

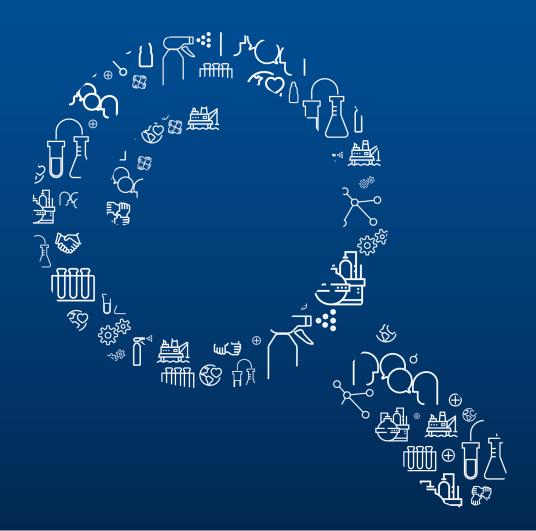




October 2021: improved dossier preparation and submission

- Dossier preparation: changes to poison centre notification (PCN) and IUCLID formats
- Dossier submission: improvements to ECHA submission portal and System-to-System service

Improvements to dossier preparation

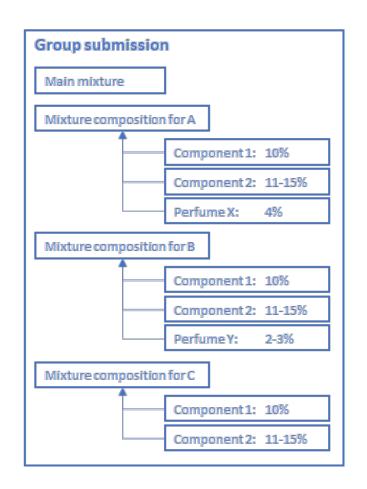






Preparing a group submission

- Possibility to create a dossier containing more than one mixture
 - All mixtures in a group must have the same classification for health and physical hazards
- Include multiple Mixture composition documents
 - Each Mixture composition document reflects a different mixtures (selfcontained)

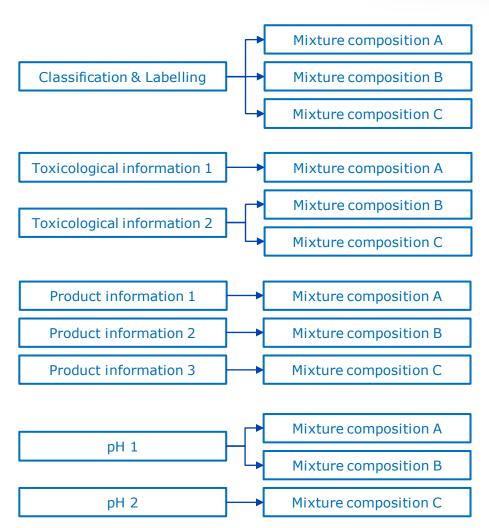






Preparing a group submission

- Possibility to include multiple 'documents' for:
 - Classification and labelling
 - Toxicological information
 - Product information
 - pH values
- Possibility to flexibly link each document to the relevant Mixture composition documents

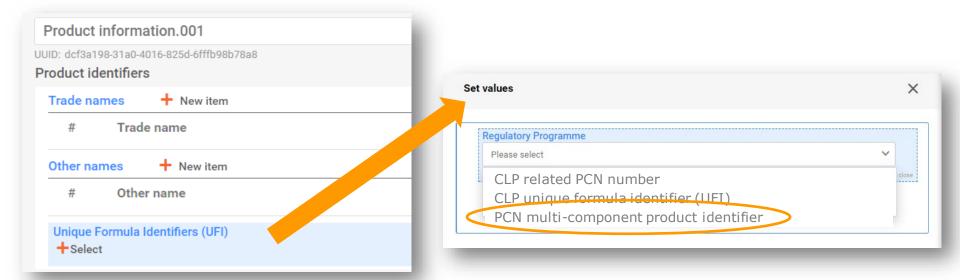






Indicating a multi-component product

- Possibility to indicate that the mixtures notified separately belong to the same product
- Possibility to add a new identifier for each product record in the dossier: PCN multi-component product identifier







Indicating a multi-component product

- New identifier can be used in all notifications related to the same multi-component product
- Companies can decide whether to use an:
 - existing identifier (e.g. one of the trade names of the multi-component product); or
 - a new identifier (e.g. a universal unique identifier (UUID))
- Validation rules are waived for the new identifier





Ceasing a product from the market

- Possibility for industry to indicate that a specific product is no longer marketed
- Possibility for appointed bodies and poison centres to still access information about ceased products
- In the dossier header, list of market areas remains as is: updates will be sent to all market areas regardless
- For each product information document, new list of market areas included to indicate that the product is ceased from one or more market areas

echa.europa.eu





Ceasing a product from the market

Product information

Market placement

Active market (country)

Belgium

Finland

Germany

Sweden

Ceased market (country)

France

Sum of:

Countries in "Active market" list +

Countries in "Ceased market" list

Dossier header

Country (market placement)

Belgium

Finland

France

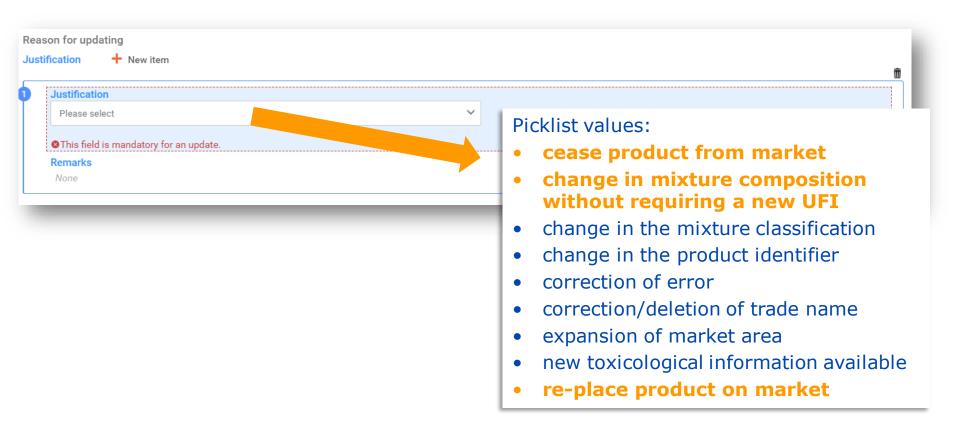
Germany

Sweden



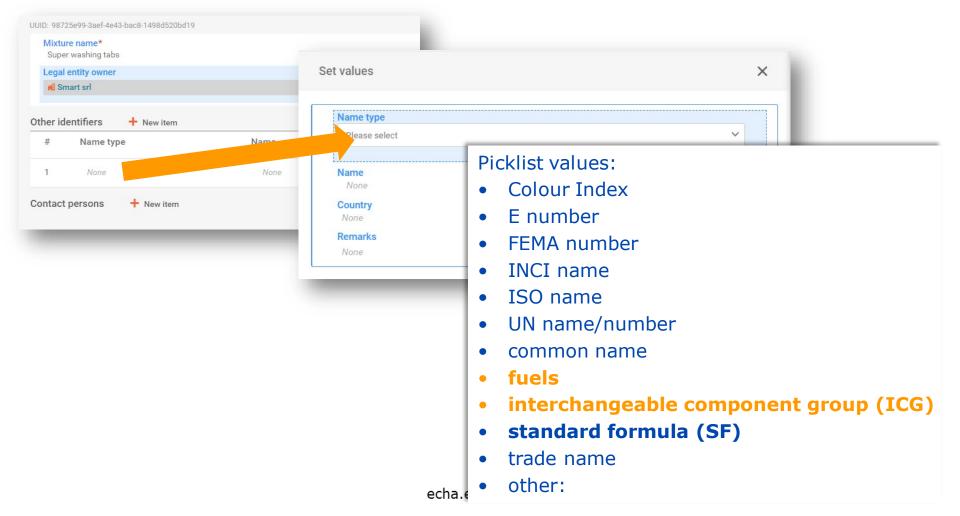


New reasons for dossier updates





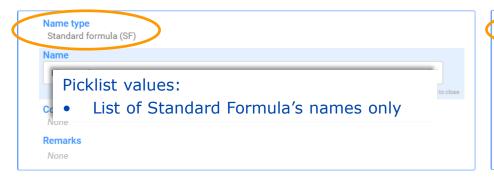
Name types for standard formulas, fuels and ICGs







Name types for standard formulas, fuels and ICGs











Product category changes in **EuPCS**

Additions to the European Product Categorisation System (EuPCS):

- PC-TEC-26 Products for molding, casting, rigid and flexible foams, including resin mixtures (excludes adhesives, construction products, paints and coatings)
- PC-TEC-27 Products for the polymerisation of resins and foams
 - [Includes curing agents, hardeners, cross-linkers]

Changes:

- PP-PRD-OTH Other plant protection products and related mixtures
- Other plant protection products not already covered, and mixtures used in plant protection products including adjuvants





Update of GHS

Following hazard phrases added:

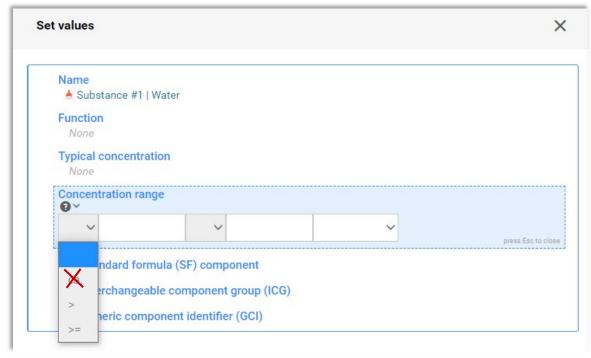
- H350i: May cause cancer by inhalation.
- H360F: May damage fertility.
- H360D: May damage the unborn child.
- H360FD: May damage fertility. May damage the unborn child.
- H360Fd: May damage fertility. Suspected of damaging the unborn child.
- H360Df: May damage the unborn child. Suspected of damaging fertility.
- H361f: Suspected of damaging fertility.
- H361d: Suspected of damaging the unborn child.
- H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.





Other format changes

- "Roll" added to values in "Type of packaging in contact with the product (container type)"
- Numeric range now without the 'ca.' value



echa.europa.eu





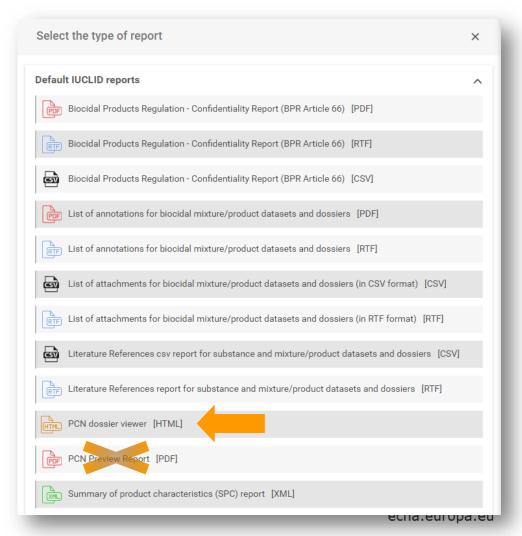
PCN format documents

- Version 4.0 DRAFT
 - Available on poison centres website
 - List of changes between versions 3 and 4
 - Modified phrase groups
 - New format in .doc files
- Version 4.0 FINAL
 - Available at the end of October (IUCLID major release)
 - List of implemented validation rules will be updated



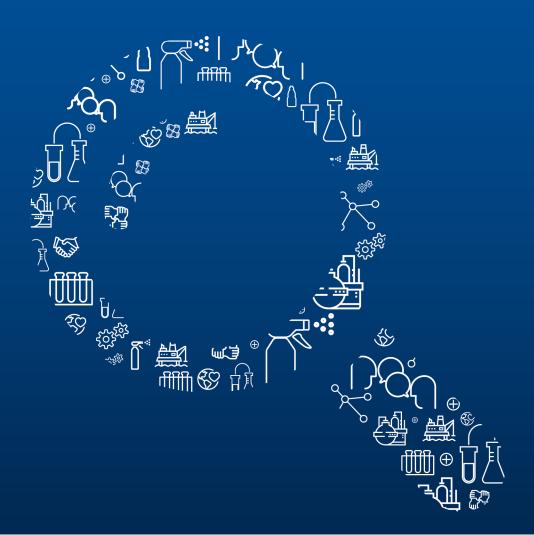


PCN preview report no longer available



- High maintenance and duplicates PCN dossier viewer
- PCN dossier viewer [HTML] remains available
- Possibility to save the HTML report in PDF

Improvements to dossier submission







Generation of multiple S2S keys

- Released in September
- Possibility to generate multiple system-to-system (S2S) keys per legal entity
- One user belonging to several legal entities can have different ("personal") S2S keys, one per legal entity (as for "human accounts")
- An industry system may perform operations on behalf of multiple associated legal entities (as for consultants/IT providers)
- For management of S2S credentials, new user interface developed in ECHA Accounts
 - Users can manage their personal API keys in all the companies where they have the S2S account
- Consult the manual "System-to-System submission for industry"

echa.europa.eu





Version 3 of S2S application programming interface (API)

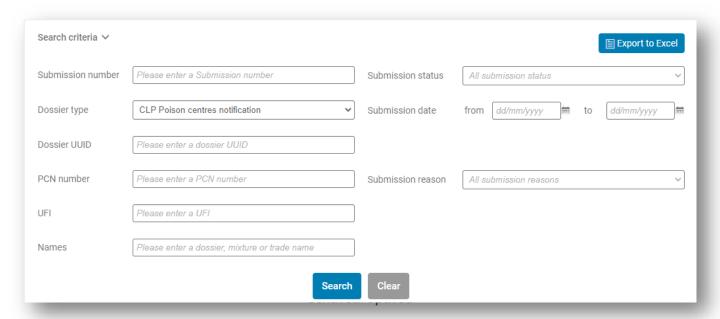
- Released in July
- Main additions/changes:
 - Includes the dossier UUID and persistent system sequence identifier (PSSI)
 - Referenced PSSI in the submission report
 - Support for multiple keys for each legal entity
 - Event flag to show passed submission with warnings
 - Correlation ID for your own use
- Version 1 available until end of October 2021
 - After October 2021, only Versions 2 and 3 active
- Consult the manual "<u>System-to-System submission for industry</u>"



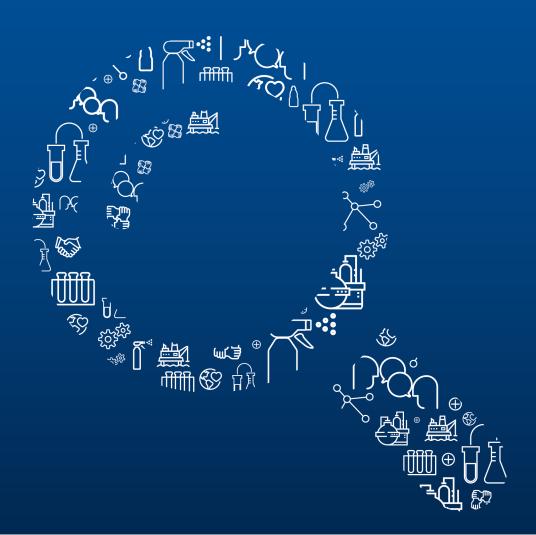


Improvements to submission search page

- Released in September
- Additional search criteria: Dossier name
- Dossier UUID added to search results
- Improved .xls file when exporting search results:
 - Column order optimised



A preview on what's coming later







Disabling submissions

- Expected by end of 2021
- Available from ECHA Submission portal and for S2S users
- Companies can disable a submission if:
 - the test dossier is submitted in the production environment by mistake;
 - data is incorrect and a simple update is not possible
 - foreign users submit their own legal entity instead of the dutyholder's.

Note!

- Disabling submission ≠ Eliminating dossiers from database
- Disabling submission ≠ Ceasing product from the market





Stay informed

- Follow <u>ECHA's poison centre notification</u> and <u>S2S support network</u> LinkedIn groups
- News on <u>ECHA's poison centres website</u>
- More instructions <u>PCN</u>: a practical guide

echa.europa.eu



Thank you!

claudia.rimondo(at)echa.europa.eu

Follow our news

News: echa.europa.eu/subscribe Facebook: @EUECHA

LinkedIn: European Chemicals Agency

Twitter: @EU_ECHA

YouTube: EUchemicals