

Notifications for poison centres as of 2020

Focus on IT tools

19 November 2018

9th User Conference on Product Notifications

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Berlin, Germany

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Dossier Submission Unit

European Chemicals Agency

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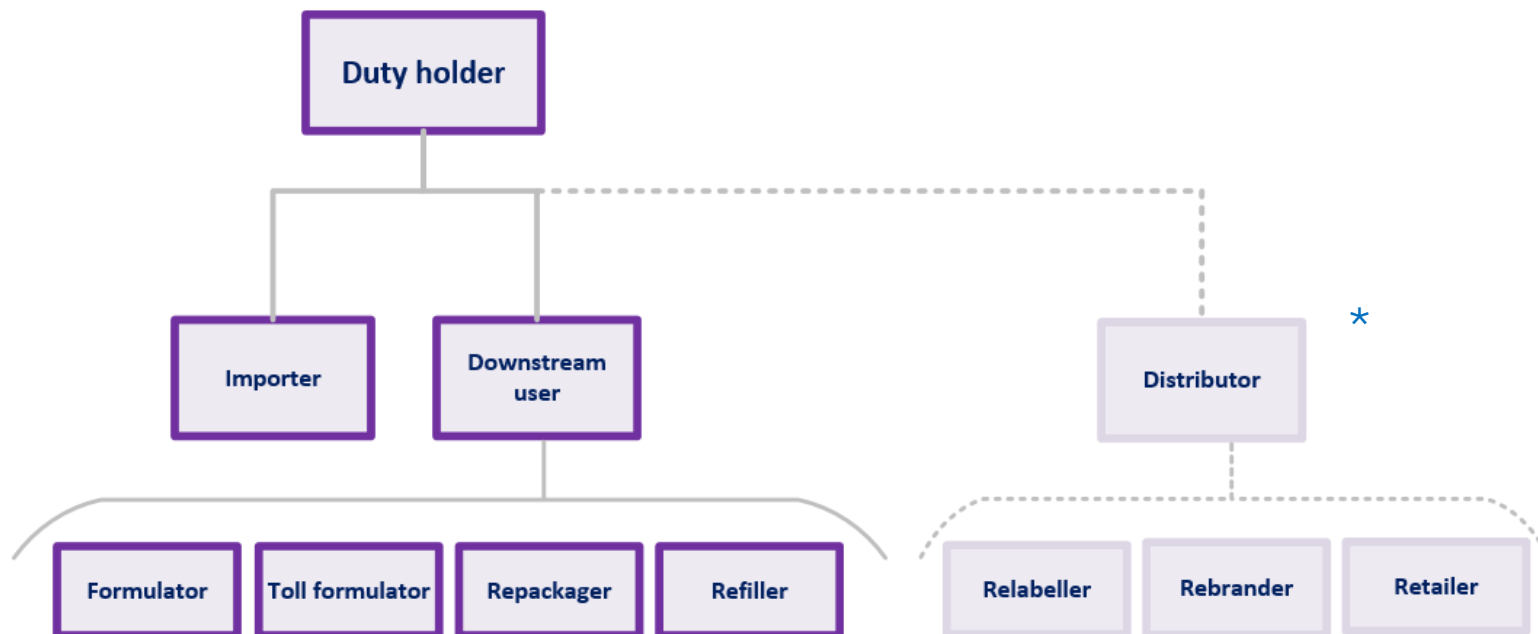
1. Information requirements in a nutshell
2. PCN dossier preparation and submission



Information requirements in a nutshell



Who has to submit information?



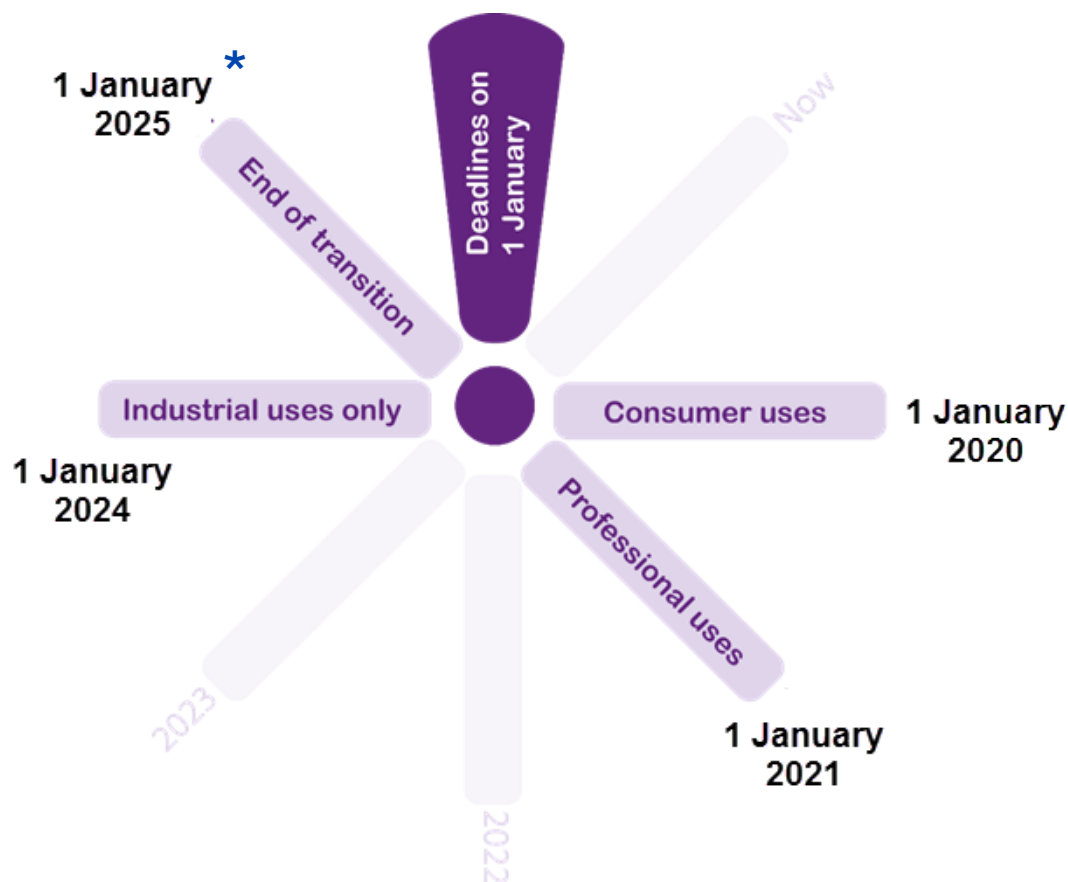
* *Distributors are not considered duty holders - discussions continuing in CARACAL about the role of distributors 'placing on the market'.*



Territorial scope

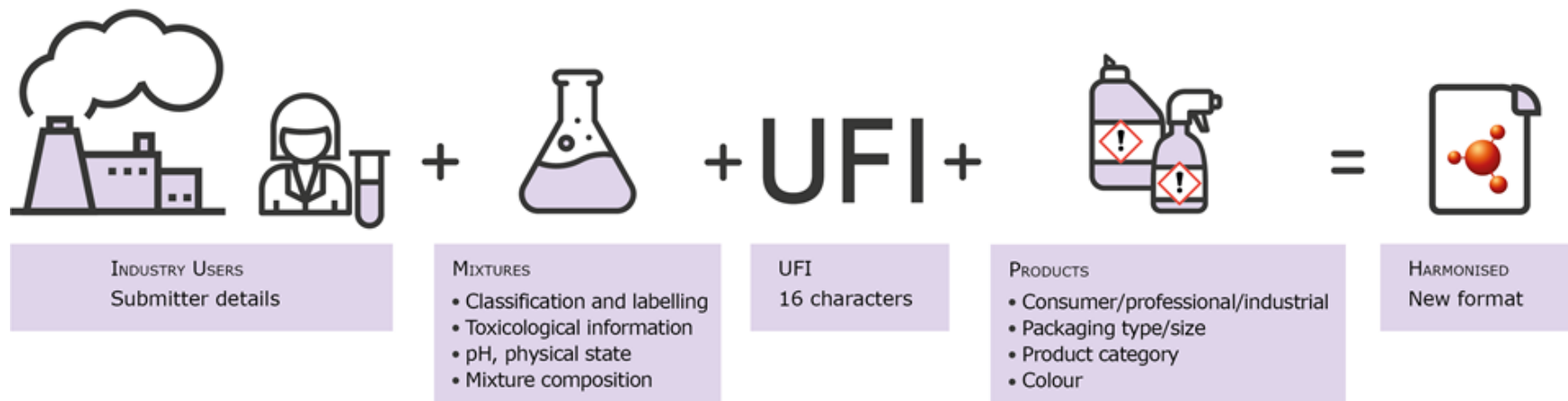
- European Economic Area
 - EU-28 + Norway, Iceland and Liechtenstein
- duty holders always from EEA
- no specific provisions for non-EU suppliers
- UK withdrawal from the EU?

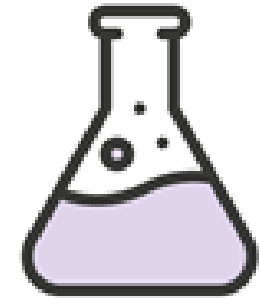
Step-wise dates of application



** Unless change made to existing notification in period from relevant deadline to end of transition period*

Information requirements in a nutshell





Mixture information

- hazard classification
- toxicological information
- pH
- physical state
- colour
- **full composition**

Health - Hazard Class	Associated Hazard Category
Acute toxicity – Oral / Dermal / Inhalation	Categories 1-5 (with 1 being the most dangerous)
Skin corrosion / irritation	Categories 1A, 1B, 1C, and 2
Skin irritation	Categories 1A, 1B, 1C, and 2
Serious Eye damage / eye irritation	Categories 1, 2, 2A, and 2B
Respiratory Sensitization (Skin or Eye)	Category 1, 1A and 1B
Aspiration toxicity	Category 1 and 2
Germ cell mutagenicity	Categories 1A, 1B, and 2 (+ Route of exposure)
Carcinogenicity	Categories 1A, 1B, and 2
Reproductive toxicity	Categories 1A, 1B, 2, and additional category for effects on or via lactation (+ Route of exposure)
Specific Target organ systemic toxicity: single and repeated exposure (STOT)	Single: Categories 1-3 Repeated: Categories 1 and 2 (+ Route of exposure)



14 different **Colours** available for selection:

1. black	8. pink
2. blue	9. purple
3. brown	10. red
4. gold	11. silver
5. green	12. violet
6. grey	13. white
7. orange	14. yellow

4 different **Intensity** values:

1. Transparent
2. Dark
3. Light
4. Fluorescent

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



What is the UFI and what does it mean for your product labels?



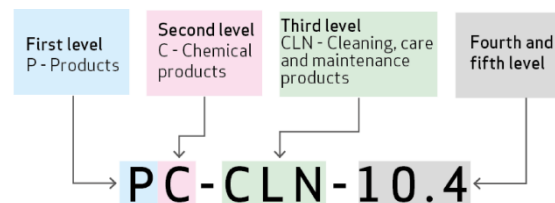
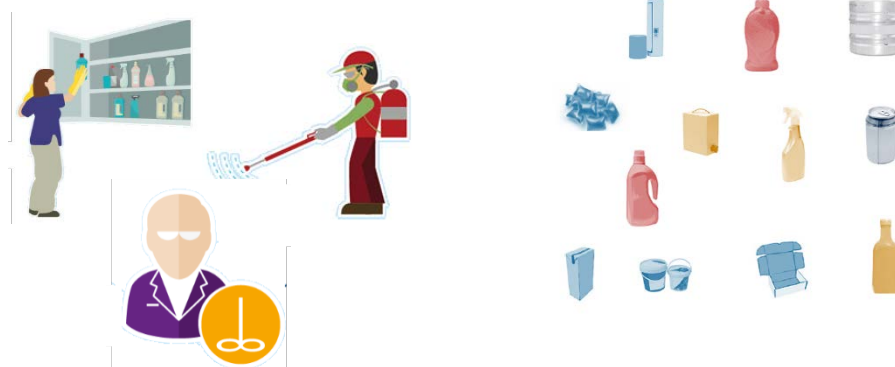
Der UFI und die Kennzeichnung Ihrer Produkte

Wichtige Informationen für Unternehmen, die im EWR gefährliche Gemische auf den Markt bringen



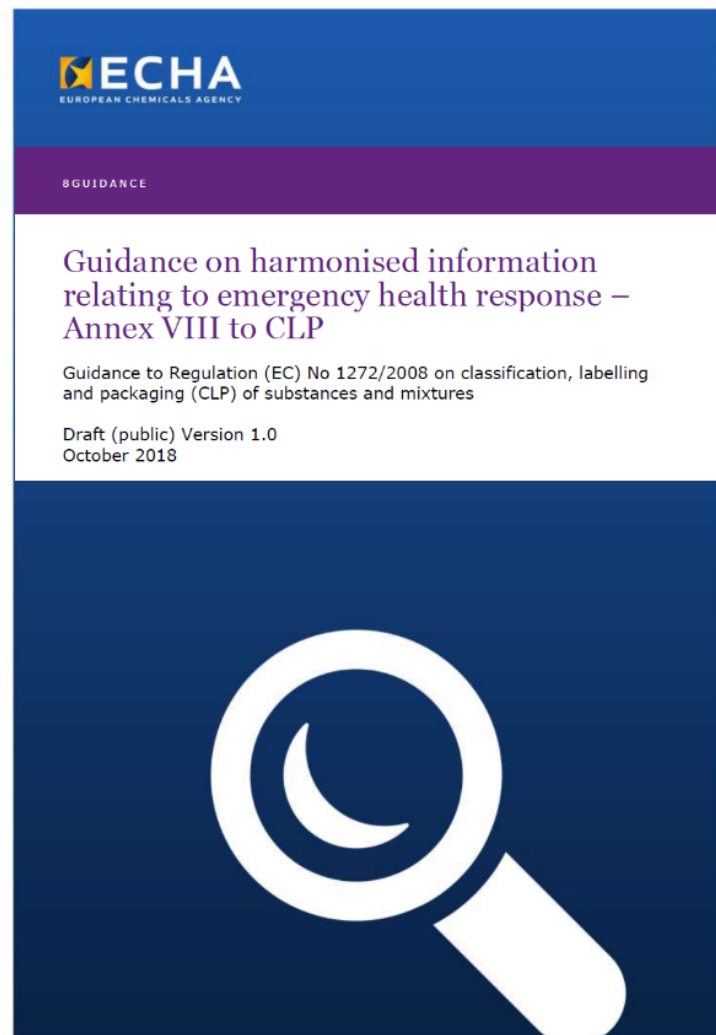
Product information

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



Regulatory guidance

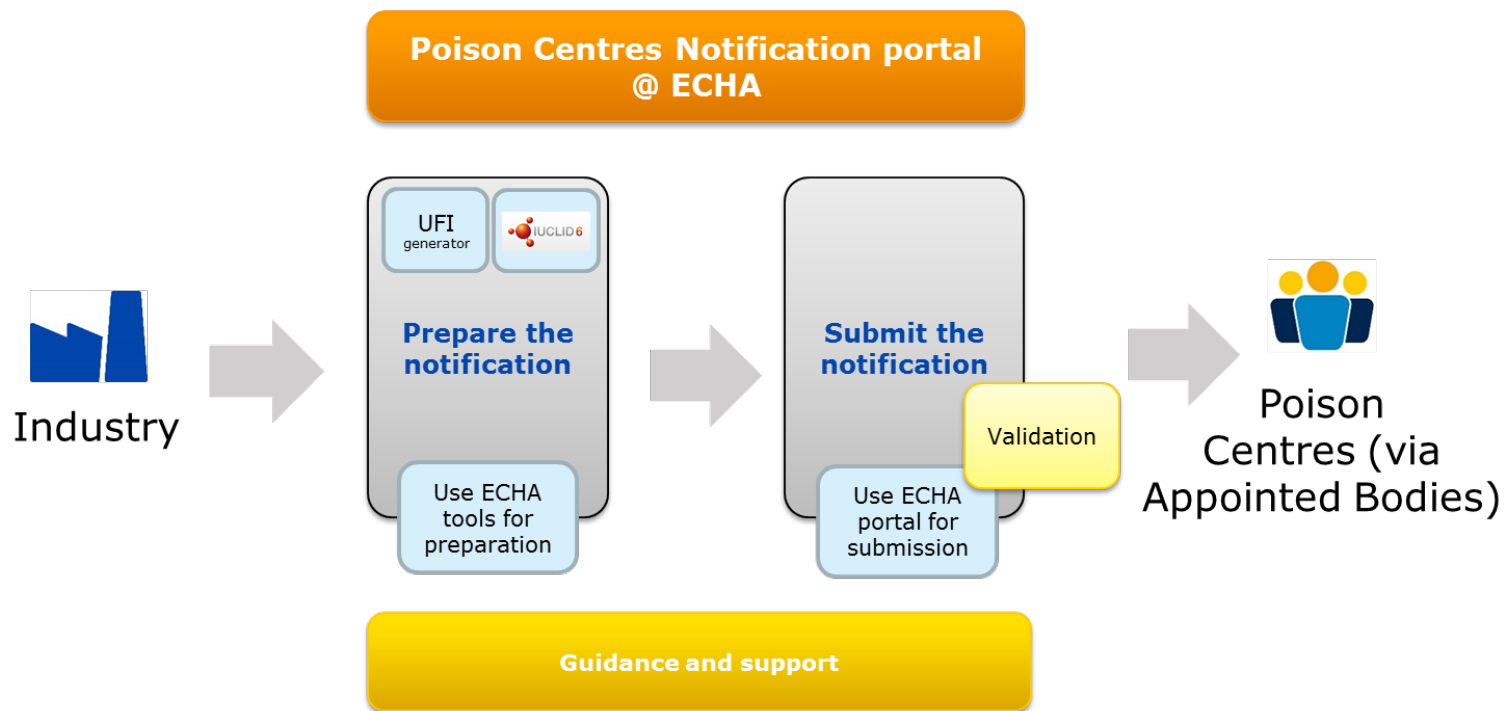
- Two consultation steps finished:
 - Partner expert group (PEG)
 - Forum (enforcement)
- CARACAL consultation underway
- Open issues e.g.:
 - Role of distributor
 - UFI on packaging/SDS
- Expected finalisation:
 - end of 2018
 - translations early 2019



PCN dossier preparation and submission

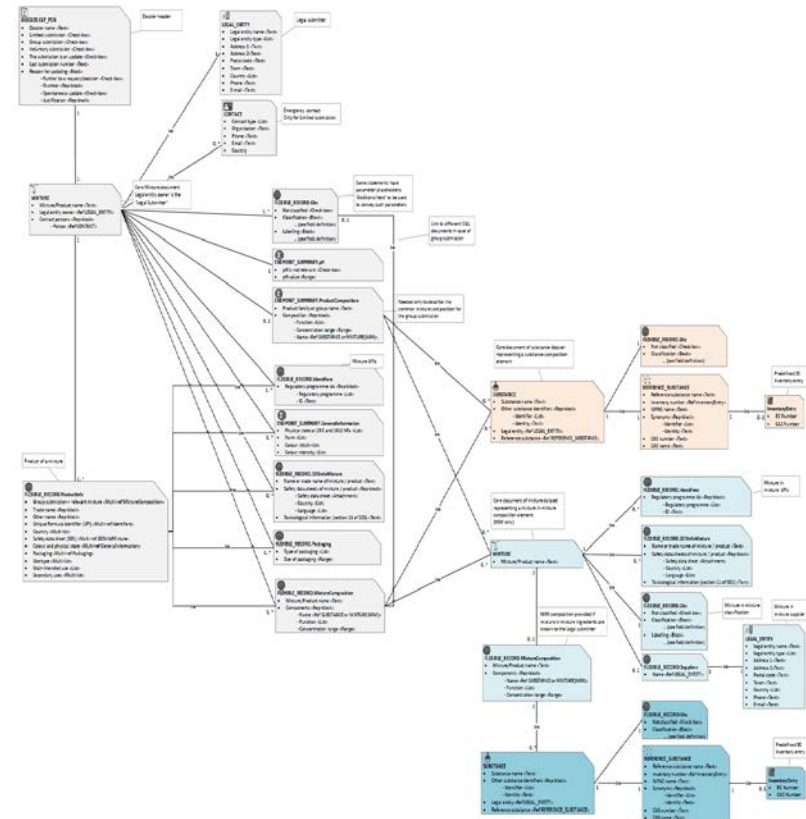


PCN dossier preparation and submission



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



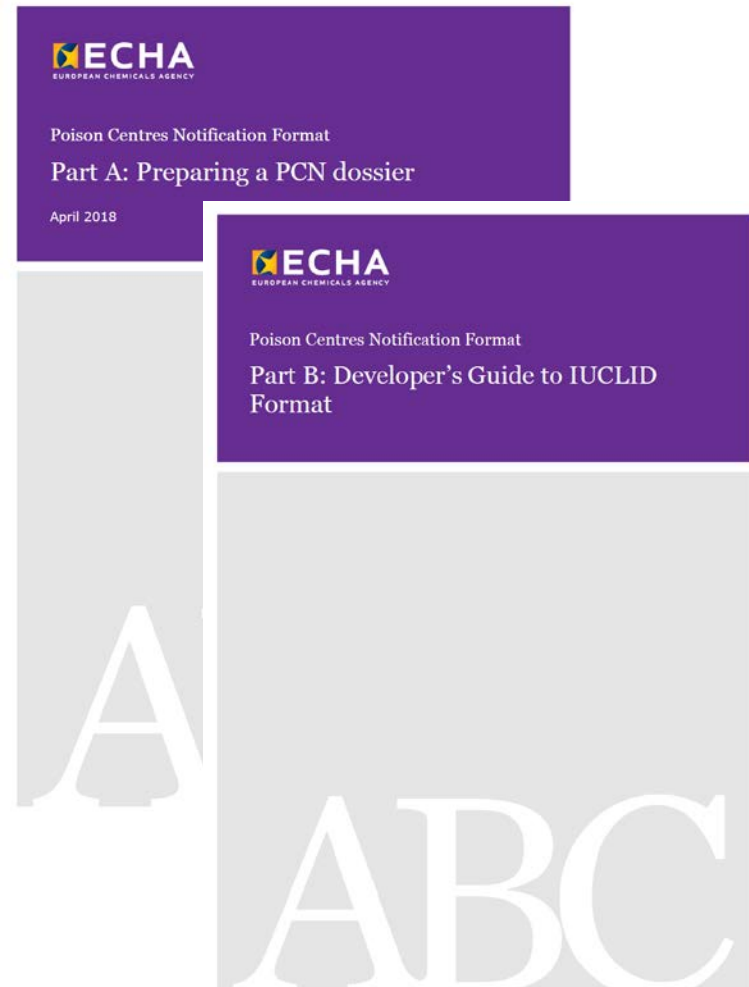
PCN format (ii)

- **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

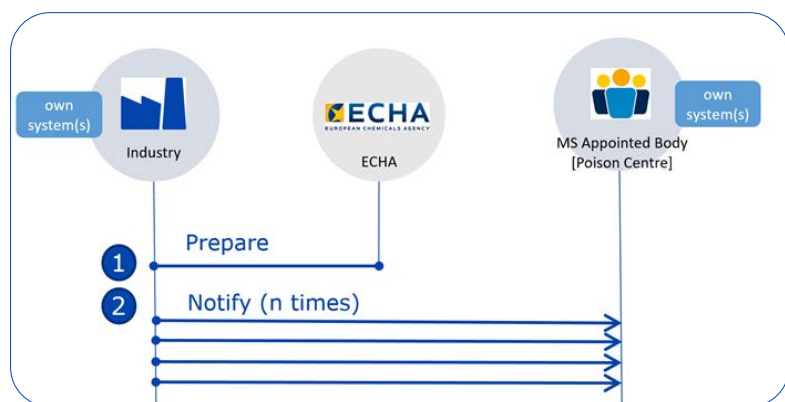
- **Part B – Developer’s Guide to IUCLID format**

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



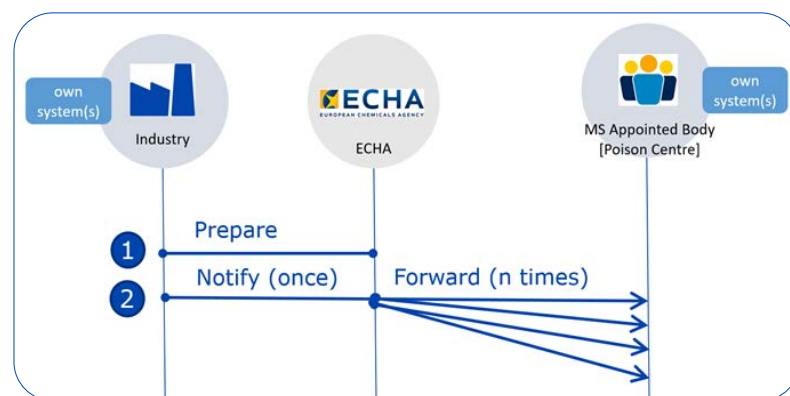
PCN dossier preparation and submission

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



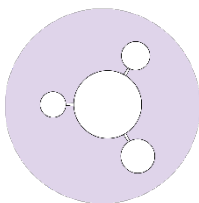
- one notification submitted once to ECHA
- notification dispatched to n relevant Member States by the central portal

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

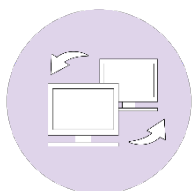
Ways to prepare and submit a PCN dossier at ECHA



- Online through the portal



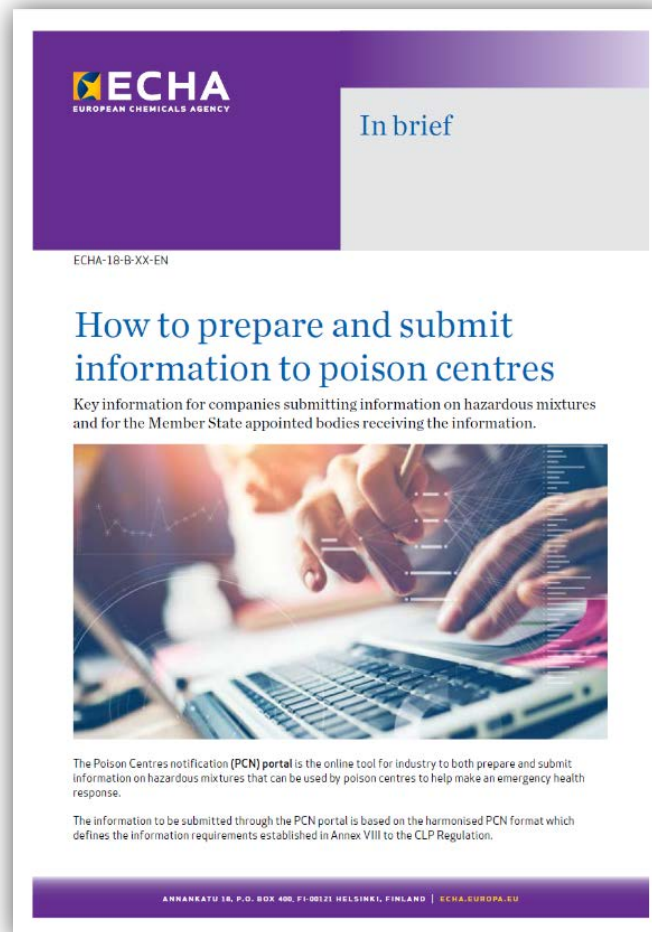
- Offline using IUCLID



- System-to-system integration

In Brief on IT tools

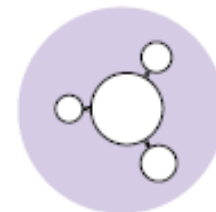
How to prepare and submit information to Poison Centres





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)


Dashboard


Search dossier by UUID 

 Guided dossier preparation 
2  

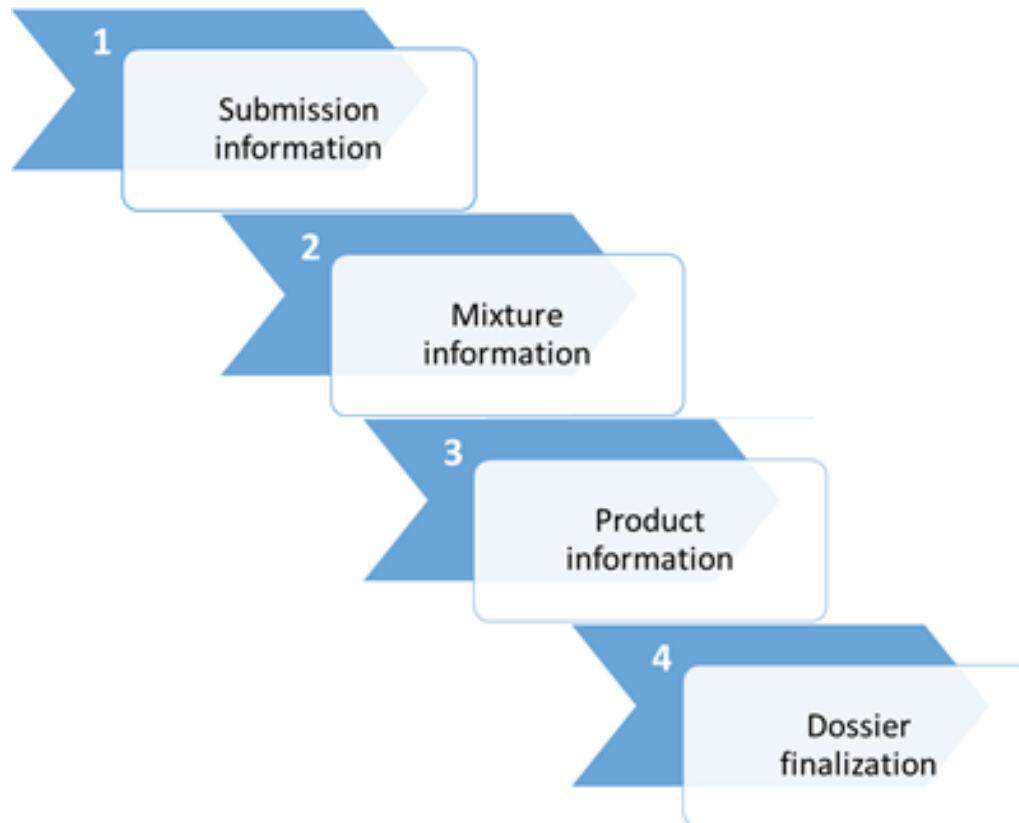
 Substances
10 

 Mixtures
4 

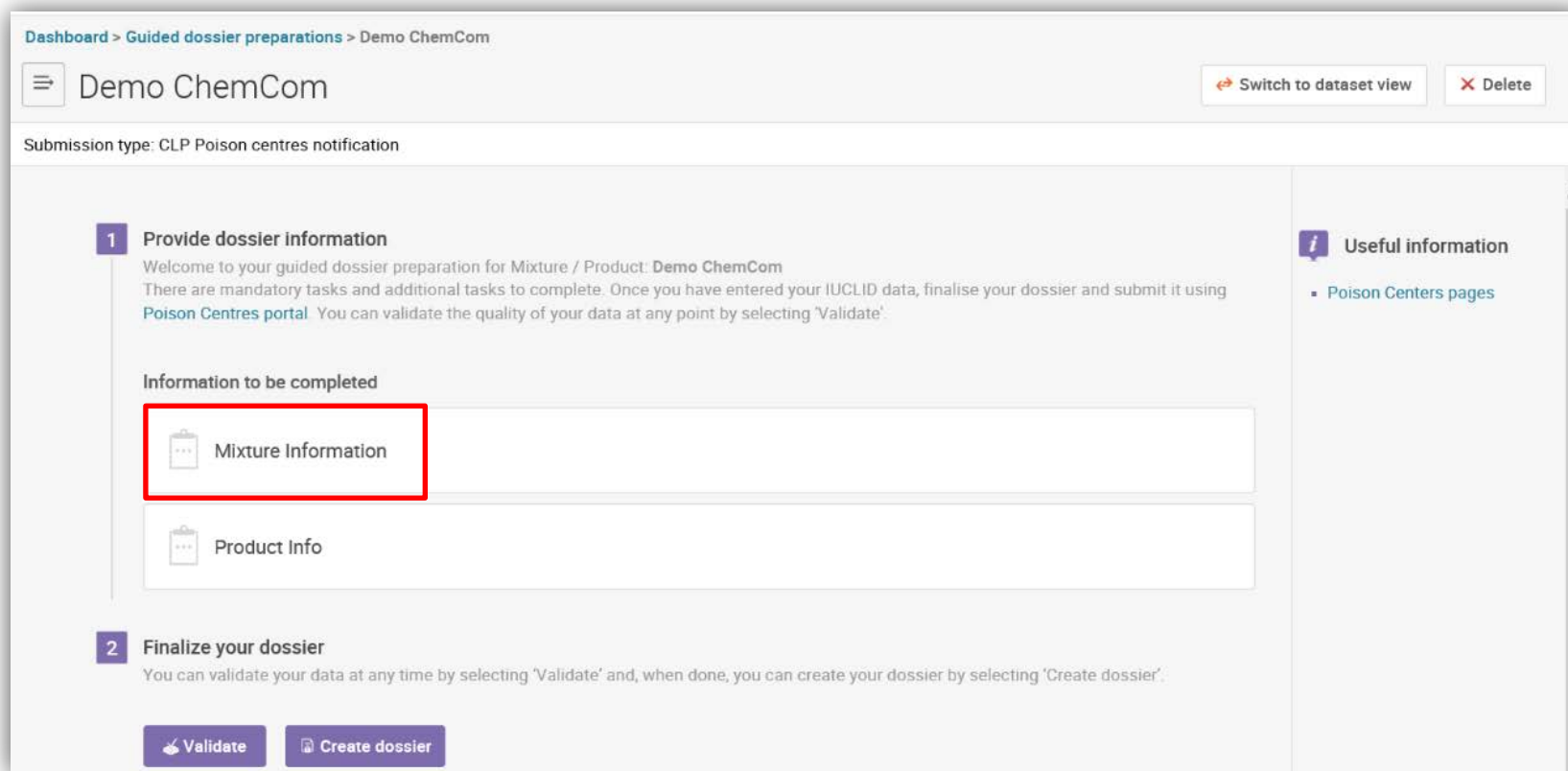
Import IUCLID file(s) 

 Drop file to upload or

Guided dossier preparation tool



PCN portal UI – Mixture information



Dashboard > Guided dossier preparations > Demo ChemCom

☰ Demo ChemCom Switch to dataset view Delete

Submission type: CLP Poison centres notification

1 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

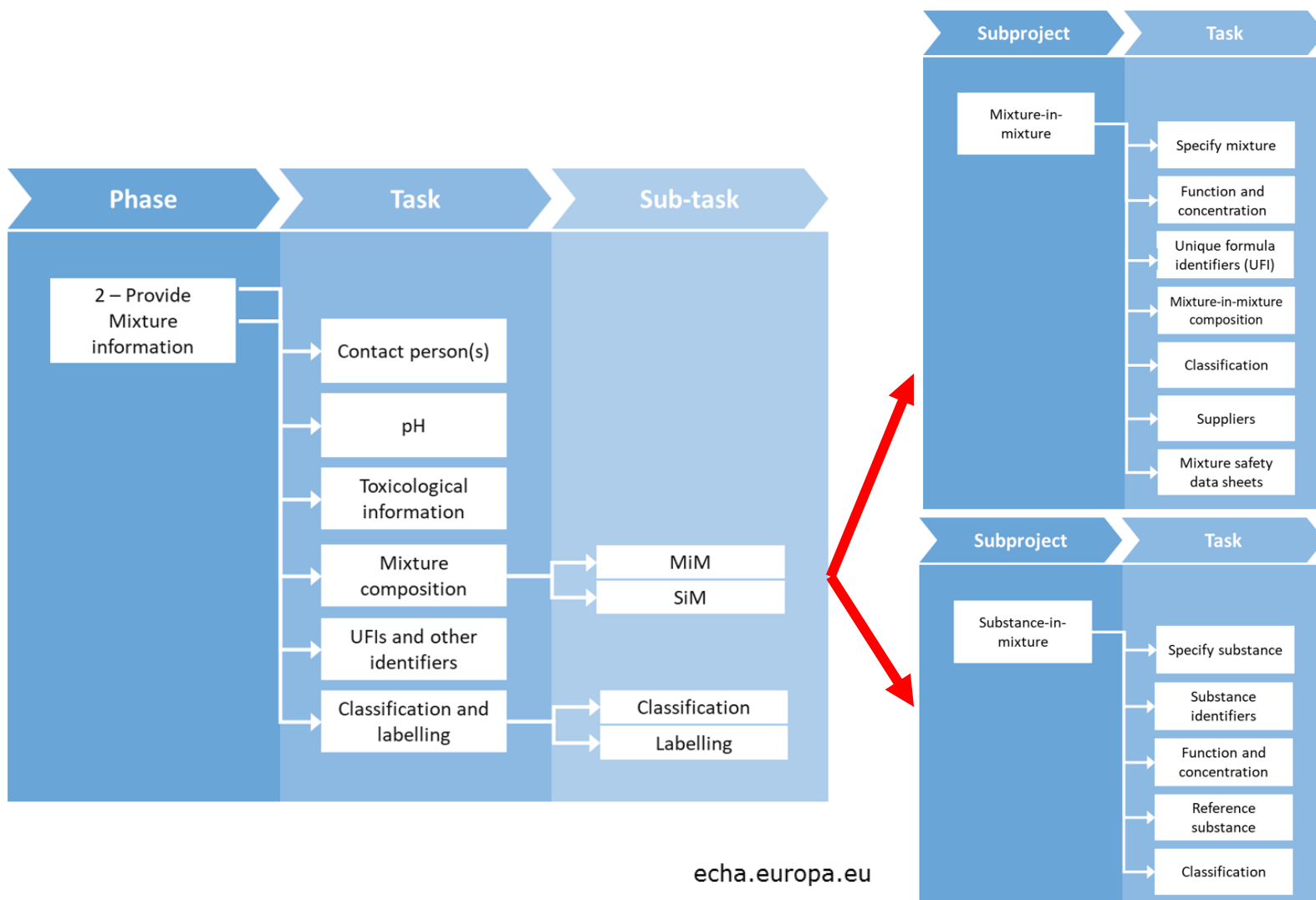
2 Finalize your dossier
You can validate your data at any time by selecting 'Validate' and, when done, you can create your dossier by selecting 'Create dossier'.

Validate Create dossier

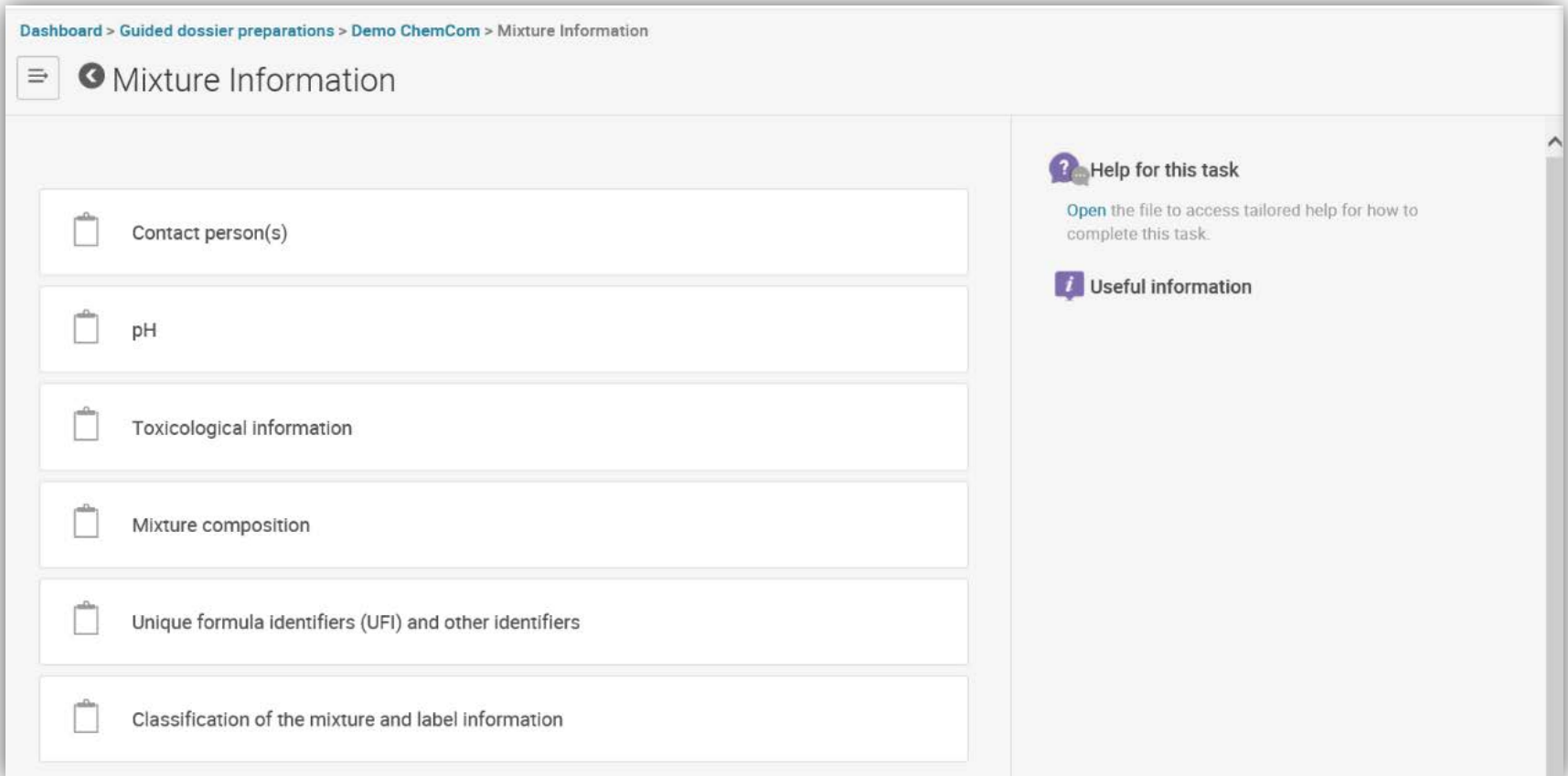
Useful information

- [Poison Centers pages](#)

Online tool - Mixture information



Online tool - Mixture information (user interface)



The screenshot displays the user interface for the 'Mixture Information' tool. At the top, a breadcrumb trail reads: 'Dashboard > Guided dossier preparations > Demo ChemCom > Mixture Information'. Below this, a navigation bar shows a hamburger menu icon and a back arrow icon followed by the title 'Mixture Information'. The main content area is a vertical list of six white rectangular boxes, each with a clipboard icon on the left and a text label on the right. The labels are: 'Contact person(s)', 'pH', 'Toxicological information', 'Mixture composition', 'Unique formula identifiers (UFI) and other identifiers', and 'Classification of the mixture and label information'. On the right side of the interface, there is a sidebar with two sections: 'Help for this task' (indicated by a question mark icon) with the text 'Open the file to access tailored help for how to complete this task.', and 'Useful information' (indicated by an 'i' icon).

Mixture information UI - pH

Dashboard > Guided dossier preparations > Demo ChemCom > Mixture Information > pH > pH

← pH

1 pH

Key value for chemical safety assessment

pH is not relevant

pH value

Solution concentration (%)

Mixture information UI – C&L

Dashboard > Guided dossier preparations > Demo ChemCom > Mixture Information > Classification of the mixture and I... > Classification of the mixture and label information

Classification of the mixture and label information

- 1 Classification
- 2 Labelling

General Information

Not classified

Classification

Physical Hazards

Explosives

Hazard category
Expl. Div. 1.3

Hazard statement
H204: Fire or projection hazard.

Flammable gases and chemically unstable gases

Hazard category
Please select

Dashboard > Guided dossier preparations > Demo ChemCom > Mixture Information > Classification of the mixture and I... > Classification of the mixture and label information

Classification of the mixture and label information

- 1 Classification
- 2 Labelling

Labelling

Signal word
Danger

Hazard pictogram

01

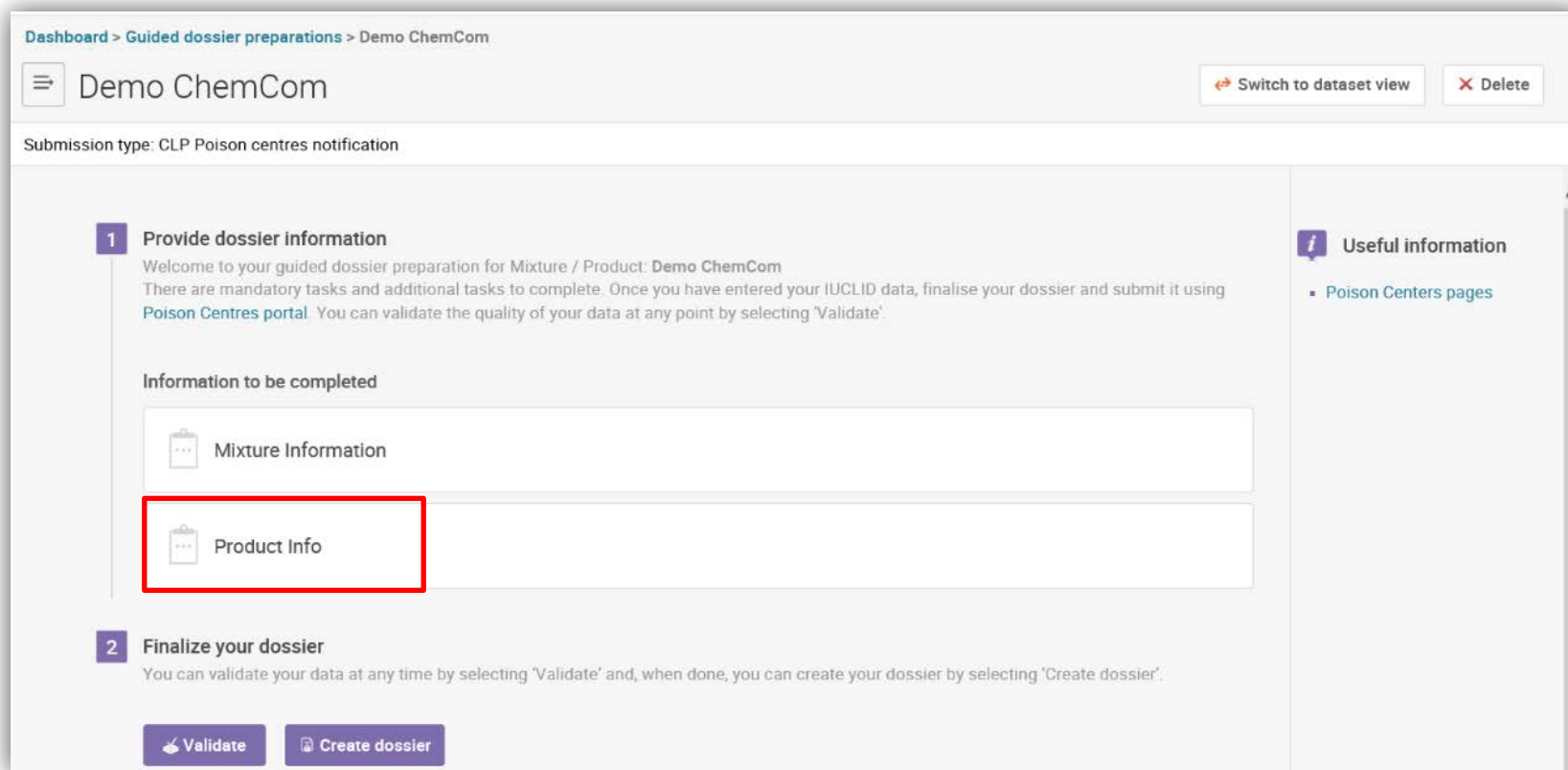
Hazard statements

01

Precautionary statements

No items added
+ New item

PCN portal UI – Product information



Dashboard > Guided dossier preparations > Demo ChemCom

☰ Demo ChemCom Switch to dataset view Delete

Submission type: CLP Poison centres notification

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Information to be completed

- Mixture Information
- Product Info**

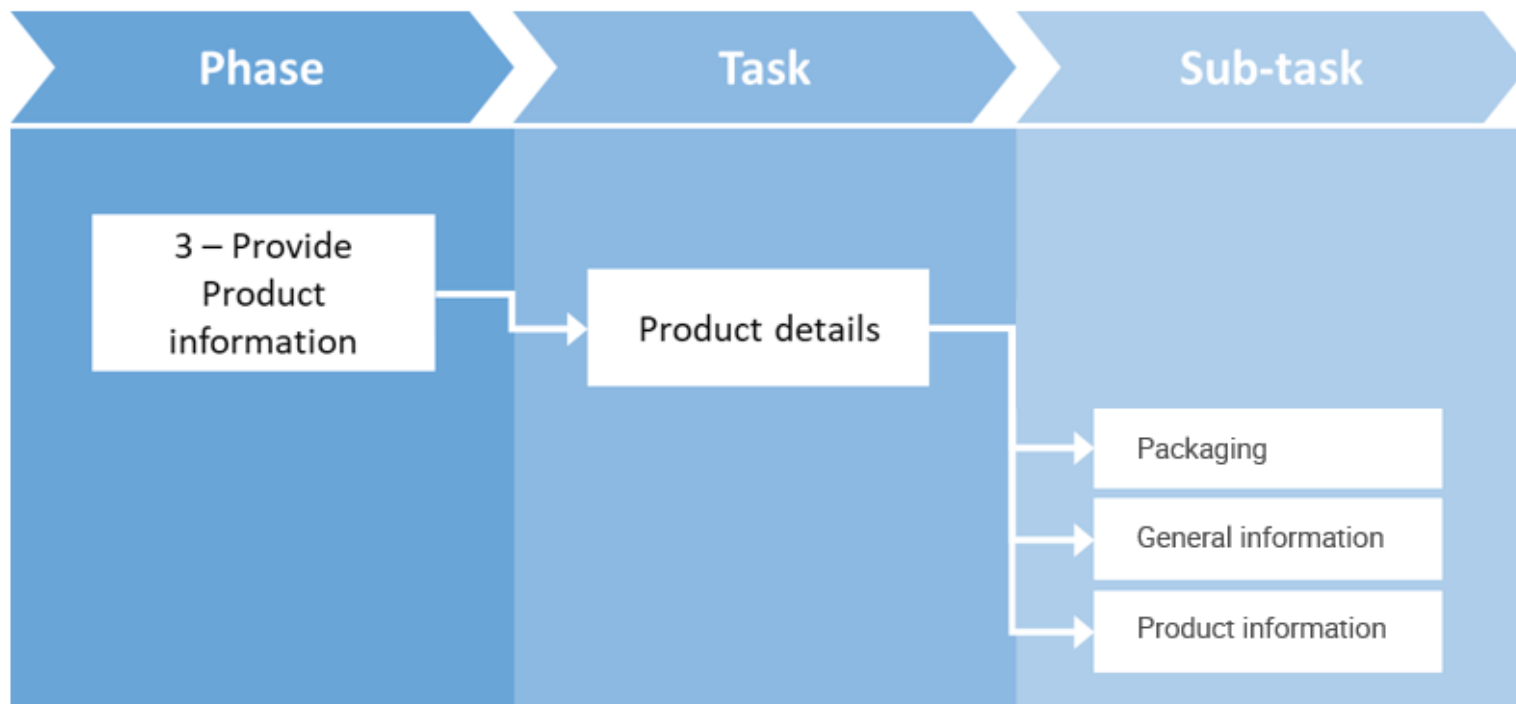
2 Finalize your dossier
You can validate your data at any time by selecting 'Validate' and, when done, you can create your dossier by selecting 'Create dossier'.

Validate Create dossier

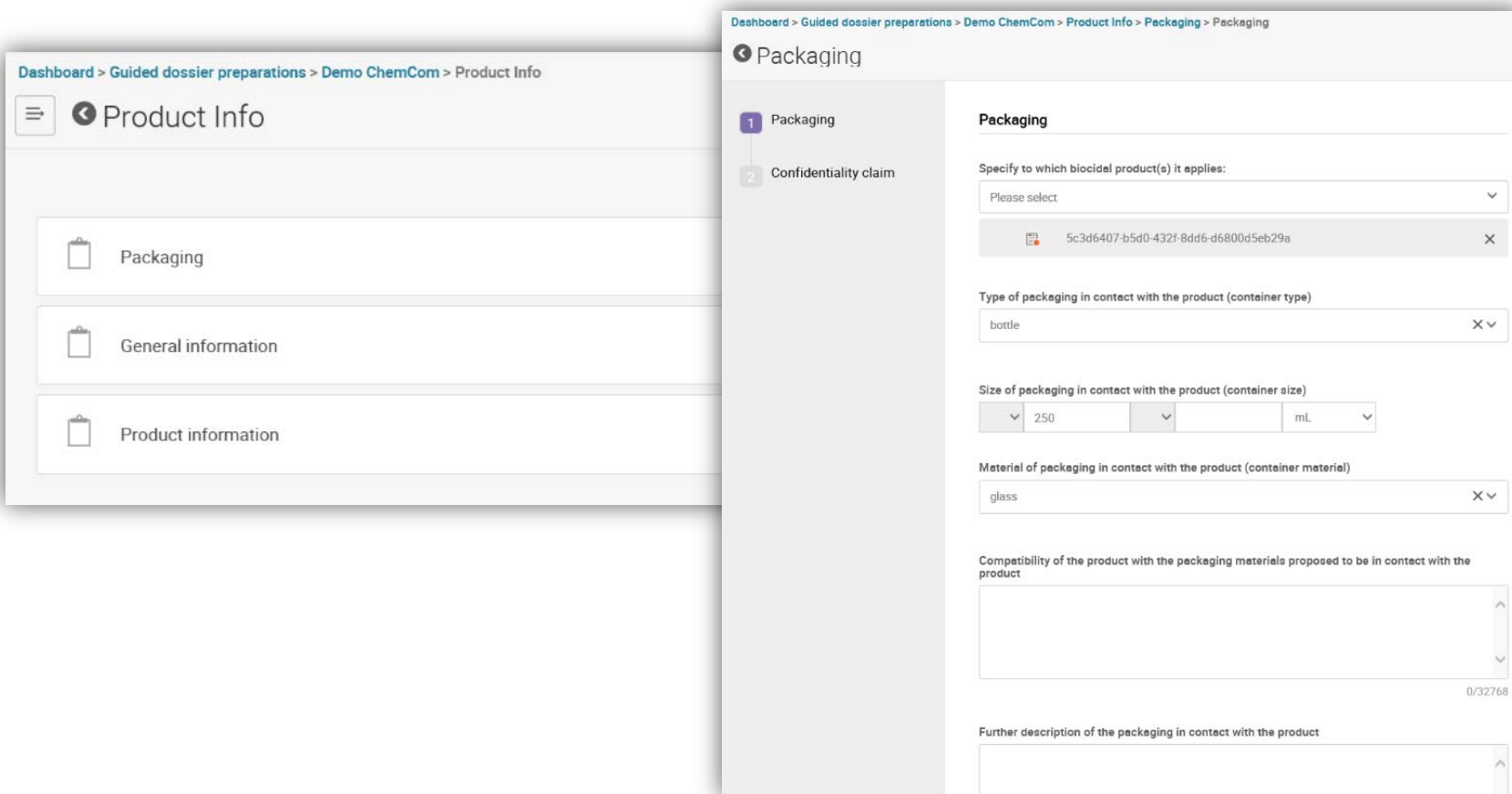
Useful information

- [Poison Centers pages](#)

Online tool - Product information



Online tool - Product information (user interface)



The image shows two overlapping screenshots of the ECHA online tool interface. The background screenshot shows the 'Product Info' section with three main categories: Packaging, General information, and Product information. The foreground screenshot is a detailed view of the 'Packaging' section, which is divided into two steps: 'Packaging' (step 1) and 'Confidentiality claim' (step 2).

Dashboard > Guided dossier preparations > Demo ChemCom > Product Info > Packaging > Packaging


Packaging

1 Packaging
2 Confidentiality claim

Packaging

Specify to which biocidal product(s) it applies:

Please select

 5c3d6407-b5d0-432f-8dd6-d6800d5eb29a

Type of packaging in contact with the product (container type)

bottle

Size of packaging in contact with the product (container size)

250 mL

Material of packaging in contact with the product (container material)

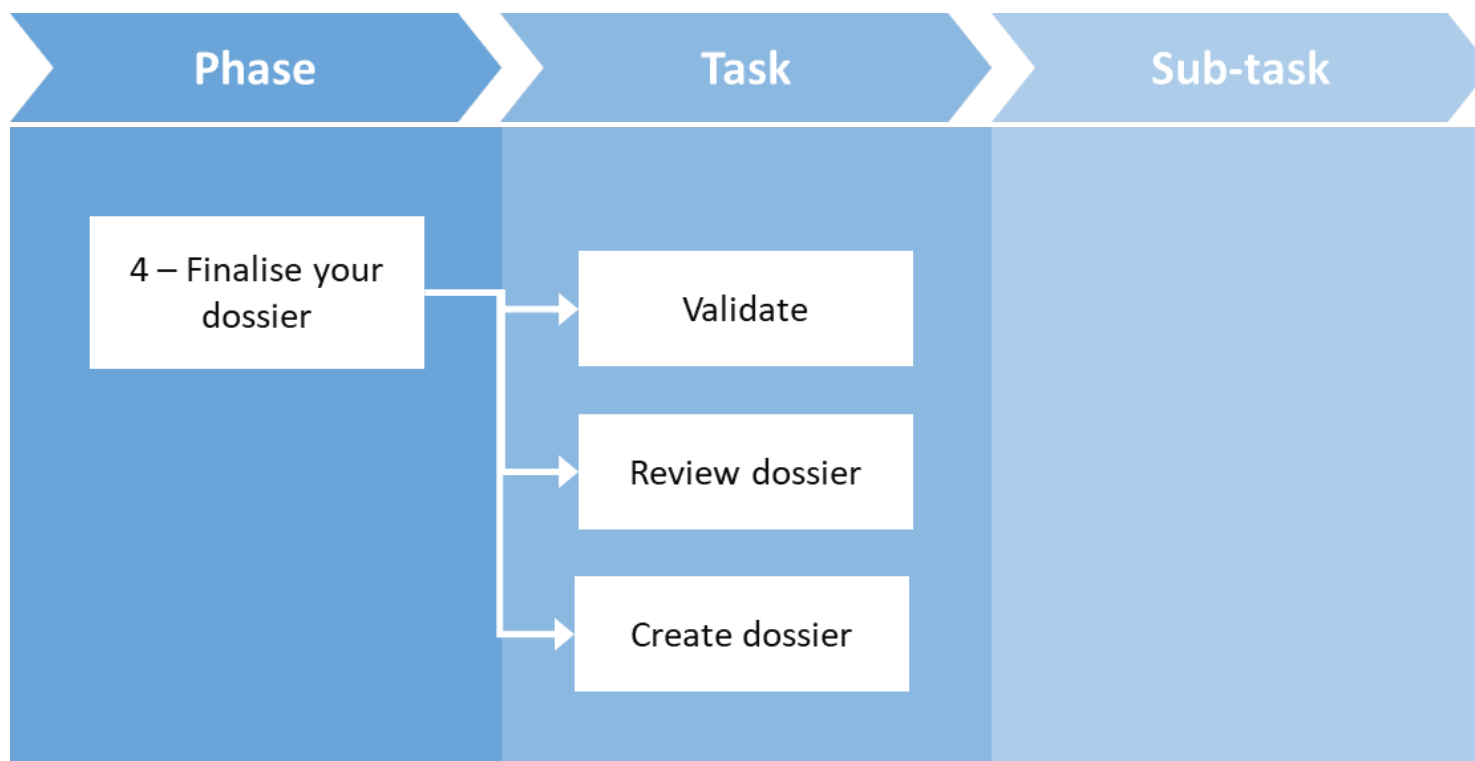
glass

Compatibility of the product with the packaging materials proposed to be in contact with the product

0/32768

Further description of the packaging in contact with the product

Online tool – Dossier finalisation



Online tool – Dossier validation

Dashboard > Guided dossier preparations > Demo ChemCom

☰ Demo ChemCom ↔ Switch to dataset view ✕ Delete

Submission type: CLP Poison centres notification

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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

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'.

Useful information

- [Poison Centers pages](#)

Validations

1 Provide dossier information
Welcome to your project page for entity:
Test Mixture
The project guides you through your Poison Centers your dossier and submit it. You can validate the qua

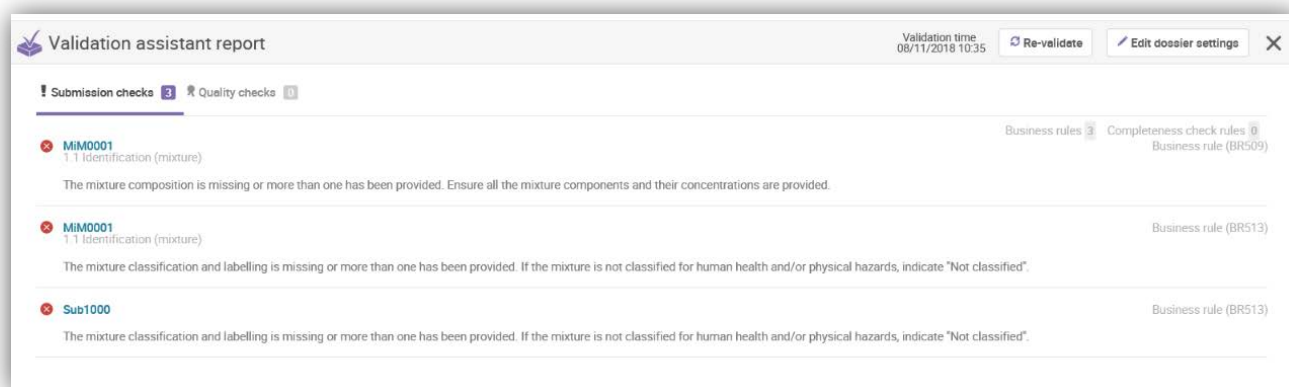
Information to be completed

- Mixture Info
- Mixture Components
- Product Info

2 Finalize your dossier
When done entering the data, finalize your dossier

- 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 ↔ Switch to dataset view ✕ Delete

Submission type: CLP Poison centres notification

1 Provide dossier 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'.

Useful information

- [Poison Centers pages](#)

Online tool – Dossier creation

Dashboard > Mixture / Products > Demo ChemCom

ChemCondossier
f11fda21-4dee-4f40-b93b-976124df12ec

Dissemination preview | Generate CSR | Export | Export to PDF | Compare | ?

Table of contents

- Mixture information and product identity (4)
- Classification of the mixture and label elements (1)
- Mixture safety data sheets and toxicological information (1)
- Additional information (4)

Dossier information Validate

Submission type: CLP Poison centres notification
 Dossier name: ChemCondossier
 Subject: Demo ChemCom
 Submitting legal entity: Undefined Company Name
 Created on: 08/11/2018 10:41

[View complete information](#) →

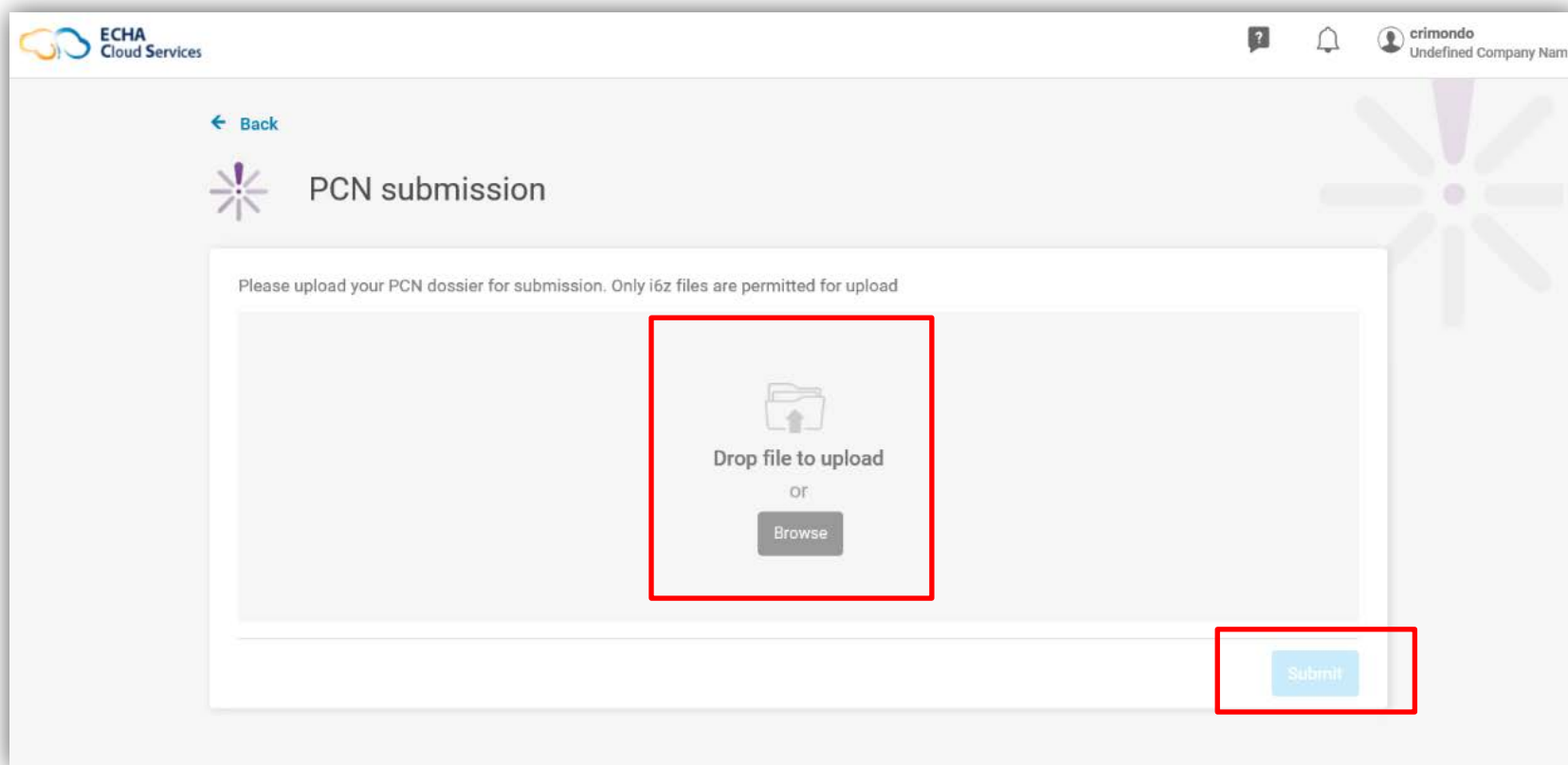
Mixture / Product information View Dossiers Go to source →

Mixture / Product name: Demo ChemCom
 Legal entity: Undefined Company Name
 UUID: 42c06bc0-73ac-44e9-a0d8-52208d38898a

Mixture information and product identity (4)

- Mixture identity and legal submitter (1)
 - Demo ChemCom
Last Modified: 08/11/2018 10:41
- Mixture composition (1)
 - 5c3d6407-b5d0-432f-8dd6-d6800d5eb29a
Last Modified: 08/11/2018 10:41
- Product identity (2)
- Product information (1)


PCN dossier submission (i)




ECHA Cloud Services

crimondo
Undefined Company Name

[← Back](#)

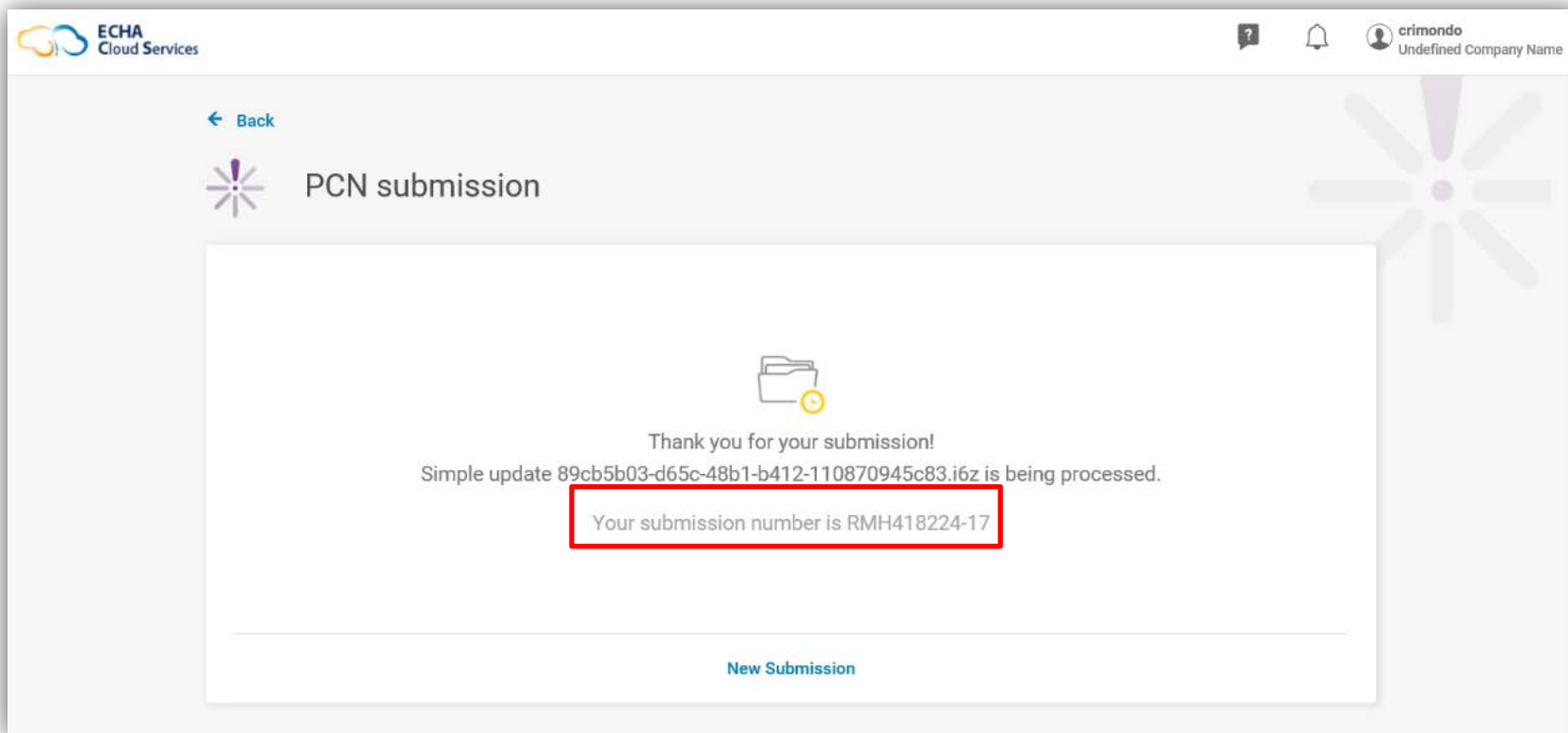
 PCN submission

Please upload your PCN dossier for submission. Only i6z files are permitted for upload


Drop file to upload
or
Browse

Submit

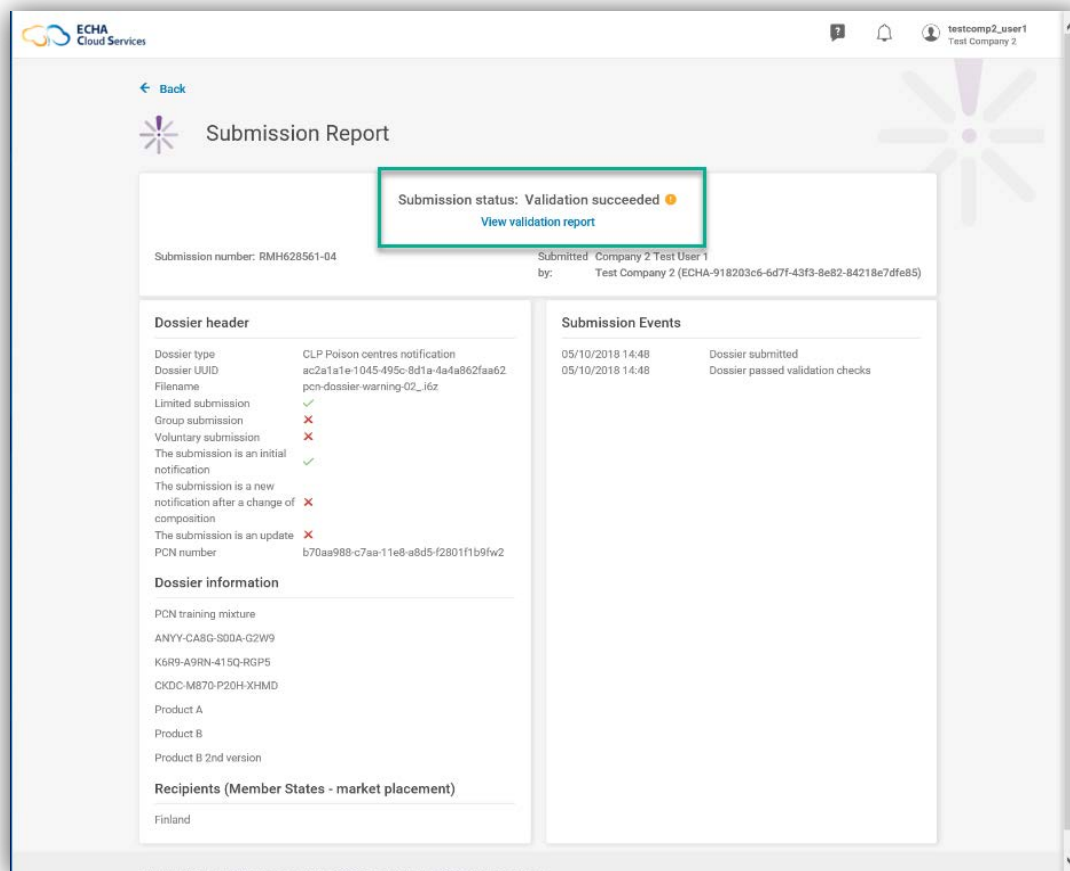
PCN dossier submission (ii)



The screenshot shows the ECHA Cloud Services interface. At the top left is the ECHA Cloud Services logo. At the top right, there are icons for help, notifications, and a user profile for 'crimondo' with the text 'Undefined Company Name'. Below the header, there is a 'Back' link and a star icon next to the text 'PCN submission'. The main content area features a folder icon with a yellow checkmark, followed by the text 'Thank you for your submission!' and 'Simple update 89cb5b03-d65c-48b1-b412-110870945c83.i6z is being processed.'. A red box highlights the text 'Your submission number is RMH418224-17'. At the bottom of the main content area, there is a 'New Submission' link.

PCN submission report (i)

- Submission status
- Dossier information
- Recipients
- History of the submission



← Back

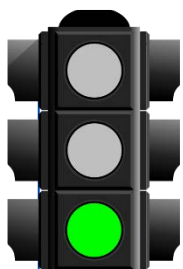
Submission Report

Submission status: Validation succeeded ●
[View validation report](#)

Submission number: RMH628561-04 Submitted by: Company 2 Test User 1
 Test Company 2 (ECHA-918203c6-6d7f-43f3-8e82-84218e7dfe85)

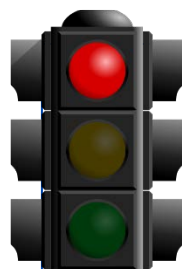
Dossier header		Submission Events	
Dossier type	CLP Poison centres notification	05/10/2018 14:48	Dossier submitted
Dossier UUID	ac2a1a1e-1045-495c-8d1a-4a4a862faa62	05/10/2018 14:48	Dossier passed validation checks
Filename	pcn-dossier-warning-02_16z		
Limited submission	✓		
Group submission	✗		
Voluntary submission	✗		
The submission is an initial notification	✓		
The submission is a new notification after a change of composition	✗		
The submission is an update	✗		
PCN number	b70aa988-c7aa-11e8-a8d5-f2801f1b9fw2		
Dossier information			
PCN training mixture			
ANYI-CASG-S00A-G2W9			
K6R9-A9RN-415Q-RGP5			
CKDC-IM870-P20H-XHMD			
Product A			
Product B			
Product B 2nd version			
Recipients (Member States - market placement)			
Finland			

PCN submission report (ii)



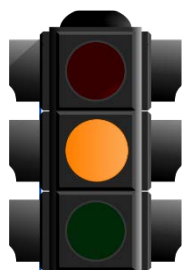
Pass

- 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

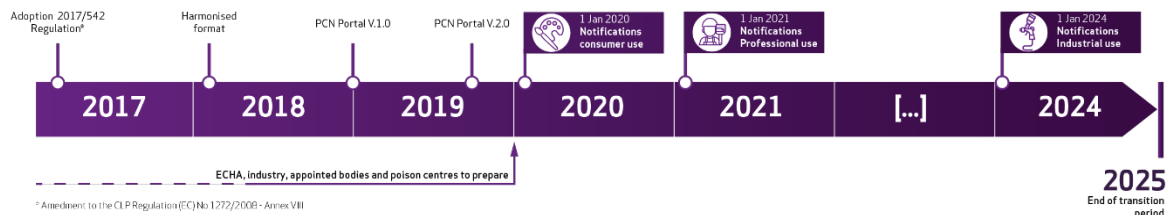
PCN submission report (iii)

 Validation Report

Submission number: RMH418224-17
Submitted by: Claudia RIMONDO
Submission type: CLP Poison centres notification
Validation time: 31/10/2018 09:09
Undefined Company Name (ECHA-c169b4c2-3ab3-45d2-940e-374a359a6a81)

Error	Rule	Document name Section number and name	Message
	BR568		The PCN number provided in the dossier header for submission updates cannot change and must be the same as that of a valid initial submission.
	BR571		The UFI has been notified by another legal entity. Ensure that there is a valid reason for re-using this UFI in this submission (e.g. you are a successor of that legal entity, you are a toll formulator's customer and you act with an agreement on the re-use of the UFI, same UFI is used by different subsidiaries companies, etc).

- 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



Deutsch (de) Anmelden ECHA

Suche auf der Poison Centres-Website

Über uns Schritte für die Industrie Tools Hilfe

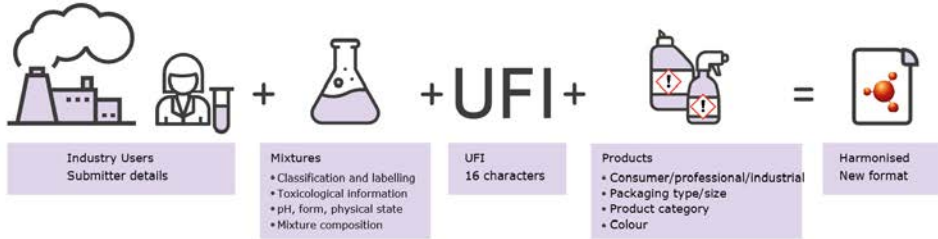
Poisoncentres > Schritte für die Industrie > Standard-Informationsanforderungen kennen

1. Verpflichtungen kennen
2. **Standard-Informationsanforderungen kennen**
3. Eigenes Portfolio kennen
4. UFI erzeugen
5. Eigene Daten anpassen
6. Einreichung vorbereiten
7. Informationen aktuell halten

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.



Industry Users
Submitter details

Mixtures

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

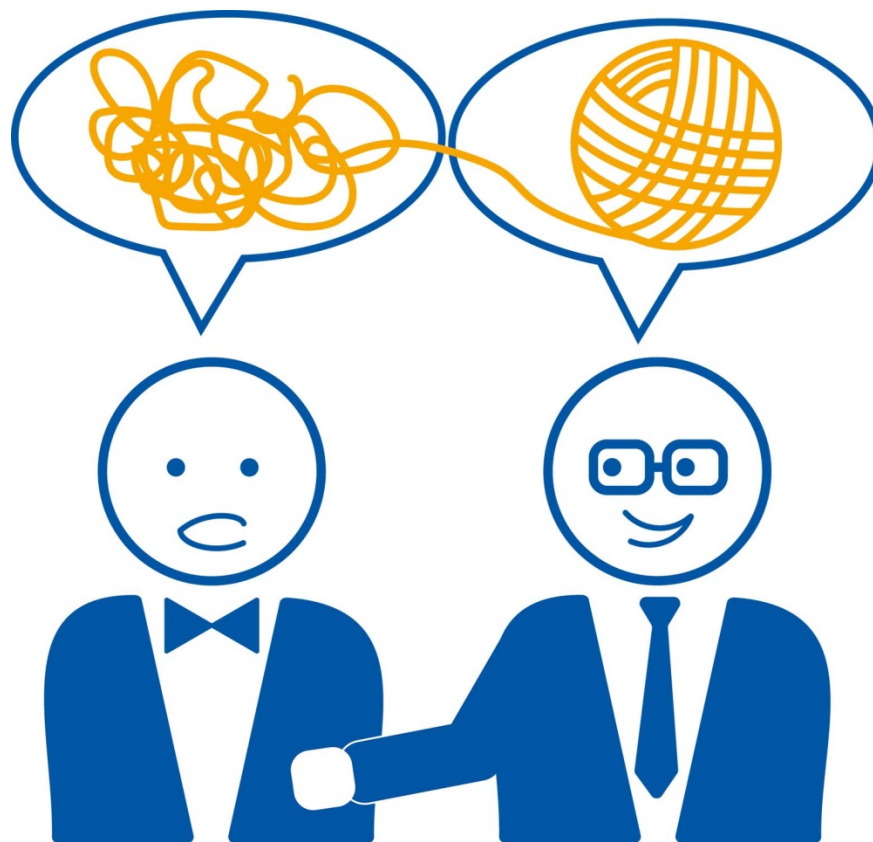
UFI
16 characters

Products

- Consumer/professional/Industrial
- Packaging type/size
- Product category
- Colour

Harmonised
New format

Questions?



Thank you!

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