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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1. Regulatory update - The information requirements in a nutshell

2. PCN dossier preparation and submission
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
The scope

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)
Who has to submit information?

**Duty holders under Art.45**
- Downstream user
- Importer
- Refiller
- Toll formulator
- Repackager
- Formulator

**Potential duty holders under Art.4**
- Distributor
  - Retailer
  - Relabeller
  - Rebrander

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**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

N.B.

Lack of agreement among CAs

Dissenting view Note attached to the Guidance
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* ≥0.1%
- Not classified* ≥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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Use types consumer/professional/industrial
Product category from the EuPCS
Packaging types/sizes
Information requirements in a nutshell

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

N.B.: Full chemical composition:
- Classified ≥0.1%
- Not classified* ≥1%

*Not classified indicates that the substance is below reporting limits or below the detection limit of the analytical method.
Information requirements in a nutshell

Mixture component information
- Concentration
- Identifiers
- Classification

N.B.: Full chemical composition:
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- Not classified* ≥1%

*With regard to Health/Physical hazards
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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

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

**Mixture component information**
Mixture component information
- Concentration
- Identifiers
- Classification

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Use types consumer/professional/industrial
Product category from the EuPCS
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Mixture component information
Mixture component

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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

Harmonisation
PCN Format

Composition:
- Classified* ≥0.1%
- Not classified* ≥1%

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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

Guidance, support material & Helpdesk

ECHA TOOLS FOR PREPARATION
- UFI Generator
- EuPCS
- IUCLID 6
- Validation assistant

ECHA SUBMISSION PORTAL

Annex VIII CLP Regulation

INDUSTRY
Prepare

MEMBER STATES
Receive

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Pre-preparation phase
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
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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.

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**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.

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
PCN format changes

- 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
**PCN format changes**

- Changes **initiated by other IUCLID users** (but still relevant to PCN)
  - Classification and labelling information (*GHS document*) updated to take into account ATPs 10\textsuperscript{th} to 14\textsuperscript{th} (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 30\textsuperscript{th} 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.
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

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.
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.


**SYSTEM TO SYSTEM (S2S)**

**NATIONAL SUBMISSION SYSTEMS**
Tools to submit a notification

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**SYSTEM TO SYSTEM (S2S)**
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- Industry need to submit a request to ECHA before access to this functionality can be granted.
- Available since October 30th 2019.

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

**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:
Tools for authorities
Tools to receive and access notifications & validation reports

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
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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

PCN DATABASE
Tools to receive and access notifications & validation reports

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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.

https://poisoncentres.echa.europa.eu/ tools-for-authorities
ECHA Submission portal – Online preparation
Online preparation

Guided dossier preparation 2

Substances 17

Mixtures 7
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)
Online preparation

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 the 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 hand.

   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, submit it through the Submission portal. Additionally, you can preview the provided information in PDF.

   🔄 Validate 🔄 Create dossier 🔄 Preview notification

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Online preparation
Dossier validation

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 preparation

Dossier validation

Online using IUCLID Cloud available in the ECHA Submission portal.

• Maintained, backed-up, updated by ECHA.
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  ➢ Prepare step by step
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• https://poisoncentres.echa.europa.eu/ echa-submission-portal

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!
poisoncentres@echa.europa.eu

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Follow us on Facebook Facebook.com/EUECHA
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
Successfull Submissions

April – October: 2622

Use of Poison Centre Portal

- April – October: 2622 submissions
- Logins and submissions graph
Validation rules
Development status: 110 rules

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<th>Status</th>
<th>Amount</th>
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<tr>
<td>Total</td>
<td>22</td>
</tr>
<tr>
<td>Implemented</td>
<td>22</td>
</tr>
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</table>

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)

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

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