Notifications for poison centres as of 2020

Focus on IT tools

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Information requirements in a nutshell
Who has to submit information?

*Distributors are not considered duty holders - discussions continuing in CARACAL about the role of distributors ‘placing on the market’.*
Territorial scope

- European Economic Area
  - EU-28 + Norway, Iceland and Liechtenstein

- duty holders always from EEA
- no specific provisions for non-EU suppliers

- UK withdrawal from the EU?
Step-wise dates of application

*Unless change made to existing notification in period from relevant deadline to end of transition period
Information requirements in a nutshell

Industry Users
Submitter details

Mixtures
- Classification and labelling
- Toxicological information
- pH, physical state
- Mixture composition

UFI
16 characters

Products
- Consumer/professional/industrial
- Packaging type/size
- Product category
- Colour

= Harmonised
New format
Mixture information

- hazard classification
- toxicological information
- pH
- physical state
- colour
- full composition
**UFI – unique formula identifier**

- unique 16 character code
- included
  - on the label (or SDS if not packaged)
  - in the notification
- one UFI can be assigned to only one mixture composition
- makes a link between a specific product on the market to the information submitted on the mixture
More information on UFI

- UFI animation
  *What is the UFI?*

- In Kürze (In brief)
  *Der UFI und die Kennzeichnung Ihrer Produkte*

- UFI webinar
  *UFI for your mixtures and products*
Product information

- label elements
- packaging types (33)
- packaging sizes
- use
  - consumer
  - professional
  - industrial
- product category
Regulatory guidance

- Two consultation steps finished:
  - Partner expert group (PEG)
  - Forum (enforcement)
- CARACAL consultation underway
- Open issues e.g.:
  - Role of distributor
  - UFI on packaging/SDS
- Expected finalisation:
  - end of 2018
  - translations early 2019
PCN dossier preparation and submission
PCN dossier preparation and submission

Poison Centres Notification portal @ ECHA

Industry

Prepare the notification
- Use ECHA tools for preparation

Submit the notification
- Use ECHA portal for submission
- Validation

Poison Centres (via Appointed Bodies)

Guidance and support

echa.europa.eu
PCN format (i)

- Published in April 2018
  - gives an overview of different components of PCN dossier
  - compatible with IUCLID 6
- Example PCN dossiers (.i6z) and their .pdf representation can be downloaded (for standard and group submissions)
- Pilot project performed to validate externally
- Validated version by end of 2018
PCN format (ii)

- **Part A – Preparing a PCN dossier**

  XML content and the inner structure of the PCN format is explained in a simple manner avoiding technical details and jargon

- **Part B – Developer’s Guide to IUCLID format**

  The structure of the IUCLID 6 file is explained in order for developers to build other systems than IUCLID 6 which can generate this format
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 MS 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 MS expressed acceptance for central system (even if in parallel to local)
Ways to prepare and submit a PCN dossier at ECHA

- Online through the portal
- Offline using IUCLID
- System-to-system integration
In Brief on IT tools

How to prepare and submit information to Poison Centres
Guided dossier preparation tool online in the PCN portal

- User friendly interface for manual entering of data
- Guided dossier preparation with step by step instructions
- Submission directly in the PCN portal
- ECHA cloud service available to store dossiers
- Dossier validated before submission
- Support SMEs
Offline preparation using IUCLID

- More advanced option for companies preferring to enter data manually
- A specific PCN user interface available in IUCLID
- IUCLID dossier can be uploaded to the portal or through national submission systems
- Dossier validated before submission (validation assistant)
System-to-system integration

- Most advanced dossier preparation and submission method
- Companies directly prepare dossier in PCN format in their own systems
- Submission through automatic transfer to the PCN portal
- Supports companies with large portfolios
- Validations only possible after submission
PCN portal user interface (UI)
Guided dossier preparation tool
PCN portal UI – Mixture information

Provide dossier information
Welcome to your guided dossier preparation for Mixture / Product: Demo ChemCom.
There are mandatory tasks and additional tasks to complete. Once you have entered your IUCLID data, finalise your dossier and submit it using Poison Centres portal. You can validate the quality of your data at any point by selecting "Validate".

Information to be completed
- Mixture Information
- Product Info

Finalize your dossier
You can validate your data at any time by selecting "Validate" and, when done, you can create your dossier by selecting "Create dossier".

echa.europa.eu
Online tool - Mixture information

Phase

2 – Provide Mixture information

Task

Contact person(s)

pH

Toxicological information

Mixture composition

UFIs and other identifiers

Classification and labelling

Sub-task

MiM

SiM

Classification

Labelling

Subproject

Task

Mixture-in-mixture

Specify mixture

Function and concentration

Unique formula identifiers (UFI)

Mixture-in-mixture composition

Classification

Suppliers

Mixture safety data sheets

Subproject

Task

Substance-in-mixture

Specify substance

Substance identifiers

Function and concentration

Reference substance

Classification
Online tool - Mixture information (user interface)
Mixture information UI - pH

Key value for chemical safety assessment

- pH is not relevant

PpH value

Solution concentration (%)
Mixture information UI – C&L
PCN portal UI – Product information

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   Information to be completed
   - Mixture Information
   - Product Info

2. Finalize your dossier
   You can validate your data at any time by selecting ‘Validate’ and, when done, you can create your dossier by selecting ‘Create dossier’.

echa.europa.eu
Online tool - Product information
Online tool - Product information (user interface)
Online tool – Dossier finalisation

Phase

4 – Finalise your dossier

Task

Validate

Review dossier

Create dossier

Sub-task
Online tool – Dossier validation

Dashboard > Guided dossier preparations > Demo ChemCom

Demo ChemCom
Submission type: CLP Poison centres notification

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Information to be completed
- Mixture Information
- Product Info

2. Finalize your dossier
   You can validate your data at any time by selecting “Validate” and, when done, you can create your dossier by selecting “Create dossier”.

Validate  Create dossier
Validations

- Presence of information
  - No empty fields

- Consistency of information
  - Limited submission only for industrial use only mixtures

- Accuracy/quality of information
  - pH in range -3 to +15 only
Validation report

- **Failures** – inform that dossier will fail at submission if deficiencies not fixed

- **Warnings** – inform that there ‘may’ be issues but submission will not fail (instead a Member State will be informed)
Online tool – Dossier creation

Dashboard > Guided dossier preparations > Demo ChemCom

Demo ChemCom

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Validate Create dossier
Online tool – Dossier creation
PCN dossier submission (i)
PCN dossier submission (ii)
PCN submission report (i)

- Submission status
- Dossier information
- Recipients
- History of the submission
PCN submission report (ii)

Pass
- Assigned a ‘successful’ submission number
- Dispatched / made available to MS

Fail
- Report listing deficiencies
- New submission must be made

Pass with warnings
- Report to industry user listing potential deficiencies
- Report to MS for their consideration
PCN submission report (iii)

- Repeating checks of validation assistant

- Performing additional checks
  - Virus scan
  - Format conformity
  - Checks against database:
    - If UFI of Mixture-in-Mixture (MiM) already notified
    - Updates:
      - If initial submission exists
      - If UFI changes when composition changes
PCN portal development

Version 1 – March/April
- Focus on industry
  - Online tool
  - ‘Offline’ upload
- Focus on Member States
  - Download mechanism
  - Security model

Version 2 – November
- Focus on industry
  - Bulk upload
  - System-to-system
  - Multilingual interface
  - Online help
- Focus on Member States
  - Dispatch mechanism
  - Searchable database
More information
7 Schritte für die Industrie

Standard-Informationsanforderungen kennen

Was hat sich geändert?

Die Harmonisierung der Informationsanforderungen bedeutet, dass die bestehenden nationalen Anforderungen in der EU durch bestimmte Informationsanforderungen und ein bestimmtes Format für die Datenübermittlung, das PCN-Format (Poison Centres Notification – Meldung an Giftnotrufzentralen), ersetzt wurden. Im Folgenden weisen wir auf einige Informationspflichten hin, die im Vergleich zu früheren Verpflichtungen auf nationaler Ebene möglicherweise neu sind. Möglicherweise müssen Sie neue Informationen erstellen oder die vorhandenen Informationen an das PCN-Format anpassen.

![Diagramm](image)
Questions?
Thank you!

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