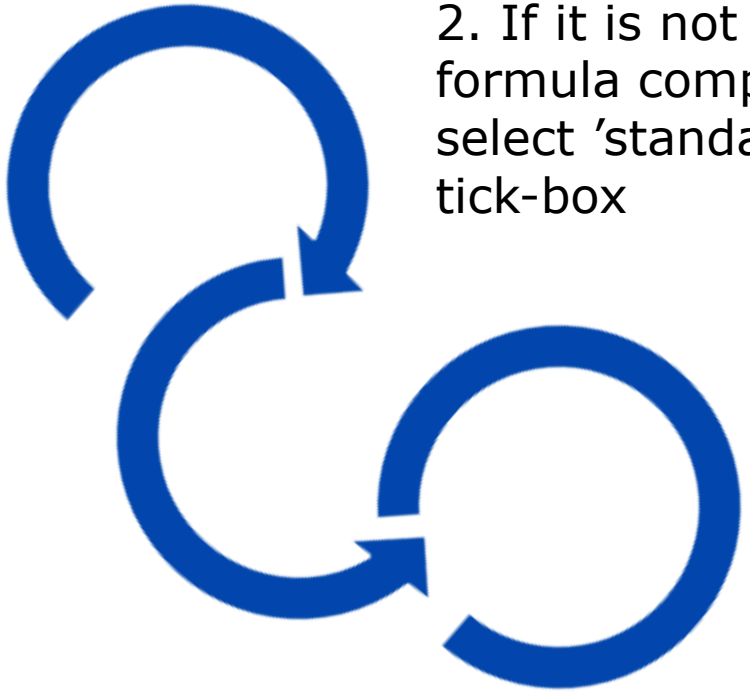
Issue? Update notifications failing if previously used standard formula

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

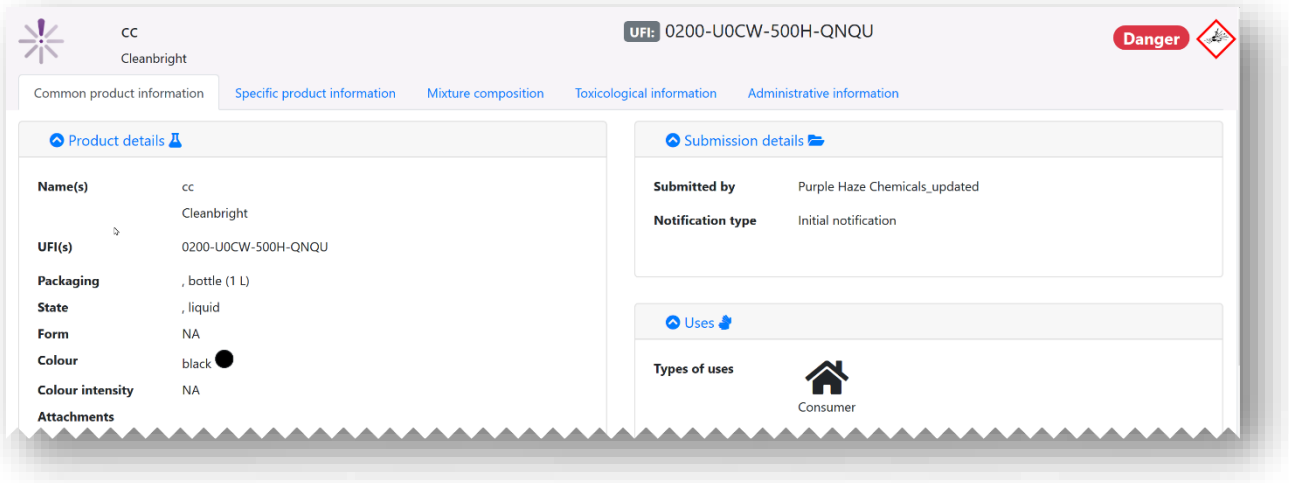
- New QLT checks that MiM supplier is EU-based

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



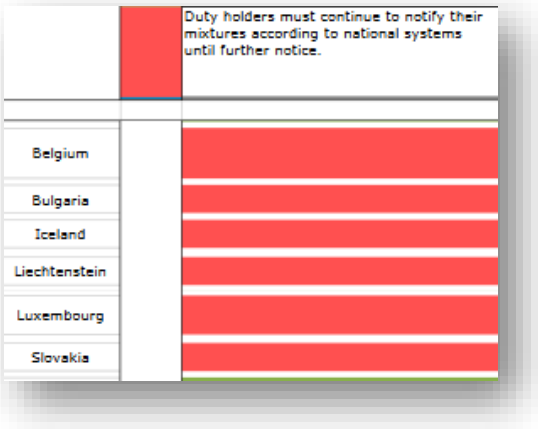
- Why? Maintaining two reporting tools not efficient. Same report used by authorities and proven to be less error prone

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



- 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 **#UFImattersEU** 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

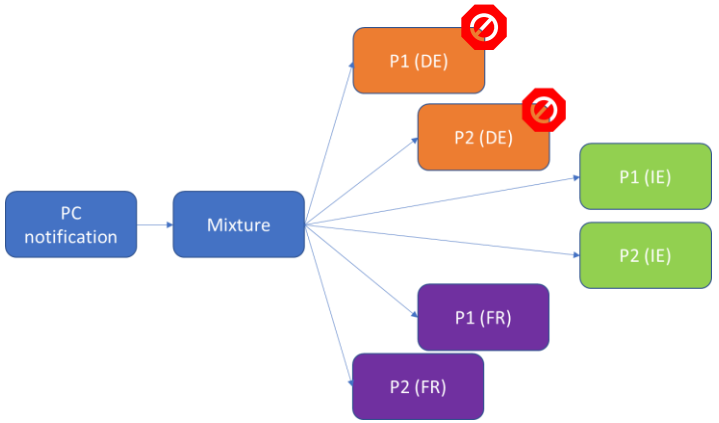
Business requirements:

- 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

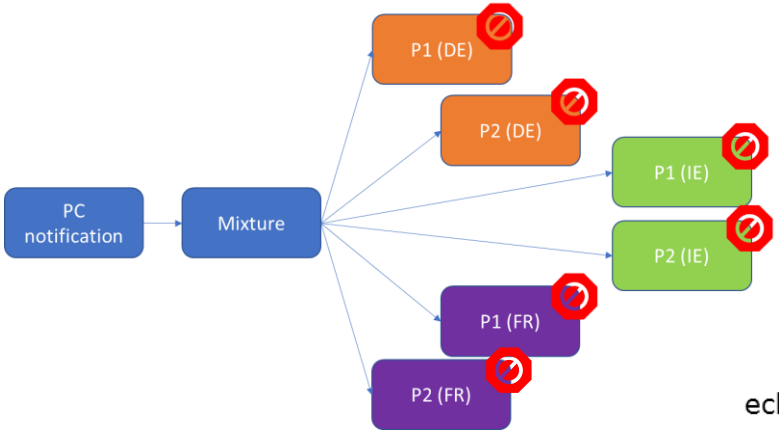
Granularity of the information

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

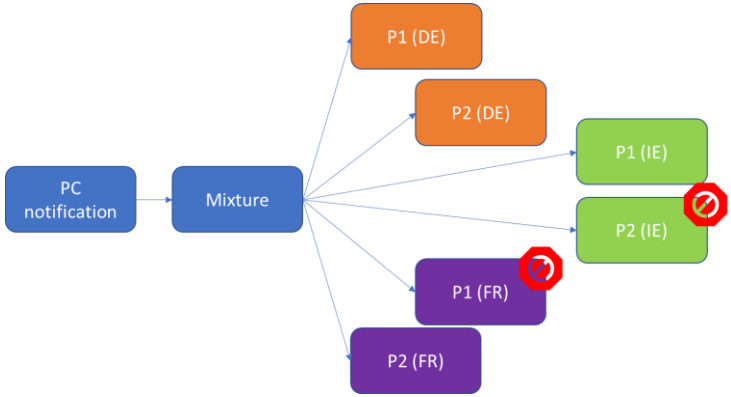
Scenario 1 – Cease all products from one market



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

↓

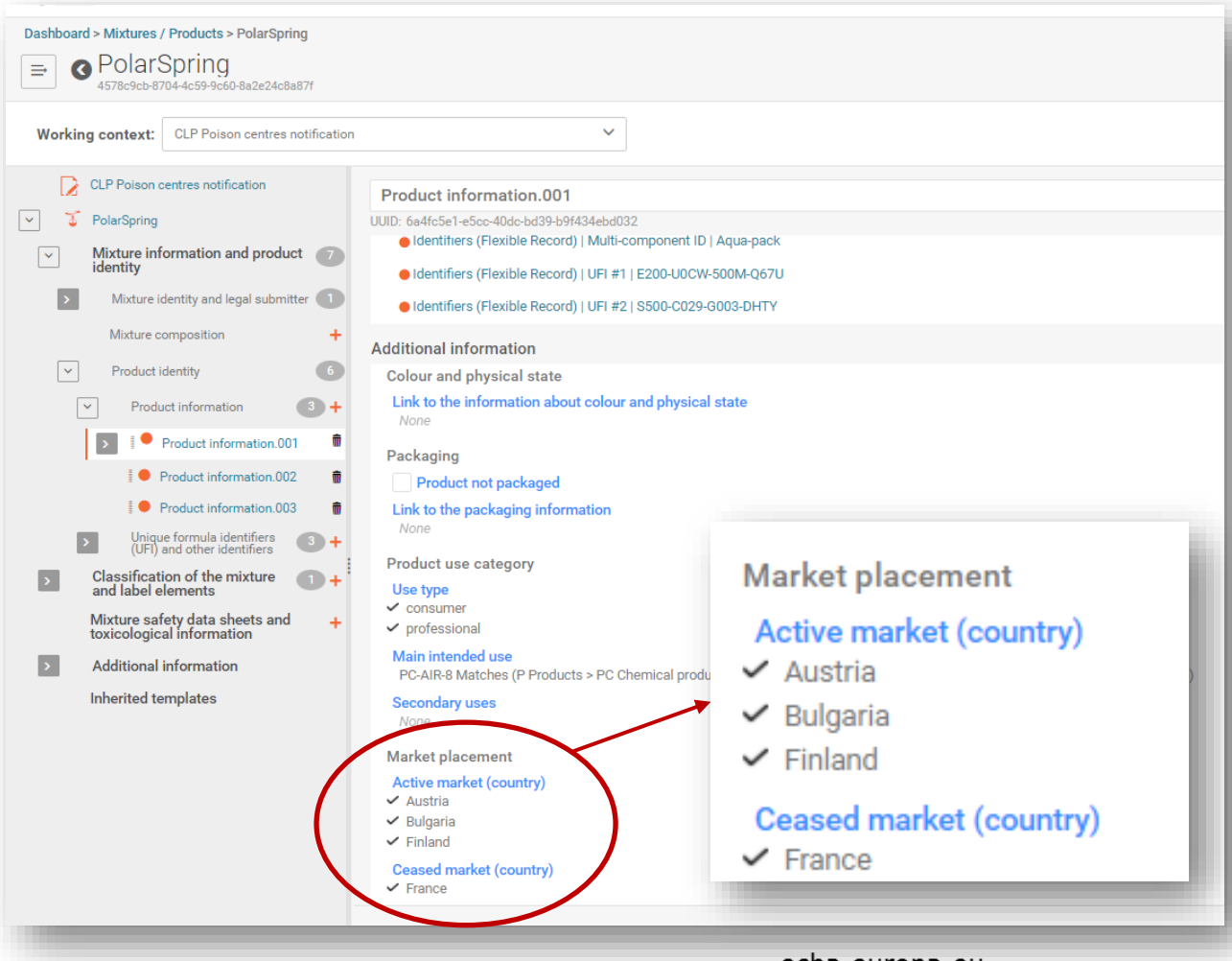
Part of the PCN v.4 format (submission of a new dossier required)

↓

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

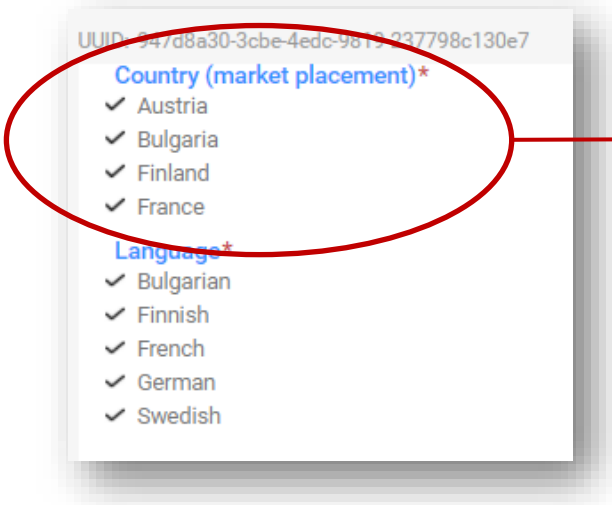
How to indicate in the PCN dossier that a product has been ceased from the market?

Manage market areas in Product record(s)

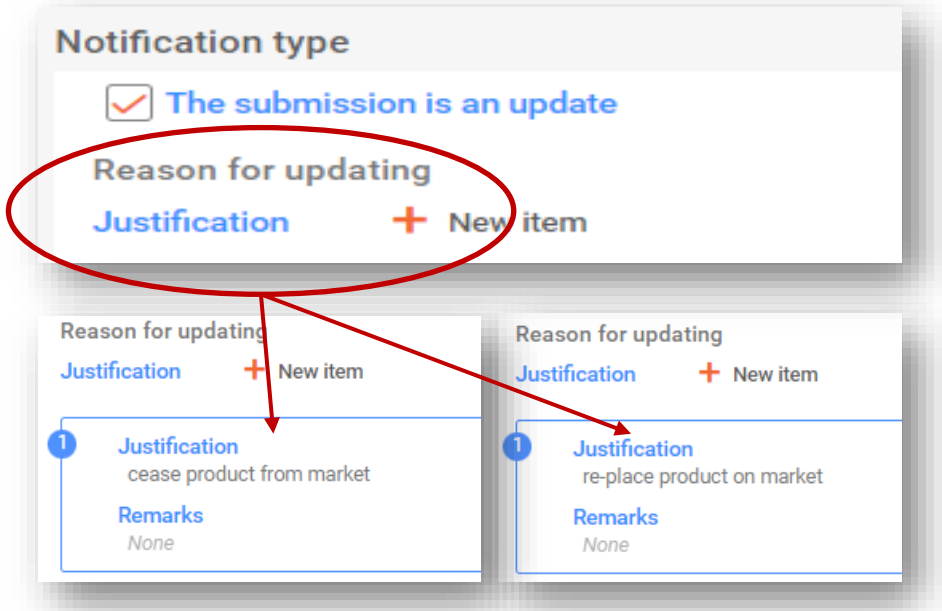


- 2 lists now available
- Select the market areas from the relevant lists
- Repeat for all the relevant product records

Adapt dossier header



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



- Possible to indicate both justifications in the same dossier

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

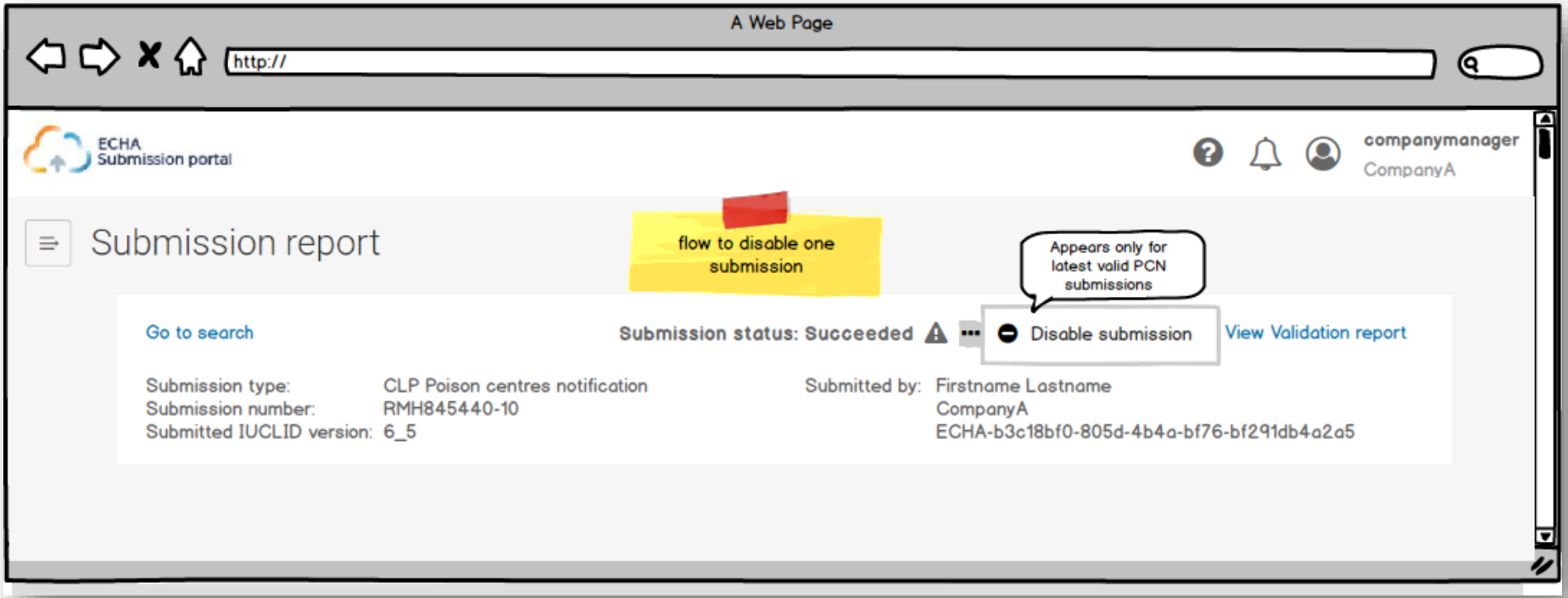
Condition #2

- Disabling only the latest submission is possible

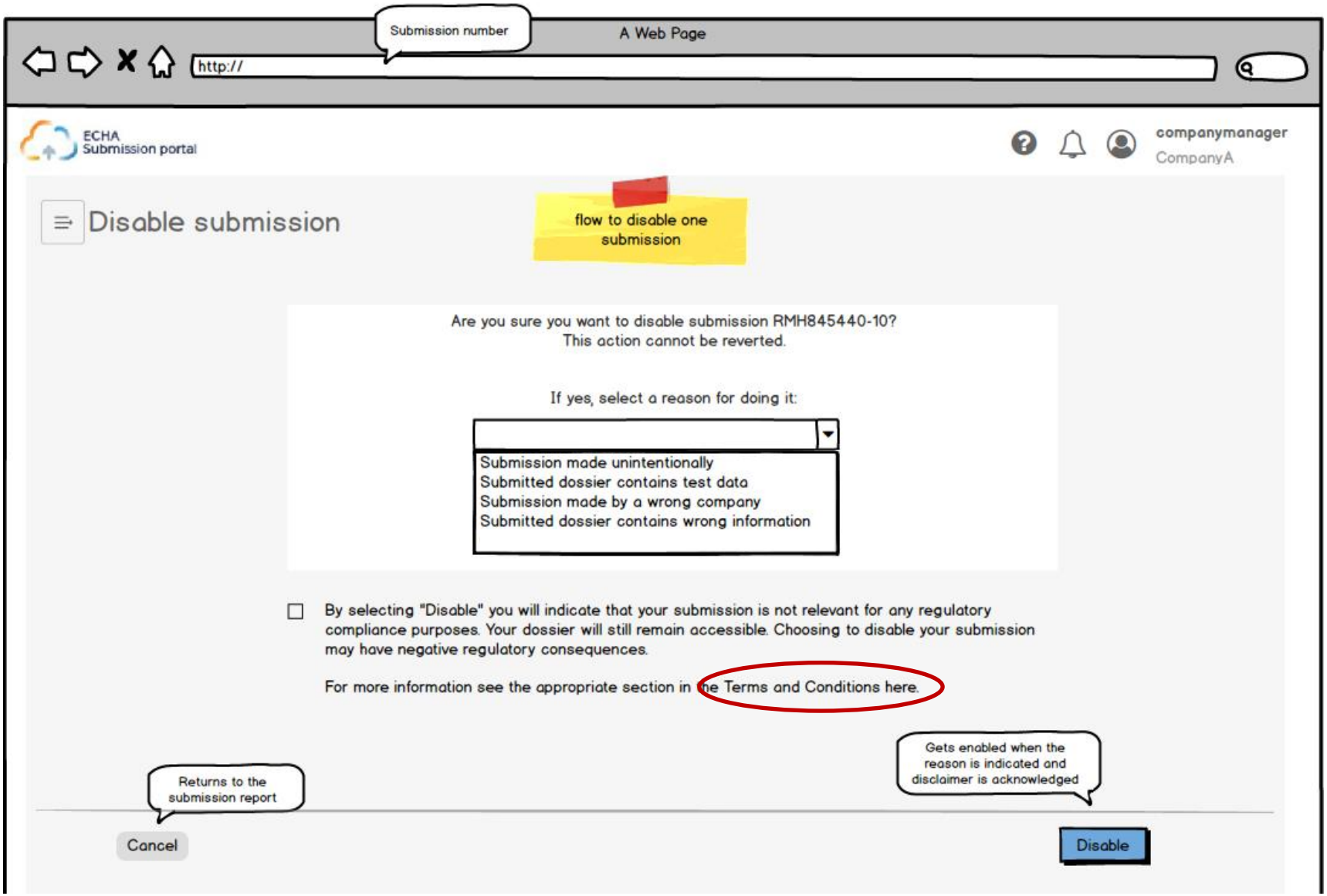
Condition #3

- Disabling only own Legal Entity's submissions is possible

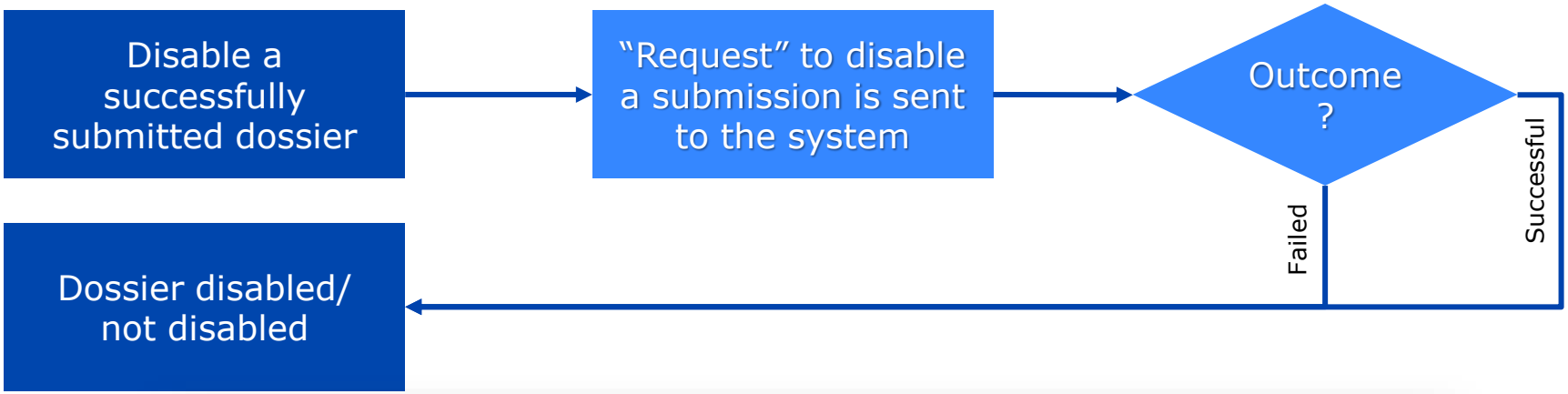
Disabling a submission from the ECHA Submission portal

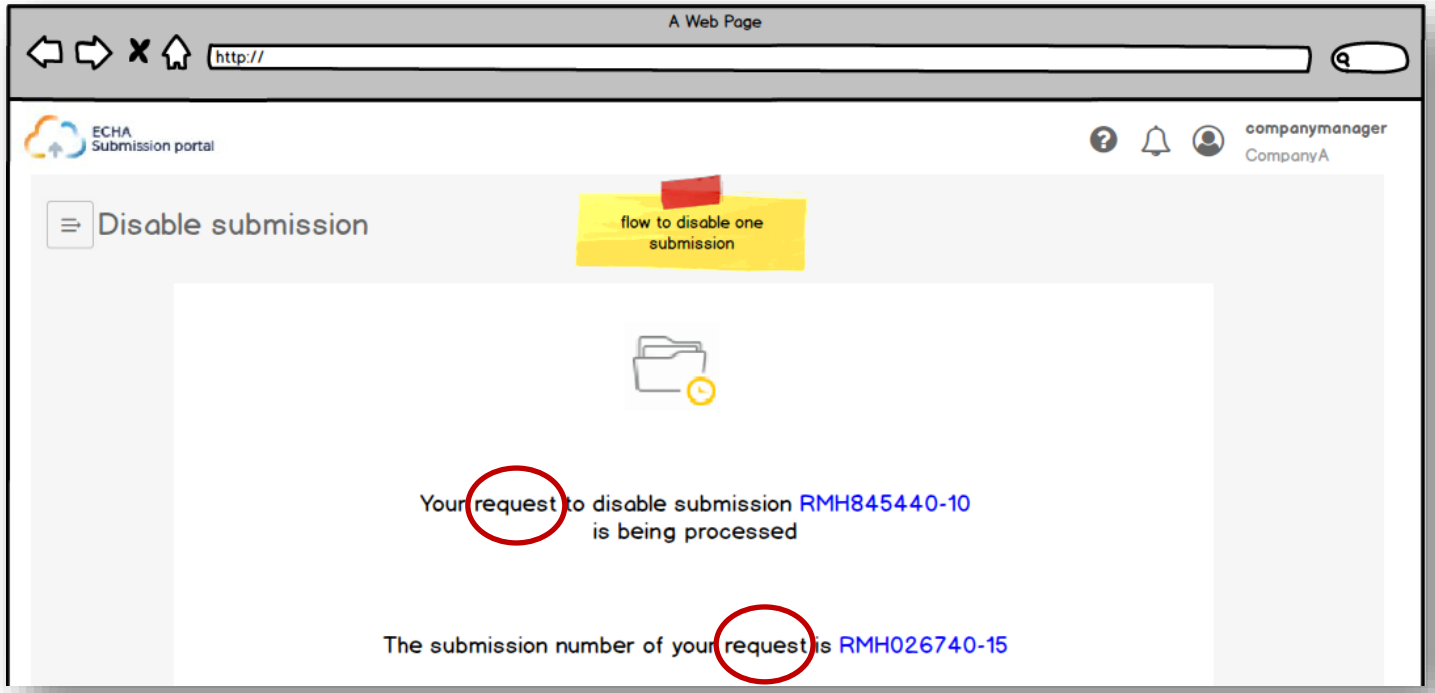


Reasons for disabling

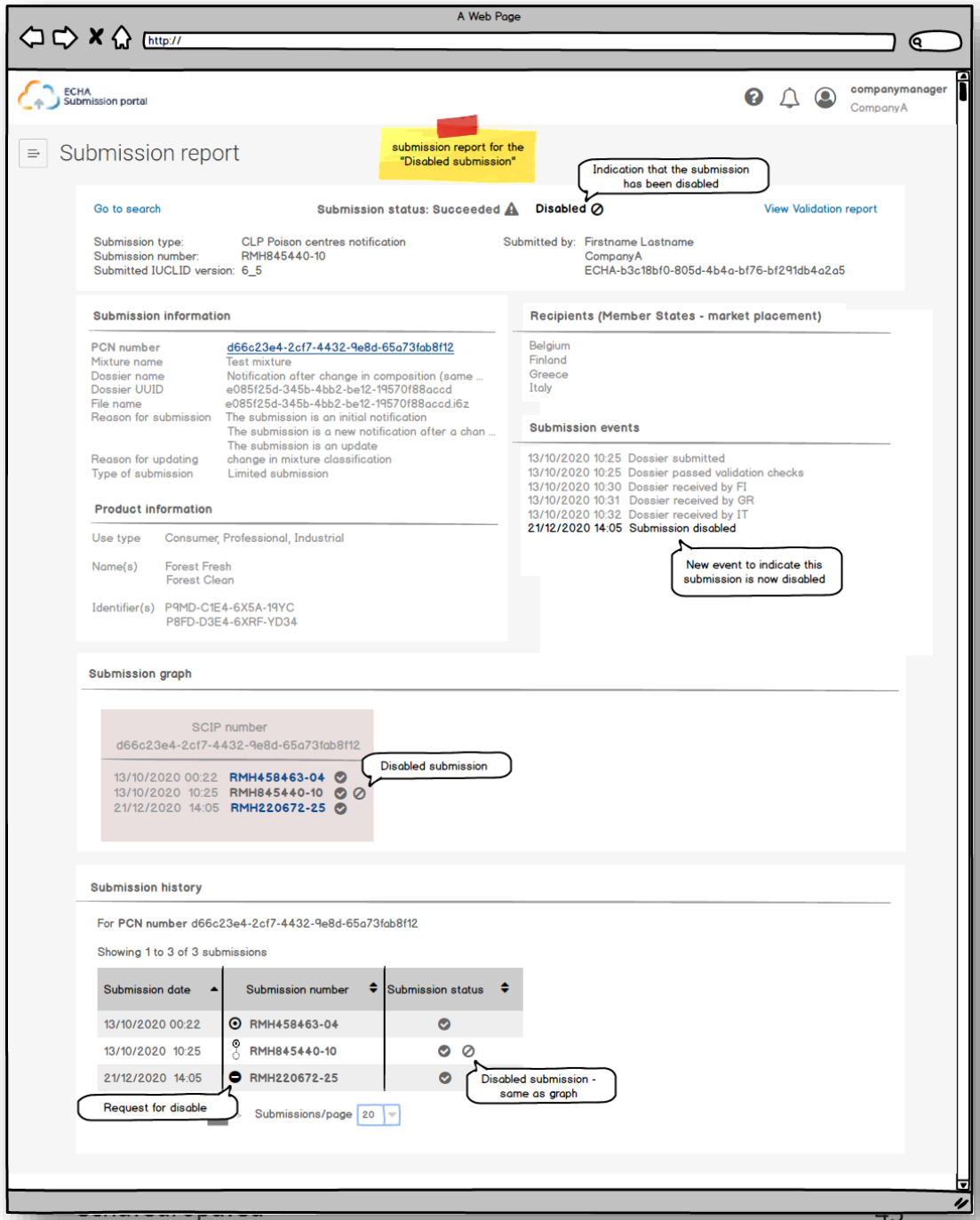


Technical consideration

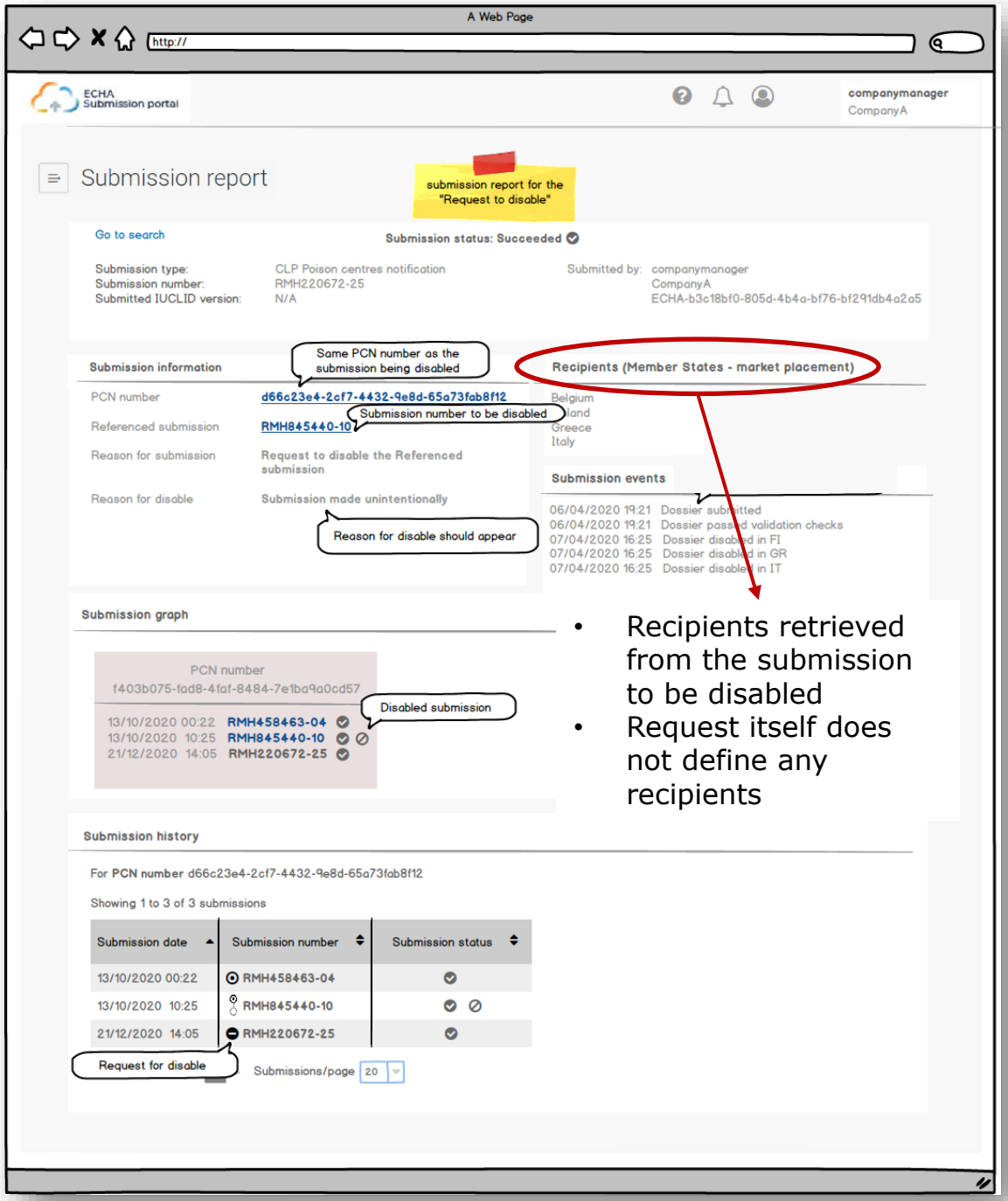




Submission report of the *Disabled* submission



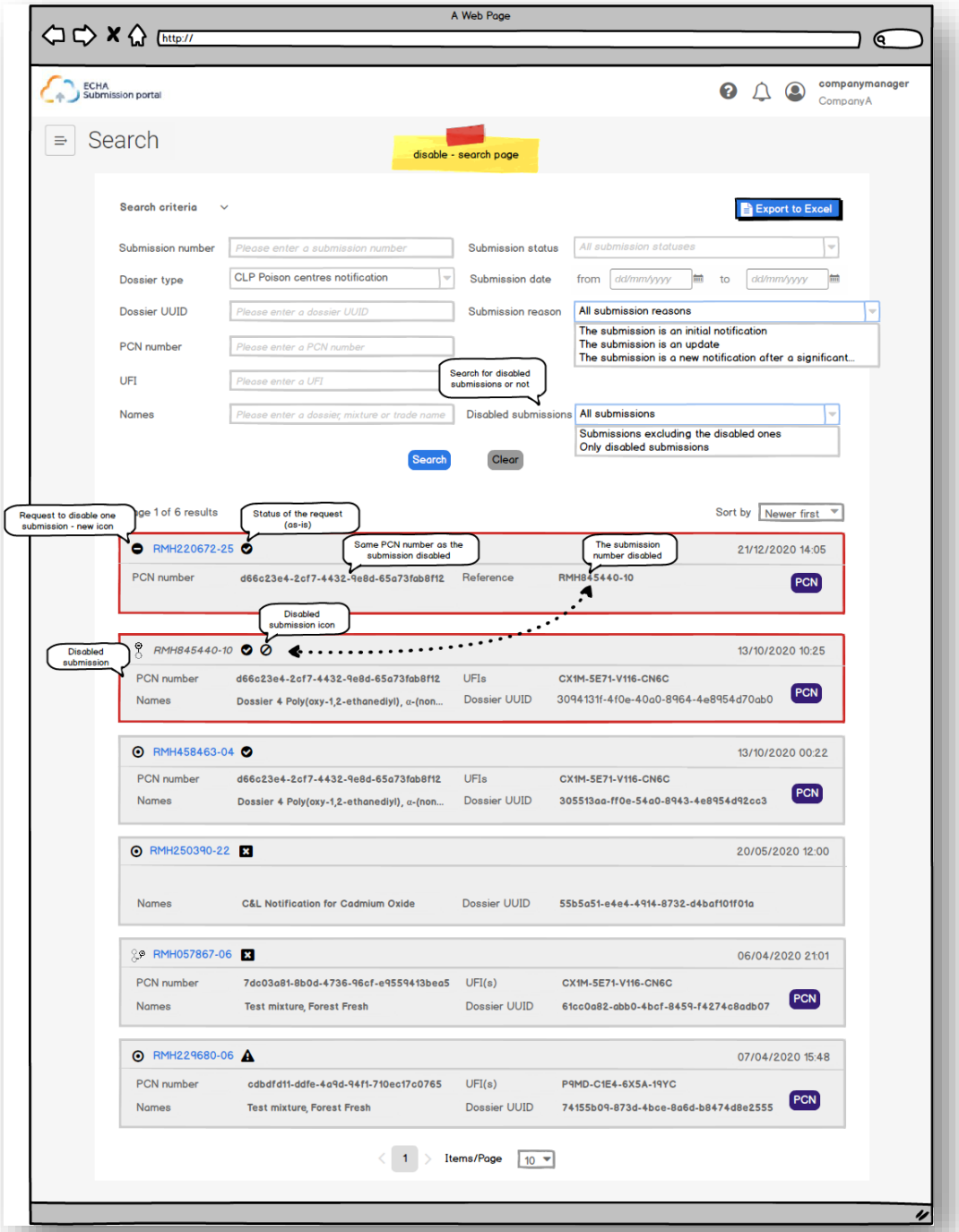
Submission report of the *Request*



- 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 ⛔



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

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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

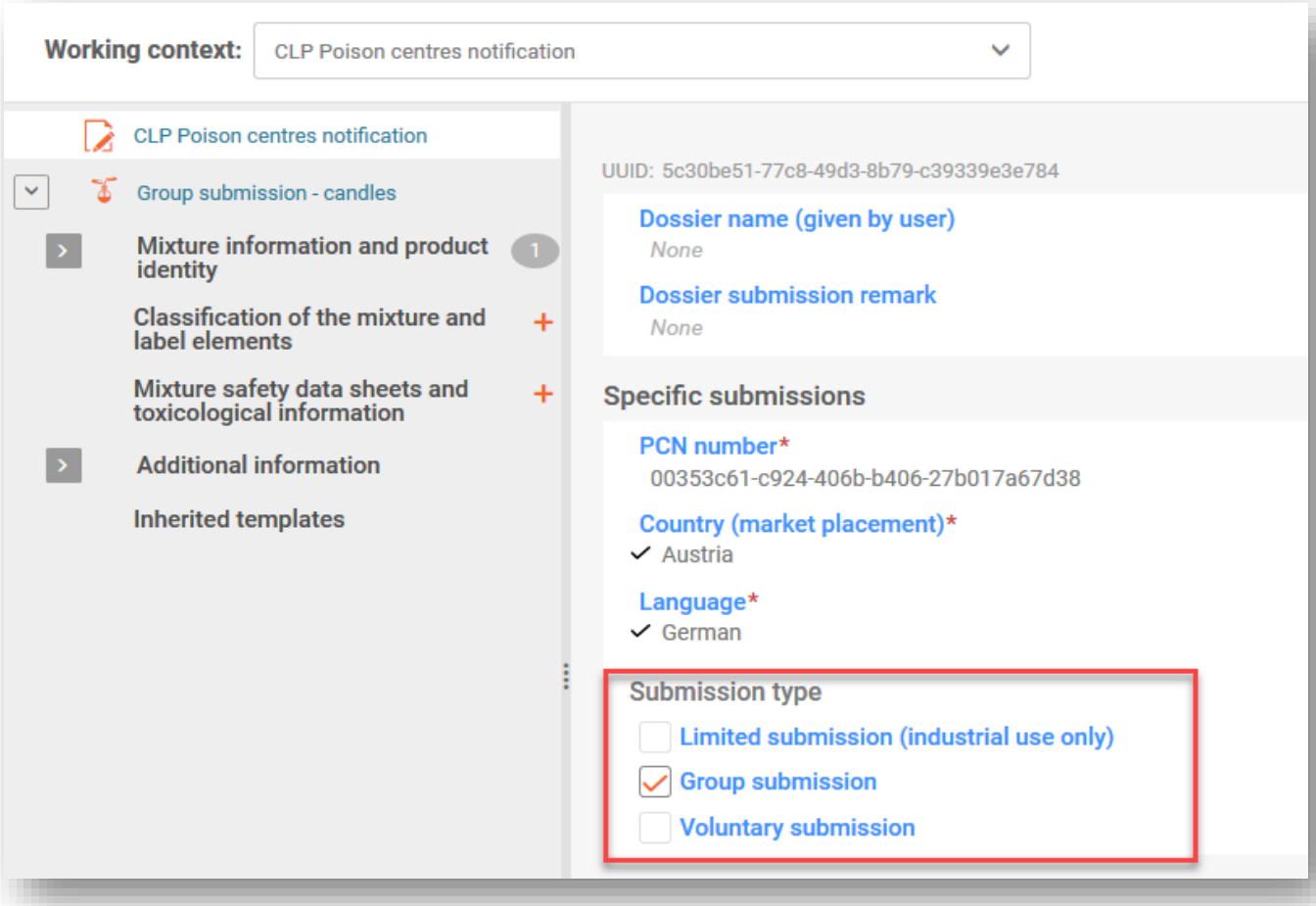
Mixture A		Mixture B		Mixture C	
Perfume components	***Conc. %***	***Perfume components***	***Conc. %***	***Perfume components***	***Conc. %***
Perfume MiM X	*Na*	*Perfumes* (GCI)	0.6 - 1.6	Perfume MiM Z	0.5 - 0.9
Perfume MiM Y	0.5 - 1.5			*Perfumes* (GCI)	0.1 – 1.1

Can Constitute max 5% of each actual mixture

How to prepare a Group Submission?

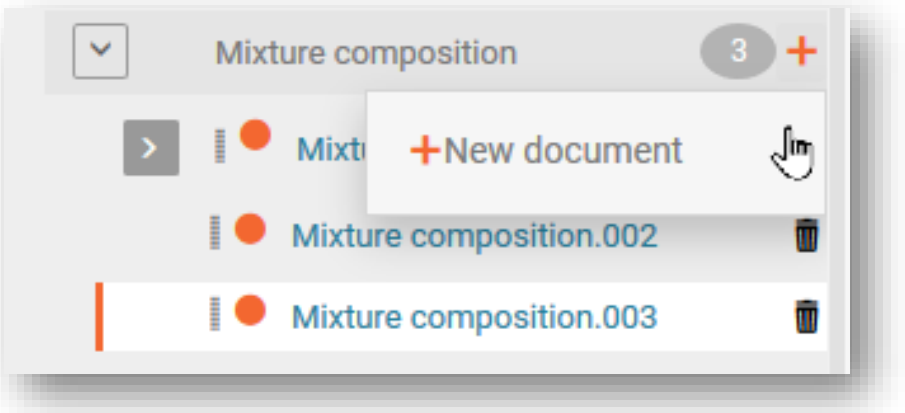
Group Submission preparation

1. Establish the correct submission type



Group Submission preparation

2. Enter individual mixture compositions



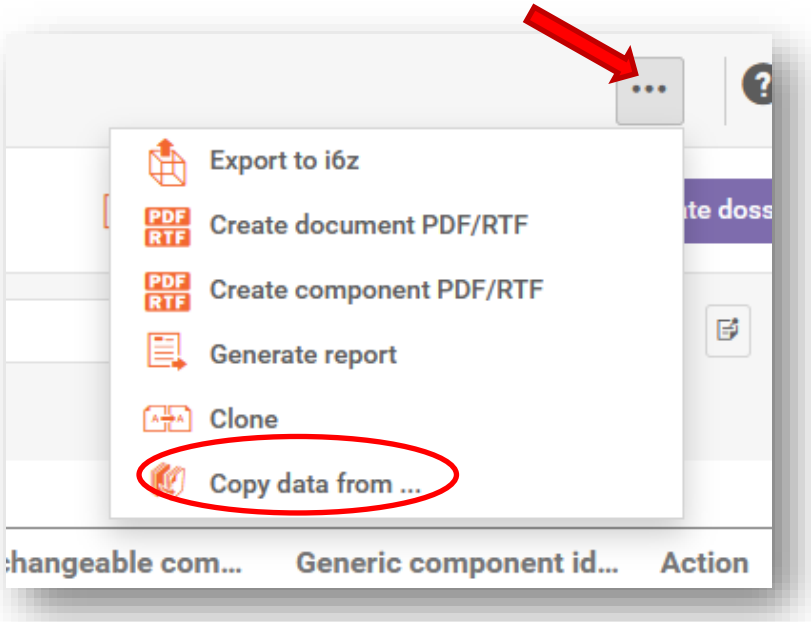
Practical way forward:

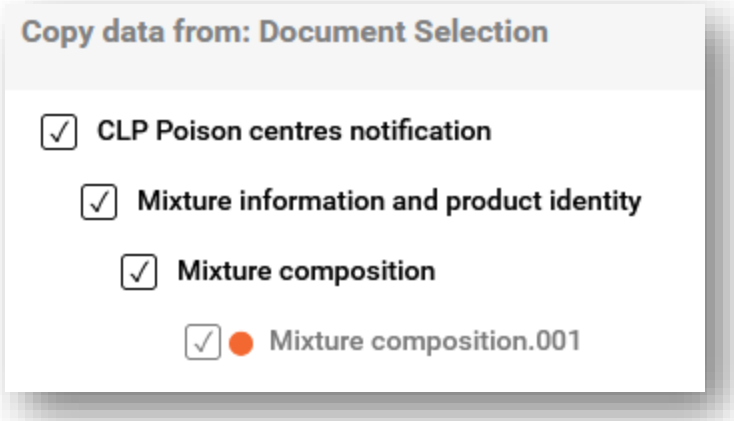
a) enter the common composition once

b) create clones

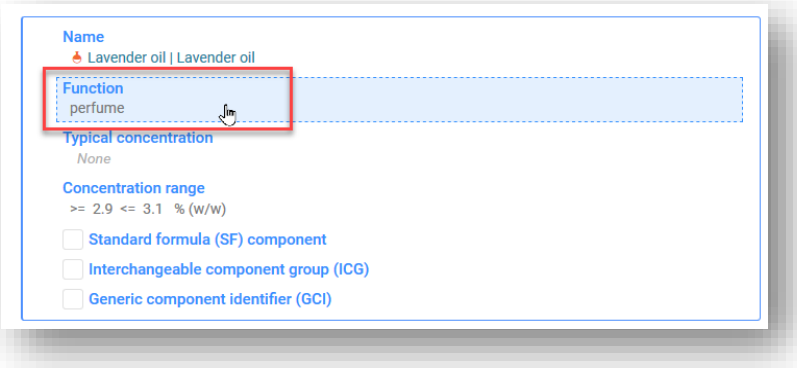
c) add specific perfume component(s) to each clone

Group Submission preparation



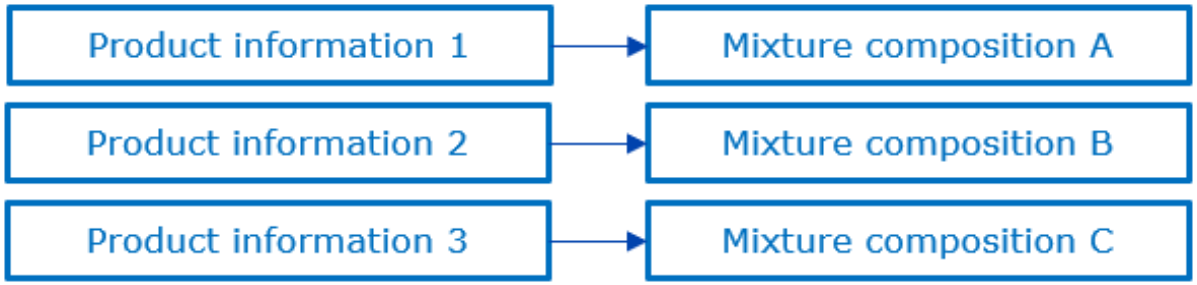


N.B.: indicate function as "*Perfumes*" to relevant component



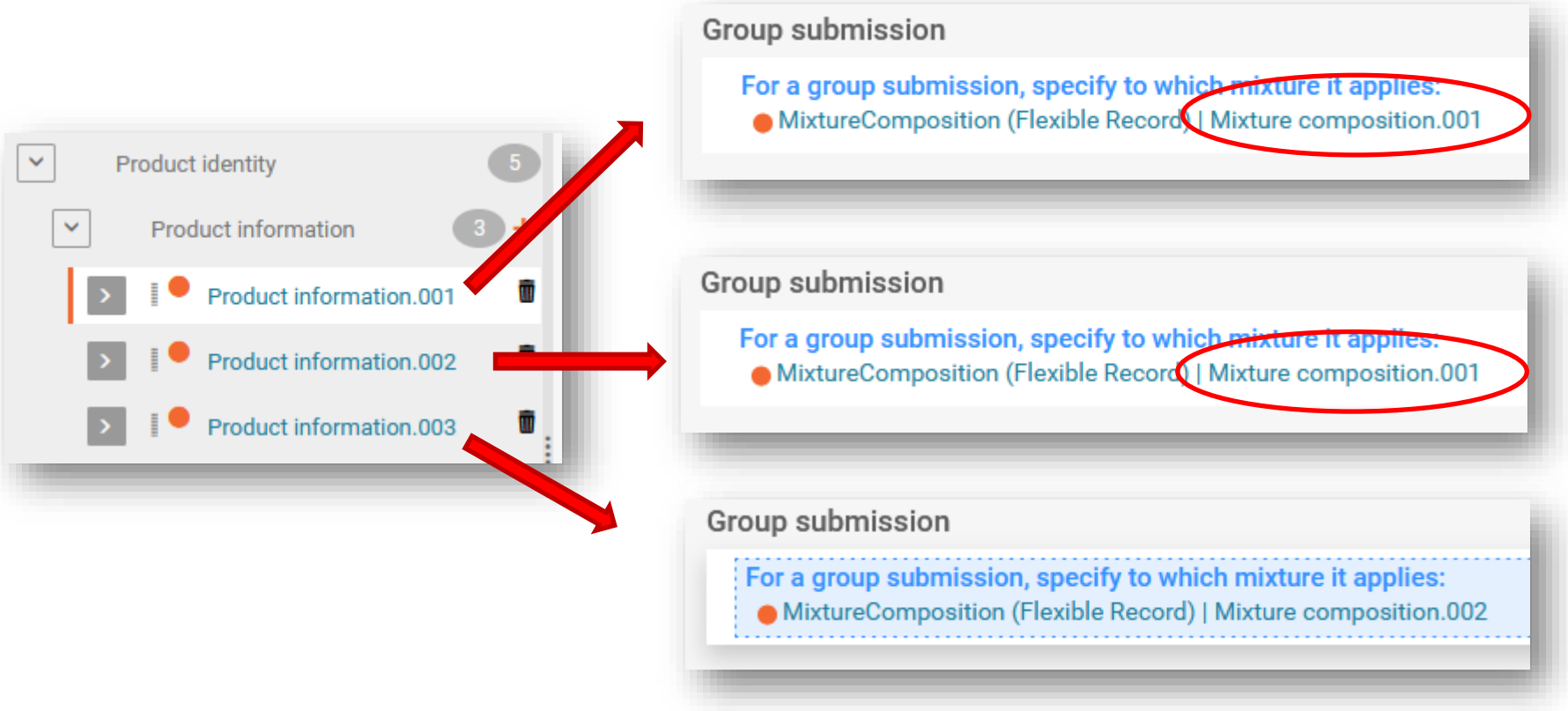
Group Submission preparation

3. Enter Product information for each mixture individually



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

Group Submission preparation



Group Submission preparation

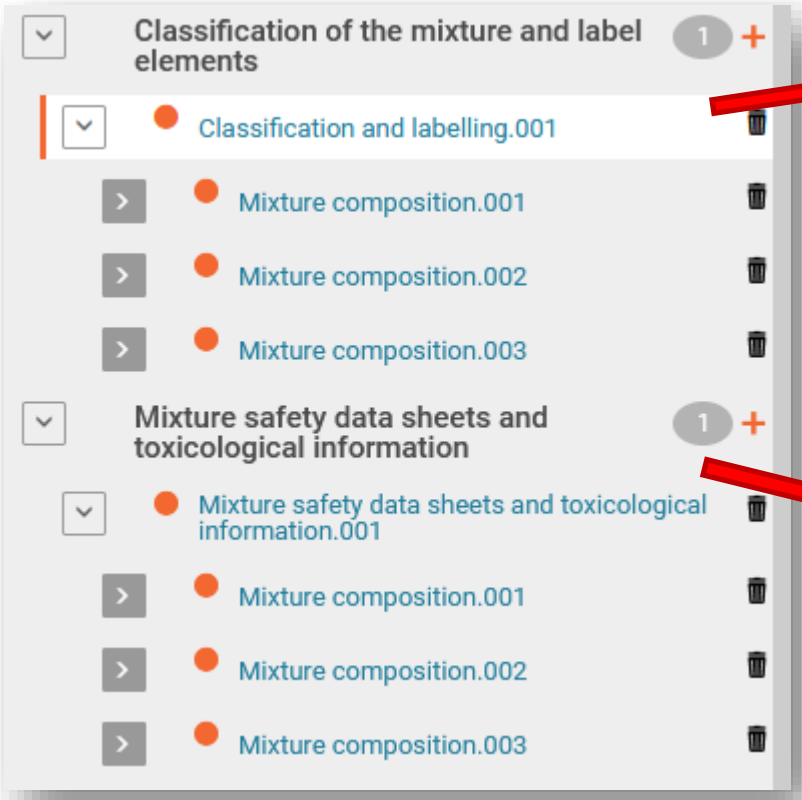
4. Enter C&L, toxicological information, pH documents for each mixture

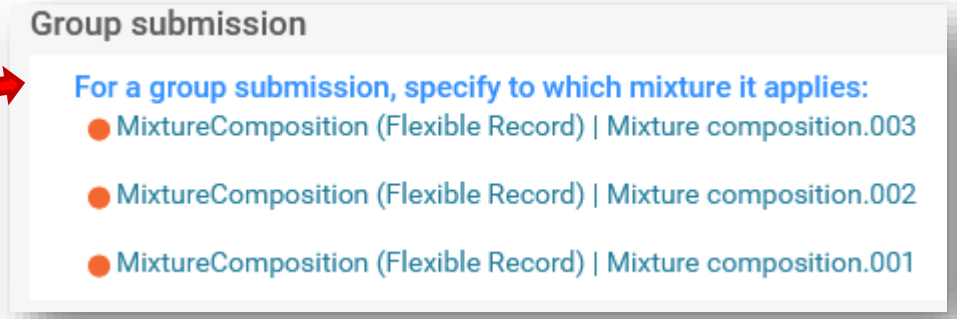
The same record can be linked to multiple mixtures

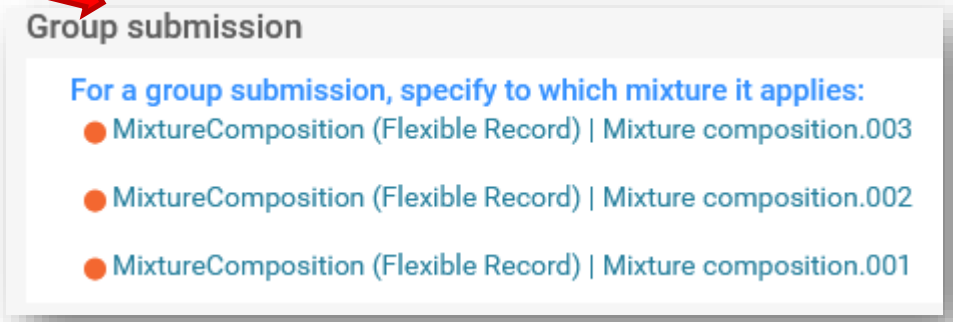
Or

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

Group Submission preparation







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)

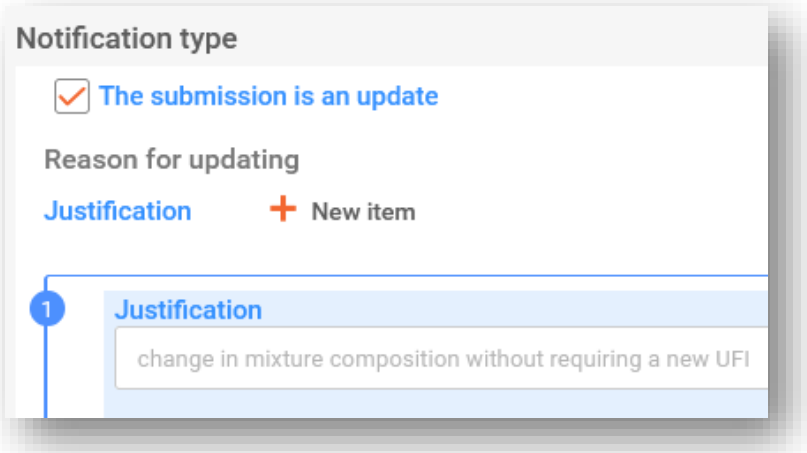
- Specific GS-requirements (e.g. minimum common composition, differing components must be *perfumes*)

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 *Perfumes* 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)



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

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