

Poison Centre Notifications

Status update after the first
compliance date

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Topics covered

- Intro: Article 45, harmonising the obligations
- Submissions: facts and figures
- Preparing and submitting notifications: main issues and solutions
- Submission portal: new features

Intro

Harmonising Article 45 obligations



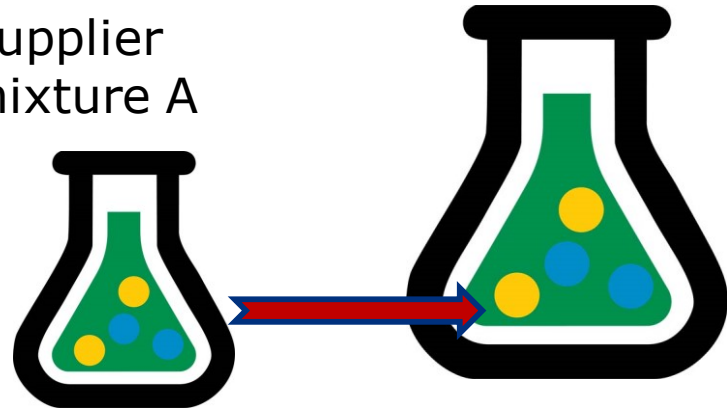
Annex VIII to CLP

- Adopted March 2017
 - First amendment adopted October 2019
 - Second amendment (workability amendment) adopted August 2020
- Harmonisation of submission format & information requirements
- ECHA role to provide tools & support for data preparation and submission process.
- Stepwise compliance dates depending on the use type of the mixture:
 - **Consumer/professional use January 2021**
 - Industrial use only January 2024
 - End of transition period January 2025

Compliance date

- Applicability of Annex VIII obligations depends on *end-use*:
 - Mixture itself
 - Final mixture which contains the original one

Supplier mixture A



Formulator mixture B
containing mixture A

- Mixtures was notified according to national obligations (and not in accordance with Annex VIII) before the relevant **compliance date**:
 - Mixture for consumer/professional: before 1 January 2021
 - Mixtures for industrial use: before 1 January 2024
- ➔ No need to notify Annex VIII info and place UFI on the label until 1 January 2025 as long as no changes occur

CLP revision

- Two amendments to Annex VIII already!
- A revision of the CLP Regulation is getting underway
- Areas for discussion that will affect Annex VIII are:
 - Online sales (relevant to also other legislations)
 - Definition of duty holders (i.e. distributors)
 - Notification of substances
- Public consultation on the revision of the CLP Regulation. Open until 15th November (!)

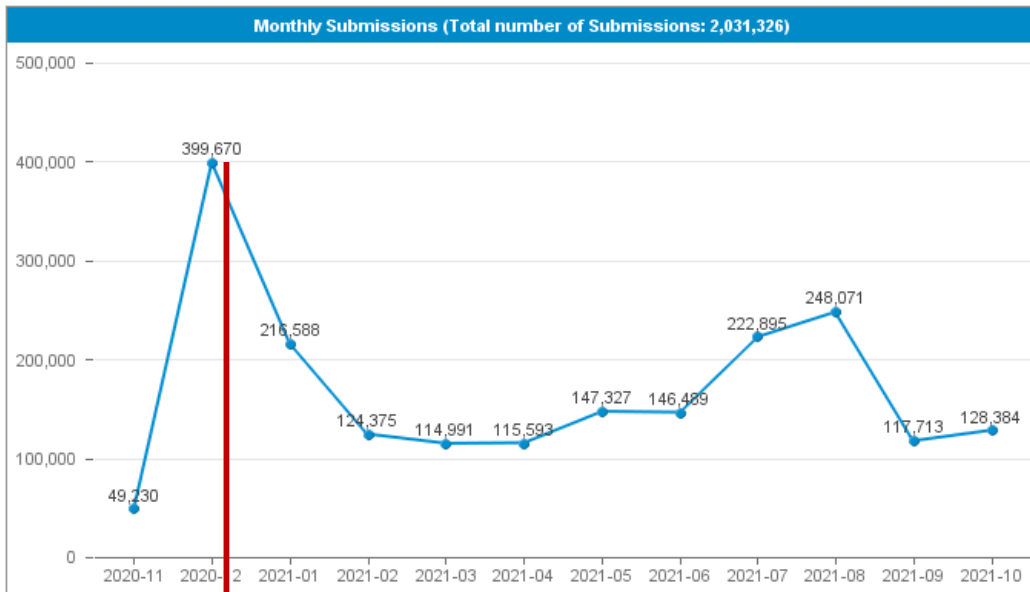
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals_en

Submissions

Facts and Figures



Submission numbers *(Nov 20 to Oct 21)*



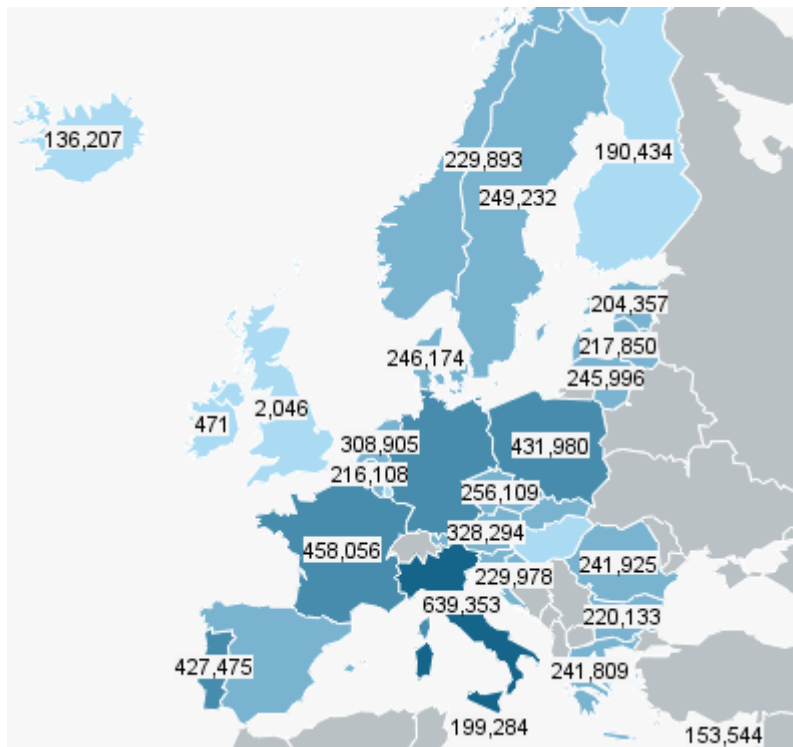
1st compliance date

More than 2 million successful submissions to date!

Peak right before 1st compliance date

Numbers include initials and updates

Market areas

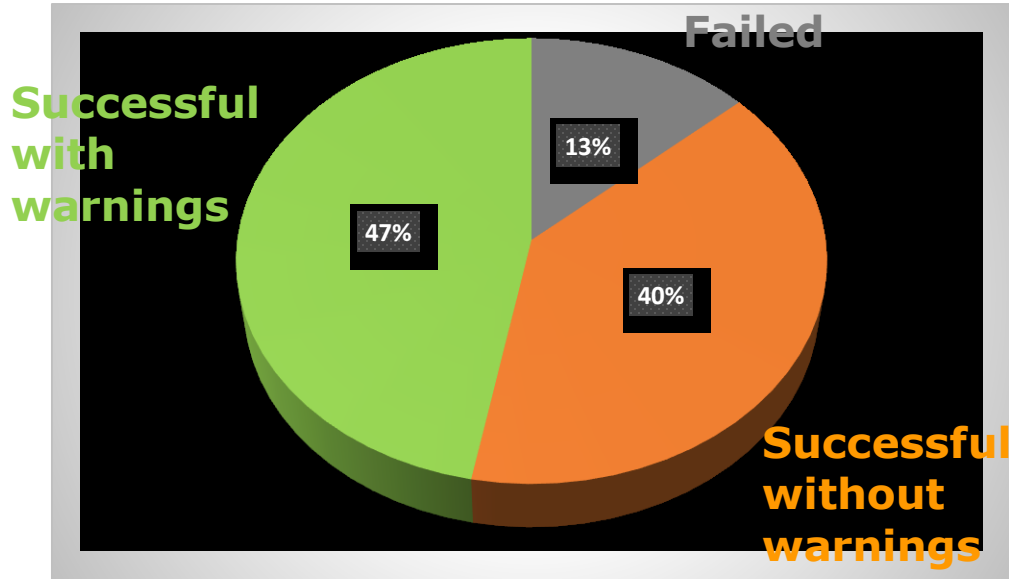


Top 5

Market Area	Submissions (#)
Italy	639,353
Germany	576,348
France	458,056
Poland	431,980
Portugal	427,475

N.B.: Submissions can be multi-country!

Submission status



Dossiers are validated by:

- the notifier in the system before submitting &
- the ECHA Submission portal at the time of submission

Business Rules: Information needs to be corrected or provided to be able to submit

Quality rules: information may need to be revised/corrected/improved but dossier is submitted

Submission failures: main issues

Inconsistency with previously submitted information about dossier's identifiers

BR564: Exactly the same dossier cannot be submitted again (Portal rule)

Dossier sent again before the first completely processed (technical delays possible).
Suggestion to check the submission report before resubmitting.

BR567: A new PCN number should be provided for initial notifications and significant changes in composition (Portal rule)

A PCN number used in previous successful notifications is used again. The same PCN number should be retained across updates only.

BR568: An existing PCN number should be used in updates (Portal rule)

An update is submitted with a PCN number not used in any previous submissions. If the first "Initial" failed, a new "Initial" should be submitted (not an "update!").

Inconsistency between Legal Entities

BR570: Submitter LE in ECHA submission portal must be the same as LE in main mixture (Mixture identity and legal submitter record) (IUCLUD rule)

The legal entity UUID in the PCN dossier (mixture level) does not match the UUID of the logged in user in the ECHA Submission portal

Reasons:

- a) The LE preparing the dossier is not the same as the one required to submit
- b) (Unwilling) creation of two versions of the same LE (UUID is unique), instead of importing the original one to ECHA Account
- c) Changes in ECHA accounts LE not replicated in the offline IUCLID
- d) 3rd party submitting via S2S for different LEs does not use the correct S2S key

Submission failures: main issues

Misuse of Standard Formula (SF) components

BR580: If component is flagged as "SF component" the SF name needs to be correctly indicated.

Components are flagged as "Standard Formula components" but the mixture does not conform to a Standard Formula and, consequently, the SF name is not provided correctly.

Name
🔥 Propylene Glycol | Propylene Glycol | propane-1,2-diol | 57-55-6

Function
solvent

Typical concentration
None

Concentration range
>= 25 <= 30 % (w/w)

Standard formula (SF) component

Interchangeable component group (ICG)

Generic component identifier (GCI)

Standard Formulas are listed in Part D to Annex VIII, with their relevant components and concentration.

Only when the mixture conforms with one of these SF, the components in the submission can be flagged as "SF component" and the specific *looser* concentration ranges can be used.

Cement Standard Formula – 5		
Product description	Portland-fly ash cement, Pozzolanic cement Portland cements with two main constituents: clinker and fly ash (siliceous and calcareous fly ash)	
Component name	EC No	Concentration (w/w %)
Portland cement clinker	266-043-4	41 – 94
Fly ash	931-322-8	5,5 – 55
Calcium sulfate	231-900-3	0 – 8
Flue dust ⁽²⁾	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

Correct use of SFs

The mixture conforms with a SF:

SF name as *mixture identifier*

Mixture name*
Mixture Super

Legal entity owner*
Undefined Company Name | Helsinki | Finland

Other identifiers + New item

#	Name type	Name
1	standard formula (SF)	Cement Standard Formula - 4 [Portland-pozzolana cement, Pozzolanic cement Portland cements with two main constituents: clinker and pozzolan (natural or natural calcined pozzolan)]

Name ? v
Portland cement clinker | Portland cement clinker | 266-043-4

Function
None

Typical concentration
None

Concentration range
None

Standard formula (SF) component

Interchangeable component group (ICG)

Generic component identifier (GCI)

Reference substance
Portland cement clinker | 266-043-4

Legal Entity*
Undefined Company Name | Helsinki | Finland

Substance name*
Portland cement clinker

Other substance identifiers + New item

#	Identifier	Identity
1	standard formula (SF)	Cement Standard Formula - 4 [Portland-pozzolana cement, Pozzolanic cement Portland cements with two main constituents: clinker and pozzolan (natural or natural calcined pozzolan)]

Part of the mixture conforms with a SF:
SF name as component identifier

Submission warnings

QLT592: Repeating the same 'reference substance' not allowed unless the related classification is different (IUCLID rule)

Different components have the same reference substance assigned. The system cannot verify the exact sameness, but same components should be merged.

QLT574: Any changes to the notification should be reported as an 'update' and not as a new 'initial' submission.

Several initial notifications from the same company, to the same market area and with the same trade name. Attempt to capture situations where the notification should be an update.

Preparing and submitting notifications





Preparing a PCN

- PCN format is incorporated into the tools for preparation:
 - [IUCLID 6](#)
 - Downloaded from IUCLID website
 - Desktop and server versions maintained by user
 - [IUCLID Cloud](#)
 - Maintained by ECHA
 - Secure data storage
 - [System-to-system service](#)
 - Prepare in company's system using .xml file format
 - Automated approach to bulk submission

Submitting a PCN

- Submissions made through ECHA Submission portal
 - 80% made via S2S
 - 20% via IUCLID
- Notifications to UK(Northern Ireland) must be submitted directly to UK authorities – not possible through the Portal
- Option additionally available for submission through national systems for:
 - Germany, France, Belgium, Latvia and Portugal

Format update

New features 2021

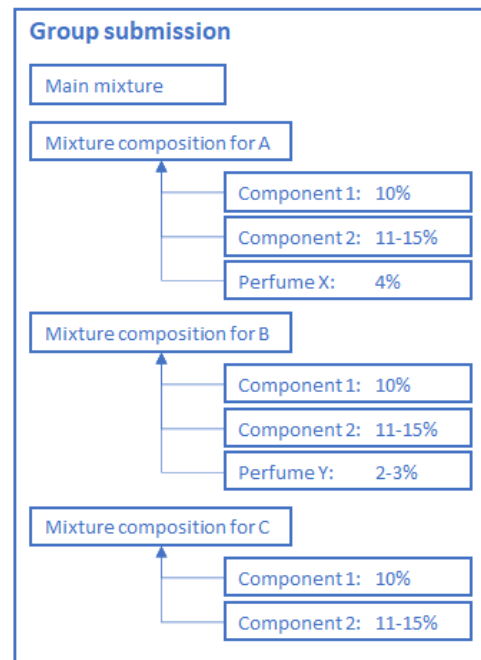


Last release of the format

- Version 4.0 release October 26th 2021, main new features include:
 - Cease product from the market
 - Make a group submission
 - Indicating a multicomponent product
 - Changes to the European Product Categorisation System
 - New/modified Validation Rules
- -> 'Disabling' a submission in plan for later 2021
- IT solution moving to maintenance mode

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
 - Can differ only for certain *perfumes* components
- Include multiple *Mixture composition* documents
 - Each *Mixture composition* document reflects a different mixtures (self-contained)



Mixtures as part of a multi-component product

- Possibility to indicate that mixtures (to be 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

The image shows a screenshot of the ECHA dossier interface. On the left, the 'Product information.001' section is visible, including a UUID and 'Product identifiers' for trade and other names. A blue box highlights the 'Unique Formula Identifiers (UFI)' section with a '+ Select' button. An orange arrow points from this section to a 'Set values' dialog box on the right. The dialog box has a 'Regulatory Programme' dropdown menu and a list of options: 'CLP related PCN number', 'CLP unique formula identifier (UFI)', and 'PCN multi-component product identifier'. The last option is circled in orange.

Ceasing a product from the market

- Possibility for industry to indicate that a specific product is no longer placed on the market
- 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

Ceasing a product from the market

Dossier header

<p>Country (market placement)*</p> <ul style="list-style-type: none">✓ Belgium✓ Germany✓ Italy
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Market placement

Active market (country)

- ✓ Belgium
- ✓ Italy

Ceased market (country)

- ✓ Germany

Product ABC



Product XYZ



Market placement

Active market (country)

- ✓ Germany

Ceased market (country)

- ✓ Italy

New reasons for dossier updates

Reason for updating

Justification + New item 🗑️


1 **Justification**

Please select ▼

⦿ This field is mandatory for an update.

Remarks

None



Picklist values:

cease product from market
change in mixture composition without
requiring a new UFI

change in the mixture classification

change in the product identifier

correction of error

correction/deletion of trade name

expansion of market area

new toxicological information available

re-place product on market

Name types for standard formulas, fuels and ICGs

UUID: 98725e99-3aef-4e43-bac8-1498d520bd19

Mixture name*
Super washing tabs

Legal entity owner
Smart srl

Set values

Other identifiers + New item

#	Name type	Name
1	None	None

Contact persons + New item

Name type

Please select

- INCI name
- ISO name
- UN name/number
- common name
- fuels
- interchangeable component group (ICG)
- standard formula (SF)
- trade name

Name type dropdown menu items:

- Name type
- Please select
- Name
None
- Country
None
- Remarks
None

Other format changes

- EuPCS: new categories (PC-TEC-26 and PC-TEC-27) and minor changes to existing
- New hazard statements (H350x and H361x)
- New packaging type (“roll”).
- Other minor improvements
- Improvements to dossier search page (in September)

Coming soon - 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

Thank you!

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