

Annex VIII to CLP and the ECHA Submission portal

18 November 2019

10th User Conference on Product Notifications

Federal Institute for Risk Assessment (BfR)

Berlin, Germany

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Submission and Processing Unit

European Chemicals Agency

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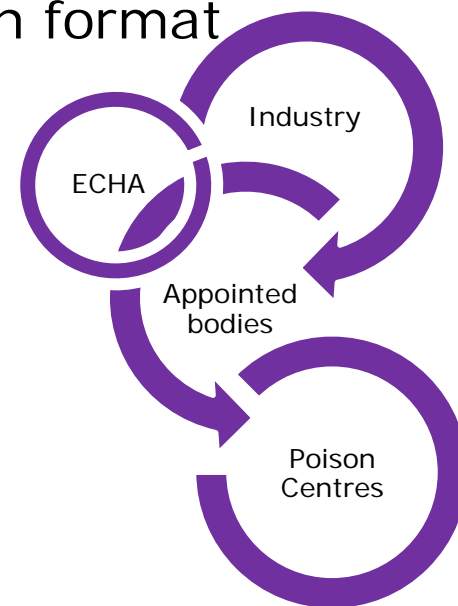


Information requirements in a nutshell



Annex VIII to CLP

- Adopted March 2017.
- Led to the harmonisation of information requirements at EU level
- Preparation of data in a harmonised submission format
- ECHA provides the tools for data preparation and transfer as well as submission process.
- Stepwise compliance dates depending on the use type of the mixture, i.e. consumer, professional or industrial.



Amendment of Annex VIII to CLP

- Editorial changes (terminology)
- Non-editorial changes
 - Simplified rules for group submission
 - Reporting of MiM components
 - Additional contact point
 - UFI on inner or outer packaging
 - pH requirements and justification if missing
- Amendment adopted and expected to be officially published by end of 2019
- Postponement of the first compliance date
 - Consumer use products to be notified from 2021 onwards (=professional use)
- No solutions for workability issues

Companies placing **mixtures** on the **market** (*before!*)

➔ In each Member States where the mixture is placed on the market

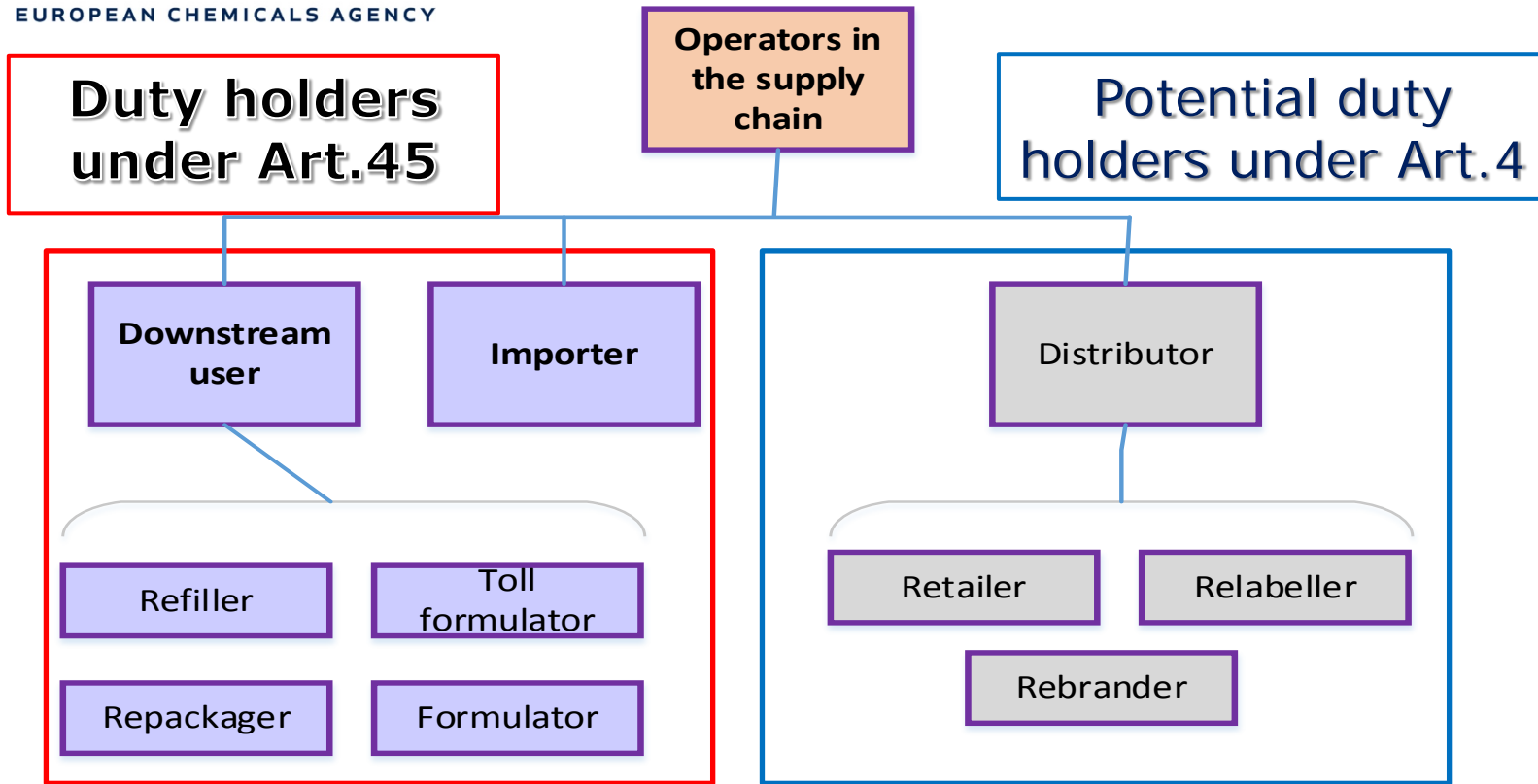
YES:

Mixture
classified for
health and
physical
hazards

Mixtures
combined with
articles

NO:

- Substances
- Mixtures not covered by CLP
- Mixtures classified only for environmental effects
- Mixtures used for R&D; PPORDs
- Gases under pressure
- Explosives (unstable explosives and divisions 1.1 to 1.6)




Article 45 - Direct obligations → Importers/Downstream user

Article 4(10) – Mixtures placed on the market have to be CLP compliant → All actors (*including distributors!*)

Shared responsibility to prevent non-compliance (i.e. Annex VIII information available to relevant)

The role of the distributor

- To avoid information gaps, distributors also have compliance obligations under CLP Regulation.
- It is possible that the upstream supplier can include the relevant information on behalf of the distributor in their own submission.
- Enhanced communication in the supply chain is needed to determine:
 - the end use of the mixture
 - the Member States where the mixture is placed on the market
 - if the importer or downstream user has submitted the mixture information in all those Member States



If the relevant information is not included in the original submission made by the upstream supplier, the distributor **may need** to make their own submission.

Interpretation clarified
in version 2.0. of the
Guidance



Lack of agreement
among CAs

Dissenting view Note
attached to the Guidance

GUIDANCE

Guidance on harmonised information
relating to emergency health response –
Annex VIII to CLP

Guidance to Regulation (EC) No 1272/2008 on classification, labelling
and packaging (CLP) of substances and mixtures

Version 2.0
July

When reading this ECHA Guidance, authorities of EU/EEA Member States of duty holders under Article 45. The current Guidance where this considers relabellers, as distributors and not distributors.

Belgium
Germany
Greece
France

The authority of Sweden does not consider distributors in relation to Annex VIII a

The authorities of the following Member States

Denmark
Portugal

This is reflected in the CA/30/2019 do

Compliance dates

- For 'new' mixtures not already notified – notification is always before you place on the market.
- Different dates for compliance depend on the use type of the mixture:
 - 1 January 2021 consumer or professional use
 - 1 January 2024: industrial use
- Before these dates, mixtures continue to be subject to existing national requirements.
- For 'existing products' already notified there is a transition period until 1 January 2025 - unless change made to existing notification in period from relevant deadline to end of transition period.

Information requirements in a nutshell



Contact details
 Submitter details
 Contact point if person having further relevant information is other than the submitter
 Emergency contact

+



Mixture information
 Product/mixture identifier
 Toxicological information
 Hazard classification and labelling information
 Physico-chemical properties

+



Mixture component information
 Mixture component information
 - Concentration
 - Identifiers
 - Classification
N.B.: Full chemical composition:
 - Classified* $\geq 0.1\%$
 - Not classified* $\geq 1\%$

+



UFI & other identifiers
 A unique formula identifier linking the mixture information to the related product on the market

+



Product information
 Use types consumer/professional/industrial
 Product category from the EuPCS
 Packaging types/sizes

Information requirements in a nutshell



+



+



+



+



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Submitter details

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Emergency contact

Mixture component information

Mixture component information

- Concentration
- Identifiers
- Classification

Substance B.: Full chemical composition:

- Classified* $\geq 0.1\%$
- Not classified* $\geq 1\%$

UFI & other identifiers

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Information requirements in a nutshell



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Submitter details
Contact point if possible
further relevant information
other than the contact details
Emergency contact

Mixture information
Product/mixture identifier
Toxicological information
Hazard classification and
labelling information
Physico-chemical properties



nt

1%
≥1%



UFI & other identifiers
A unique formula identifier
linking the mixture
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 Product/mix
 Toxicologic
 Hazard clas
 labelling
 Physico-che

Mixture component information

Mixture component information

- Concentration
- Identifiers
- Classification

N.B.: Full chemical composition:

- Classified* $\geq 0.1\%$
- Not classified* $\geq 1\%$

*With regard to Health/Physical hazards



MiMs → **UFI**
 Substances

Information requirements in a nutshell



+



+



+



+



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Mixture information
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 Physico-chemical properties

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 - Identifiers
 - Classification
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 - Not classified

UFI & other identifiers
 A unique formula identifier linking the mixture information to the related product on the market

Visibility of UFI on the product

- UFI must be included in the submission and clearly visible on the product label (printed or affixed).
- The UFI may also be provided on the packaging in close proximity to the label elements.
- Inclusion of UFIs on the label should be planned to coincide with the submission of information.
- The acronym 'UFI:' must precede the code to distinguish it from other codes.
- No specific requirements for have been set, for instance, for position, font type or size but, inclusion requires planning so that it is easy to locate to assist with its communication to poison centres.

Derogations for using UFI

- The UFI is required on the label for all hazardous mixtures, however the UFI can be included in the Safety Data Sheet (SDS; section 1.1) for mixtures:
 - used on industrial **sites** (as an alternative)
 - that are not packaged (mandatory)
- The UFI is not required in the SDS by default, only in the cases mentioned above.
- For products that have multiple packaging layers, the UFI is only required on the inner packaging.

Information requirements in a nutshell



Contact details
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 Contact point if person having further relevant information is other than the submitter
 Emergency contact

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Mixture information
 Product/mixture identifier
 Toxicological information
 Hazard classification and labelling information
 Physico-chemical properties

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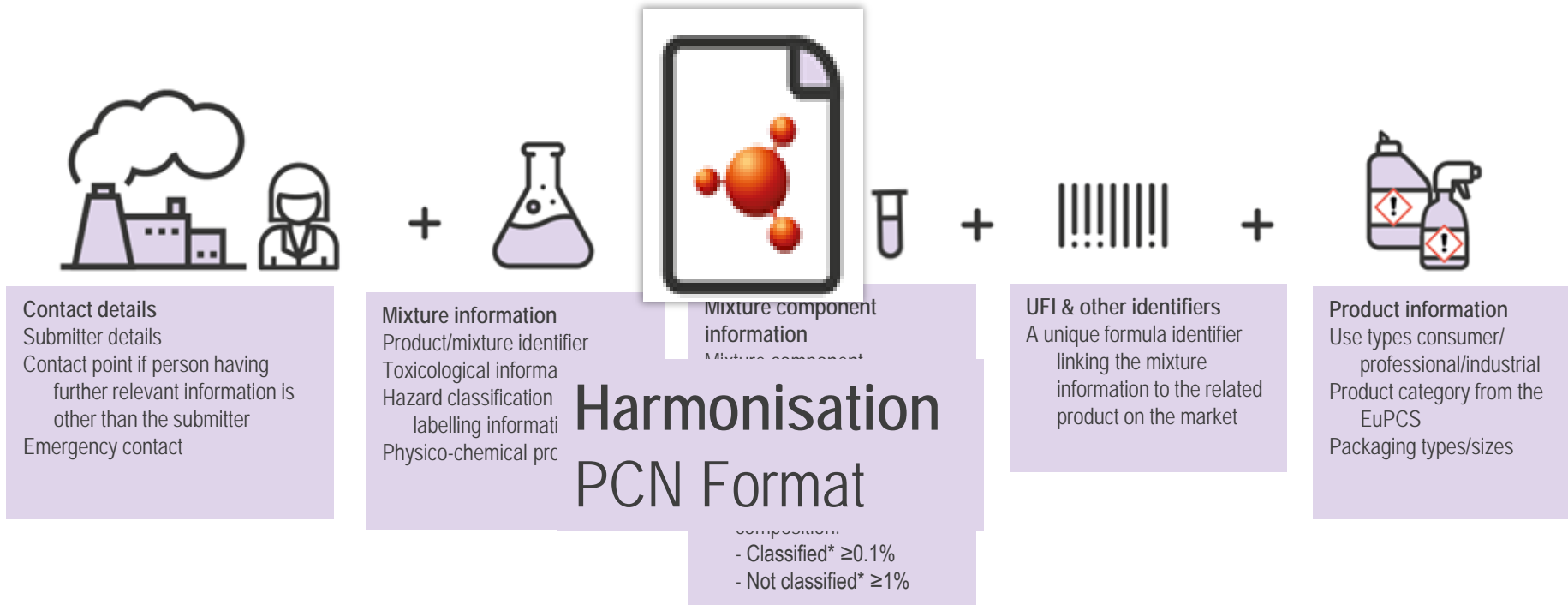
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 - Concentration
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+



Product information
 Use types consumer/
 professional/industrial
 Product category from the EuPCS
 Packaging types/sizes

Information requirements in a nutshell



Consider exceptions...

The chemical identity and concentration of components needs to be fully declared, however, in certain circumstances you may optionally consider some exceptions:

Generic product identifiers (GPI):

- Perfumes/colouring agents generically identified
- Not classified for any health hazard
- Total concentration within a threshold

Limited submission:

- Limited compositional information (from SDS)
- Industrial use only
- 24/7 emergency phone number

Group submission:

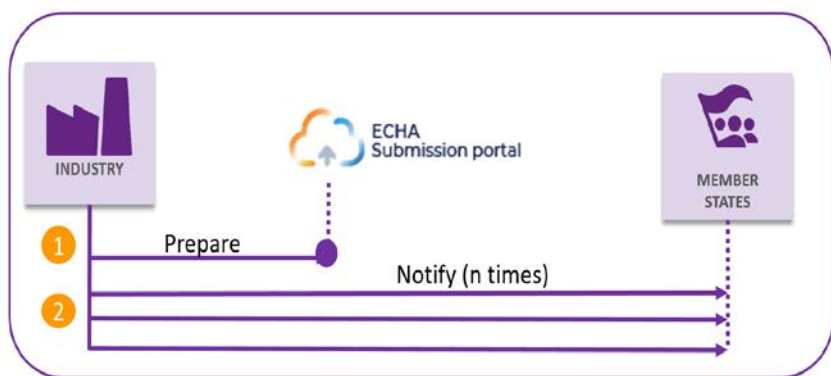
- *Not supported yet*

PCN dossier preparation and submission



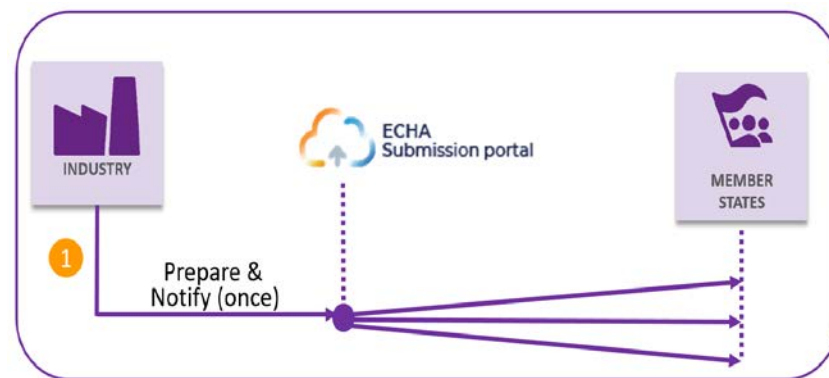
PCN dossier preparation and submission

Local systems vs. central system



- n dossiers submitted n times (once to each relevant Member States)
- submission modalities determined by MS

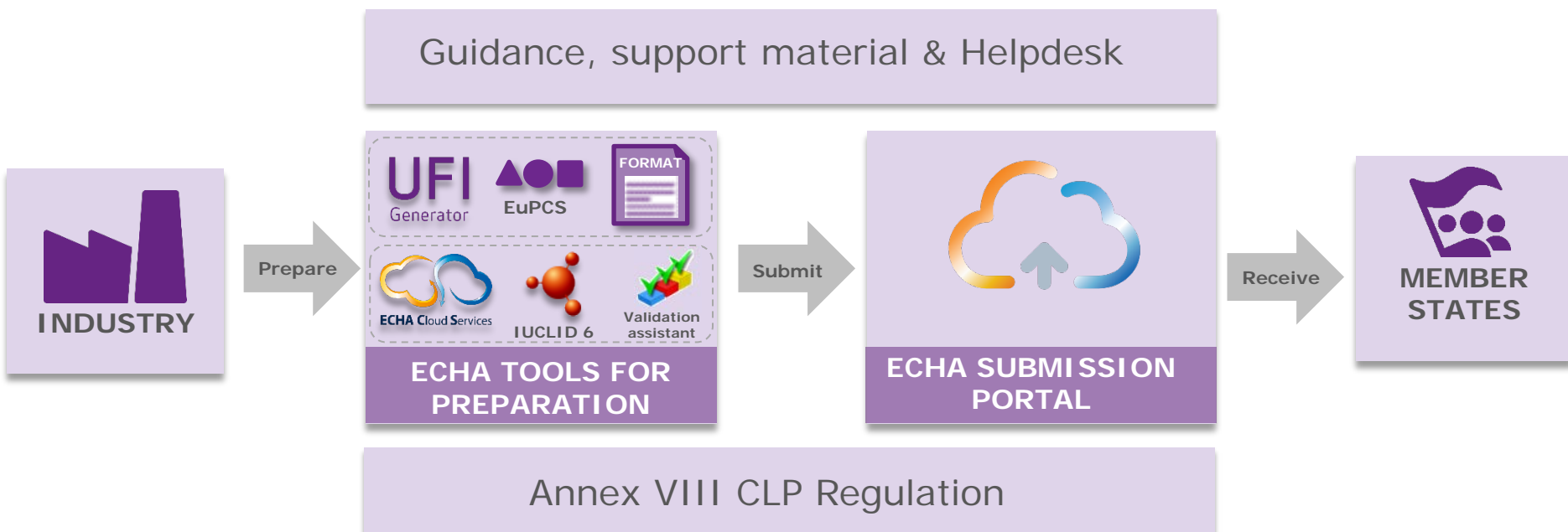
Note: not all MSs will provide option of submitting via local systems



- one notification submitted once to ECHA
- notification dispatched to n relevant Member States by the central portal

Note: so far all MSs expressed acceptance for central system (even if in parallel to local)

ECHA tools for preparation & submission



PCN dossier
preparation and
submission

Pre- preparation phase



UFI
Generator

UFI GENERATION

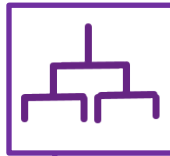
UFI assigned to a single mixture composition

UFI generating algorithm is public, but if decoded, UFI can only ever reveal a company's VAT number and the internal formulation number (between 0 and 268,435,455) of a specific mixture.

There are alternatives to using the VAT number if there are CBI issues:

- 'Company key'
- Declaration box updated in the UFI Generator

<https://poisoncentres.echa.europa.eu/ufi-generator>



EuPCS

PCN
FORMAT

<XML>

PCN FORMAT



UFI
Generator

UFI GENERATION

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EuPCS

One main intended use category required to describe the mixture/product.

Industry advised to check with their association if they are unsure of the correct product category.

Request for change process in place goes through procedure involving representatives of the EuPCS working group.

<https://poisoncentres.echa.europa.eu/eu-product-categorisation-system>



PCN
FORMAT

<XML>

PCN FORMAT

UFI
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UFI GENERATION

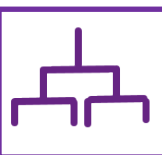
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PCN
FORMAT

<XML>

PCN FORMAT

The poison centre notification (PCN) format encompasses the harmonised information requirements.

It is the backbone of Annex VIII - submission format for all notifications and integrated in dossier preparation tools.

Subject to updates – Latest update 30th October 2019.

<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

PCN format update

30th of October 2019

- IUCLID 6.4 publication, including related format
- PCN format publication, including updated documentation
- IUCLID instances hosted in ECHA Cloud Services will be upgraded at the same time

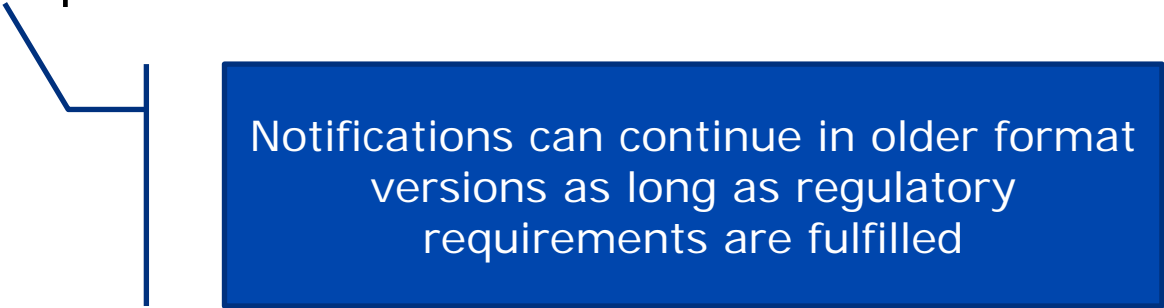
...Yearly updates

- Changes **initiated by the PCN users** (incl. ECHA)
 - Fields changed from 'multilingual' to 'not multilingual'
 - Other name
 - Trade name
 - ID under the *Identifiers document*
 - PCN number
 - External system identifier
 - 'Generic Product Identifier' checkboxes included in the *Composition* and *Composition summary* documents
 - Dossier contact added to the contact type in the *Contact document*
 - *PCN dossier header*
 - New update reason 'correction of error'
 - Reorganisation of notification types and submission types
 - 'Submission of non-hazardous mixture' replaced by 'Voluntary submission'
 - 'PCN number', 'Market placement' and 'Language' made mandatory

- Changes **initiated by other IUCLID users** (but still relevant to PCN)
 - Classification and labelling information (*GHS document*) updated to take into account ATPs 10th to 14th (and GHS rev. 6 & 7)
 - Additional text for Precautionary statement increased from 255 to 2,000 characters
 - New EU Hazard statements
 - New flammable gases categories
 - Updated Notes
 - New phrases: H350i, H360D, H360Df, H360F, H360FD, H30Fd, H361d, H361f, H361fd

Consequences for Industry (submitter)

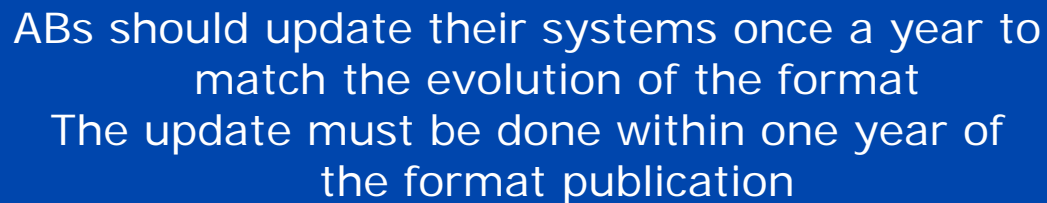
- After IUCLID 6.4 publication (after 30th October)
 - Notifications can still be prepared according to the IUCLID 6.3 format specifications
 - Notifications can also be prepared according to the new format specifications



Notifications can continue in older format versions as long as regulatory requirements are fulfilled

Consequences for Appointed Bodies (recipient)

- Poison Centre Notifications can be received in IUCLID 6.3 or IUCLID 6.4 format (from 30th October)
- Notifications will be made available in both formats for 1 year (to leave time for adaptation of existing systems)
 - IUCLID 6.3 files (original) will also be upgraded to IUCLID 6.4
 - IUCLID 6.4 files (original) will also be downgraded to IUCLID 6.3



ABs should update their systems once a year to match the evolution of the format
The update must be done within one year of the format publication

PCN dossier
preparation and
submission

Tools to prepare a PCN notification



Tools to prepare a notification



ONLINE PREPARATION

- Online using IUCLID Cloud available in the ECHA Submission portal.
- Maintained, backed-up, updated by ECHA.
- Data securely stored in ECHA Cloud.
- Guided dossier preparation
 - Prepare step by step
 - Validation assistant
 - Notification preview report
- <https://poisoncentres.echa.europa.eu/echa-submission-portal>



OFFLINE PREPARATION



SYSTEM PREPARATION

Tools to prepare a notification



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OFFLINE PREPARATION

- Offline using IUCLID 6 downloaded from the IUCLID website (PCN template).
- New web interface available visually the same as in IUCLID Cloud.
- Installed and maintained locally by users.
- Server version available for multi-user companies.
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SYSTEM PREPARATION

- System preparation uses the PCN format to prepare IUCLID compatible dossiers in a company's own system.
- Subject to IUCLID and PCN format updates which need to be maintained by users.
- Allows a more automated approach for companies to prepare and submit.
- <https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

**PCN dossier
preparation and
submission**

Tools to submit a PCN notification



Tools to submit a notification



ECHA SUBMISSION PORTAL

- Available since April 2019.
- Multimarket submissions possible.
- Monthly average ~400 successful submissions.
- Germany and Estonia are connected and accepting submissions via the Portal.
- Latest release 31st Oct, next Jan 2020.

<https://poisoncentres.echa.europa.eu/echa-submission-portal>



SYSTEM TO SYSTEM (S2S)



NATIONAL SUBMISSION SYSTEMS

Tools to submit a notification



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NATIONAL SUBMISSION SYSTEMS

- Still in place until each Member State specifies otherwise.
- So far, only four Member States will keep national systems open in addition to the Portal – Austria, France, Germany & Portugal. No information on eight*.
- Industry advised to consult with the national appointed body:

<https://poisoncentres.echa.europa.eu/appointed-bodies>

* Current data from the 'Overview of Member States' decisions on implementing Annex VIII to the CLP' table:
<https://poisoncentres.echa.europa.eu/echa-submission-portal>

**PCN dossier
preparation and
submission**

Tools for authorities





WEB SERVICE (REMOTE FOLDER)

- Available since April 2019 for poison centre notifications submitted through the ECHA Submission portal.
- Information is stored in country specific folders (FTP).
- Notifications and validation reports accessed through Remote Access Portal.
- Twelve countries have access rights in place.

<https://poisoncentres.echa.europa.eu/echa-submission-portal>



eDELIVERY SERVICE



PCN DATABASE



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eDELIVERY SERVICE

- Available since July 2019.
- Automatic receipt of dossiers submitted by industry.
- Authorities must subscribe to the eDelivery service before connectivity to ECHA.
- Currently around eight Member States are in the process to connect.

<https://poisoncentres.echa.europa.eu/tools-for-authorities>



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PCN DATABASE

- Available by **end of November 2019**.
- Basic query functionality and dossier view/download.
- Access open to PCs but Appointed bodies must ensure compliance with standard security requirements set by Security Officers Network.
- Not a 24/7 online access for emergency health response.
- Consultation kicked off with AB and PC – discussions ongoing to establish MS needs.

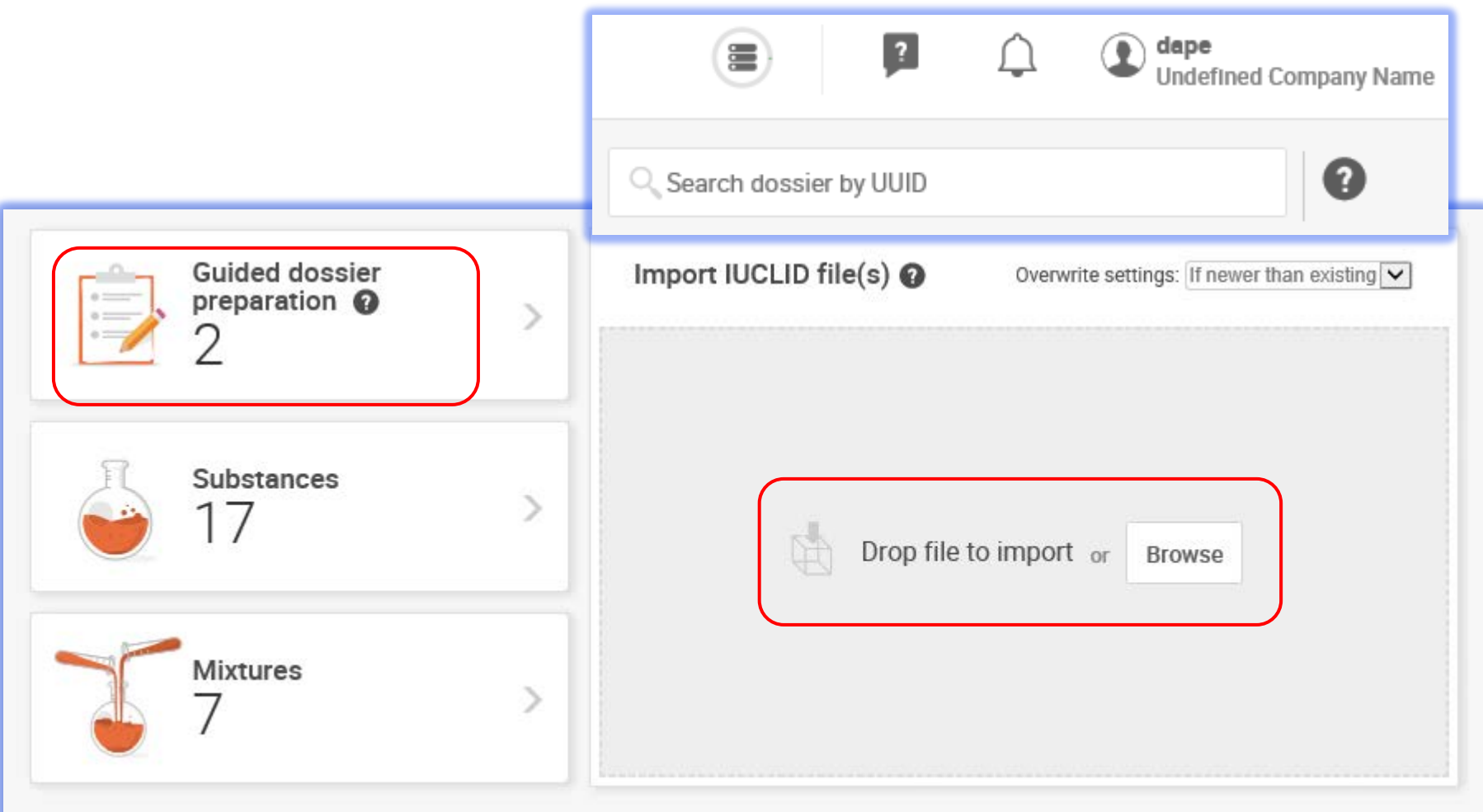
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PCN dossier
preparation and
submission

ECHA Submission portal – Online preparation



Online preparation



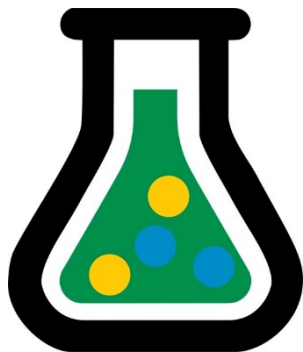
The screenshot displays the ECHA online preparation interface. On the left, a sidebar contains three menu items: 'Guided dossier preparation' with a count of 2, 'Substances' with a count of 17, and 'Mixtures' with a count of 7. The 'Guided dossier preparation' item is highlighted with a red border. The main area on the right features a top navigation bar with a hamburger menu, a help icon, a notification bell, and a user profile for 'dape' with the text 'Undefined Company Name'. Below the navigation bar is a search bar labeled 'Search dossier by UUID'. The main content area is titled 'Import IUCLID file(s)' and includes an 'Overwrite settings' dropdown menu set to 'If newer than existing'. A large dashed box contains a file upload area with the text 'Drop file to import or Browse', where the 'Drop file to import' text and the 'Browse' button are highlighted with a red border.

Mixture vs. product

Mixture

Mixture or solution containing chemical components having associated properties:

- Composition
- Tox. properties
- pH
- Labelling



Product

Mixture in the form in which it is supplied to the user and defining the other aspects:

- Trade name
- Packaging
- Product category
- (Colour)



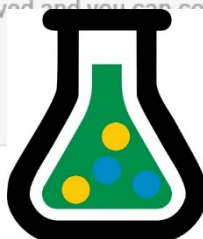

☰ Mixture test Nov19


Submission type:CLP Poison centres notification


1 Provide dossier information

Welcome! Start preparing your dossier by providing information in the following main task groups. You will be guided through main task groups below. Your work can be saved and you can come back to it later if you do not have all the information at

Information to be completed



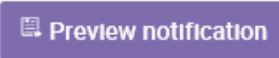
 

 **Mixture Information**

 **Product information**

2 Finalize your dossier

Once you have entered your IUCLID data, validate and review the information before creating your dossier. When the dossier is ready, you can submit it through the [Submission portal](#). Additionally, you can preview the provided information in PDF.

Online preparation Dossier validation



ONLINE PREPARATION

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 - **Validation assistant**
 - Notification preview report
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The validation assistant runs a number of checks before submission and upon submission by the user:

- Presence of information
- Quality of information
- Internal dossier consistency

- Consistency with previously submitted information



• Online
Cloud a
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• Maintai
update

• Data se
ECHA C

- Guided dossier preparation
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• <https://poisoncentres.echa.europa.eu/echa-submission-portal>

Validation assistant report

✕

Validated entity: Training mixture
 Validation time: 27/05/2019 15:19
 Validation scenario: SC0173 - Poison centres notification, Standard submission

Submission checks 8 **Quality checks** 0




Business rules 8 Completeness check rules 0 Total rules executed 68

- ✕ Unique formula identifiers (UFI) and other identifiers Business rule (BR528)
 Mixture information is incomplete. At least one Unique formula Identifier (UFI) must be provided under Unique formula identifiers (UFI) and other identifiers > Regulatory programme identifiers. To this end, you must include at least one entry with the Regulatory programme type 'CLP unique formula identifier (UFI)' and indicate the appropriate UFI value in the field 'Id'.
- ✕ Product information Business rule (BR517)
 Product information is incomplete. At least one 'Product Information' record must be provided.
- ✕ Mixture safety data sheets and toxicological information Business rule (BR515)
 Mixture information is incomplete. Exactly one 'Toxicological information' record must be provided for the mixture.

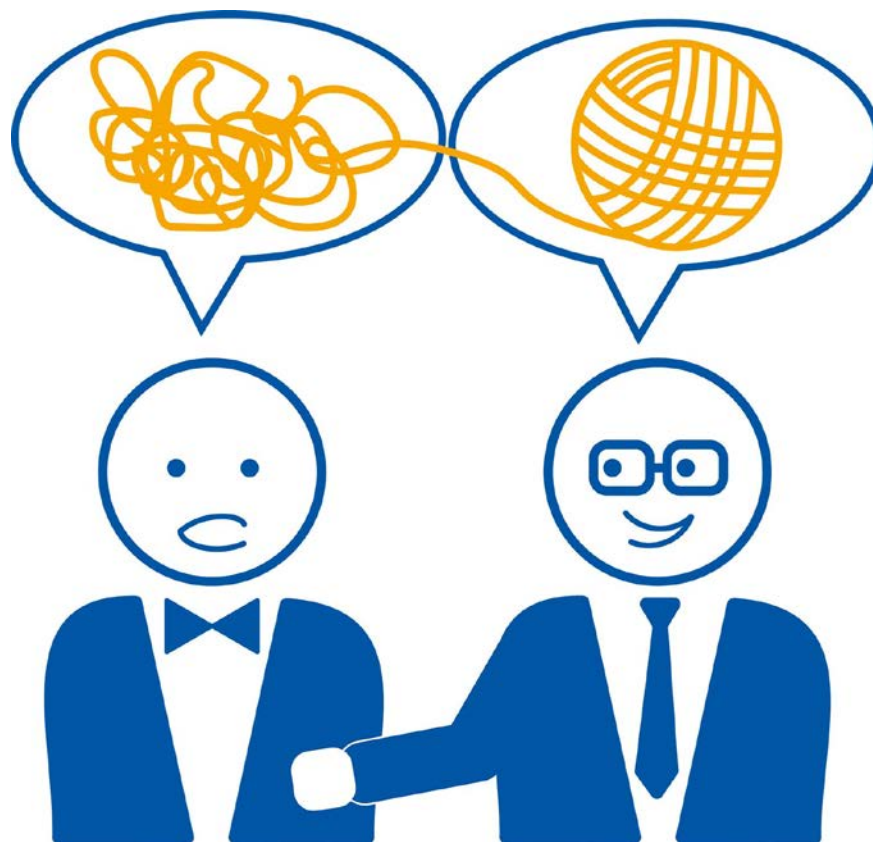
PCN validation rules annex available:

<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

Validation report

- Pass 
 - Successful submission
 - Available to Member States
- Pass with warnings 
 - As valid as 'pass'
 - Report with potential deficiencies
 - Report to Member State for their consideration
- Fail 
 - Report with deficiencies

Questions?



Thank you!

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October 2019 release

- Updated PCN format
- Implementation of the IT solution to support dispatching of multiple IUCLID dossier versions
- Submitted IUCLID dossier version added to Submission report
- Validated IUCLID version added to Validation report
- Mandatory fields highlighted in guided dossier tool

October 2019 release

- New icons for the submission status (consistency among ECHA Submission systems)
- Integration between Submission portal and Interact for the PCN database (ongoing)
- Integration between Submission portal and ECHA Data Integration Platform for reporting needs (ongoing)
- Bugs fixed
- UFI generator: possible to generate UFI without providing VAT (tool and docs)

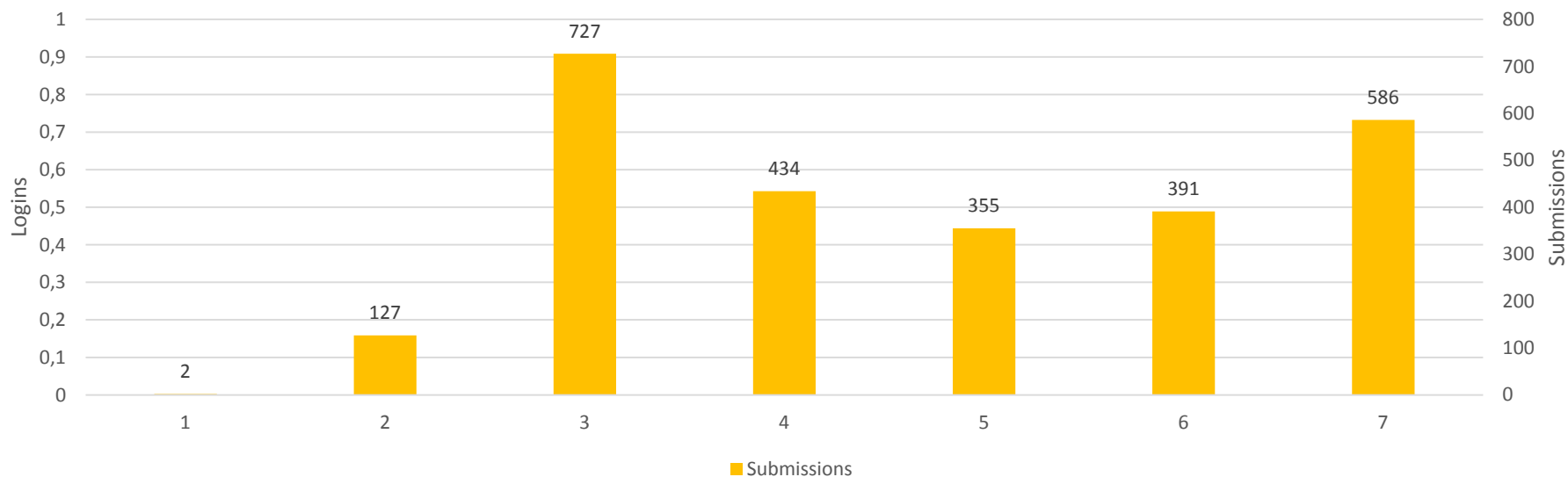
January 2020 release

- Improvement of validation report
- Multilingual fields available in dataset view
- Continuation of navigation improvements
- Re-organisation of Classification and Labelling section
- Facilitate the way to update dossiers

Successful Submissions

April – October: **2622**

Use of Poison Centre Portal



Status	Amount
VALIDATION ASSISTANT RULES	
Total	88
Implemented	88
In IT development	0
PORTAL RULES (DATABASE CHECKS)	
Total	22
Implemented	22

82 rules apply to all submission types (standard, limited, voluntary)

3 to limited submission only

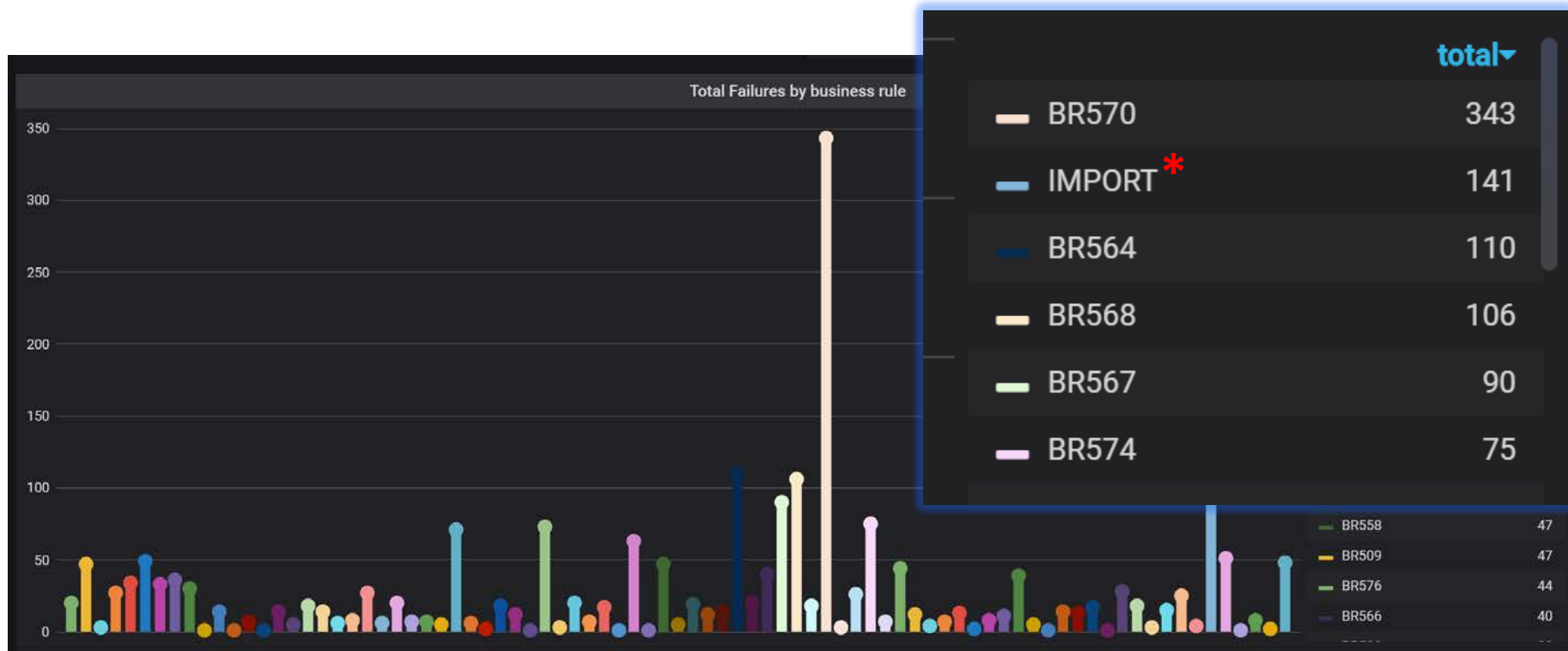
18 to limited and standard (not voluntary)

17 rules are warnings / reminders (quality rules)

pH	
BR512	Exactly one `pH` record must be provided.
BR545	Either `pH not relevant` must be selected or a pH value must be reported (value or range).
BR524	Allowed pH values: $2 \leq \text{pH} \leq 15$

- Validation rules v.1.0 list published in April 2019
 - Update to be published soon

BR Failures (April – Oct 2019)



* Not a BR as such. Possible causes: (i) submission of a mixture datasets instead of dossier; (ii) IUCLID dossier created in own systems based on the published IUCLID format specs and submit it. The dossier might be missing essential information.

Top 5 Validation failures

Rule	Description	Portal / VA	Failure /Warning
1	BR570	Legal entity in Portal has to be the same as the Legal entity of the dossier	P F
2	BR564	Dossier UUID must be unique	P F
3	BR568	Use an existing PCN number for updates	P F
4	BR567	New PCN number required for initial notification and significant changes of composition	P F
5	BR574	Changes to notification should be reported as "update" and not as new "initial" submission	P W