

Online information session

Getting prepared to notify your
hazardous mixtures according to
Annex VIII CLP

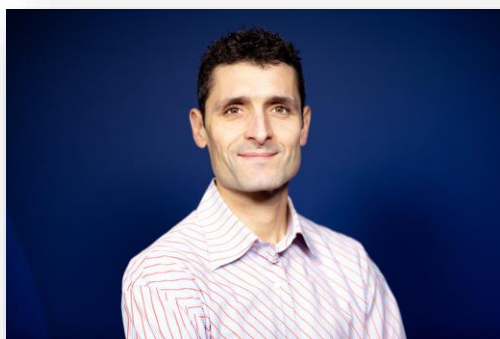
ECHA Poison Centre Team

11 December 2018

11.00 - 13.00 Helsinki time



With you today



Daniele Ape



Daniel
Sompolski

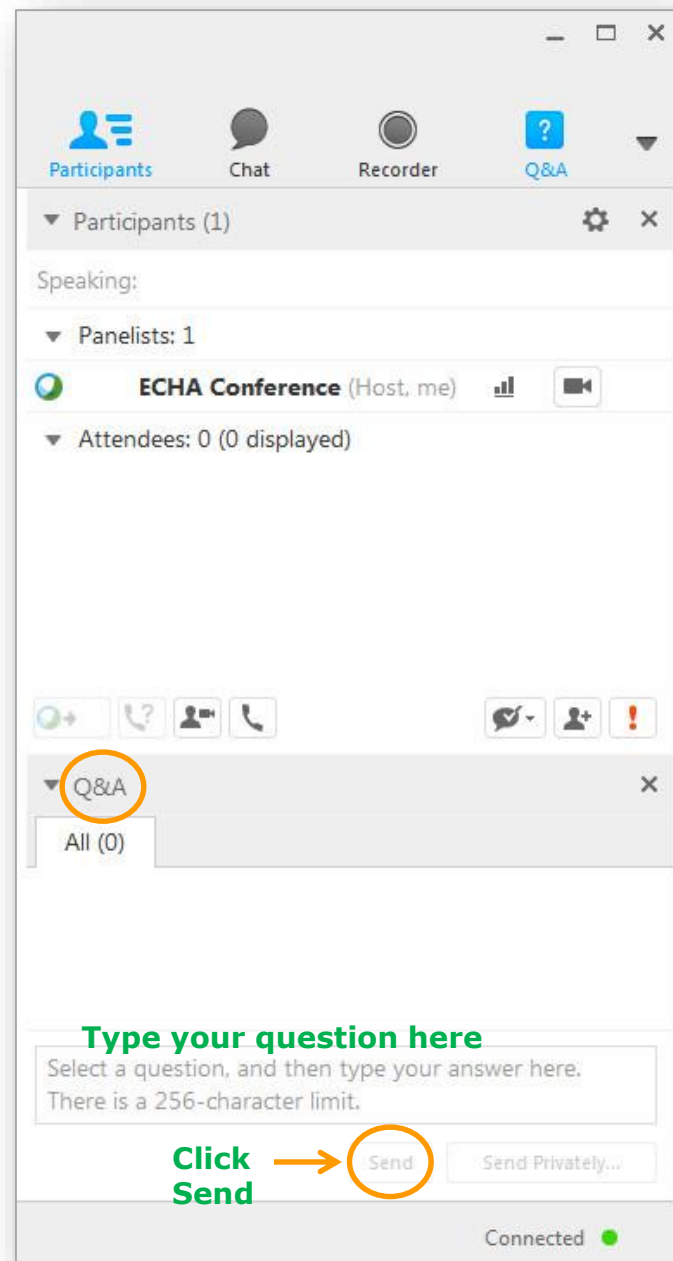


Heidi Rasikari

*Online panelists: Mercedes Viñas, Vasileios Tsifoutis,
Claudia Rimondo, Sari Jaanu, Jakob Aahauge, Stefan
Supanic, and Erika Burai*


To ask a question


- Use the Q&A panel at any time
- We will answer as many questions of general interest as we can today
- Specific questions or questions after the event to echa.europa.eu/contact



Recording available

poisoncentres.echa.europa.eu/


**Poison Centres**


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Have you categorised your hazardous mixtures?

11 December 2018

If you are an importer or a downstream user of hazardous mixtures, it is time to get familiar with the European product categorisation system (EuPCS) and categorise your mixtures.

Quick links

- > National appointed bodies
- > National helpdesks
- > Annex VIII to the CLP regulation

News

More news RSS

24 July 2018


New study on workability issues


A new study initiated by the European Commission addresses concerns raised by stakeholders on the workability of new requirements for the notification of information on hazardous chemical mixtures for emergency health response.


29 June 2018


Guide for European Product Categorisation System published

A new European Product Categorisation System (EuPCS) practical guide for industry has been published.


PCN Portal


EuPCS


UFI


ECHA term



Today's objectives

- Offer advice to industry on how to start preparing notifications already now
- Highlight harmonised information requirements beyond the safety data sheet
- Inform about expected timelines regarding the Guidance and IT tools for preparation and submission
- Opportunity to ask questions on regulatory matters related to Annex VIII of the CLP Regulation

**Getting prepared to notify
your hazardous mixtures
according to Annex VIII**





CLP Regulation – Annex VIII

- Harmonisation of information requirements for certain hazardous mixtures in all EU Member States
- Preparation of data in a harmonised submission format (.xml)
- For use by poison centres for the purposes of making an emergency health response



What mixtures are in scope?

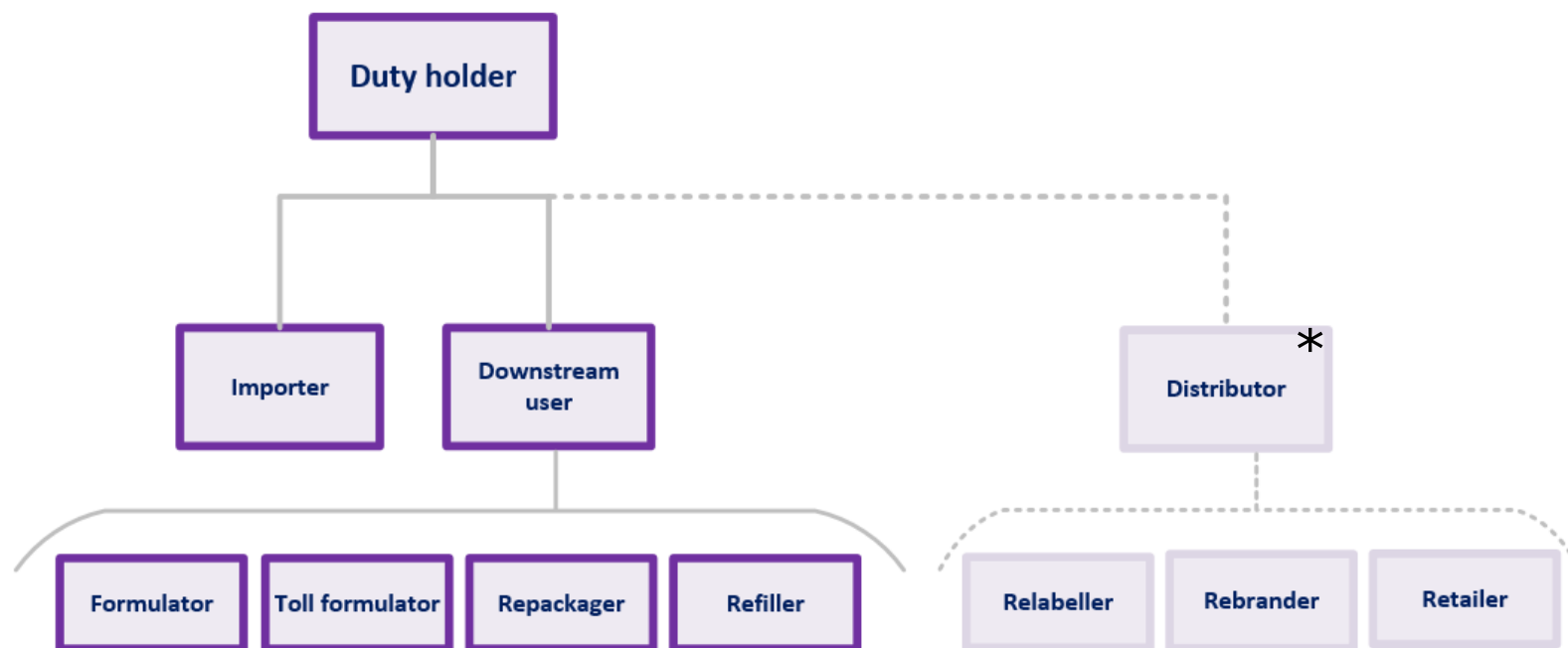
- Mixtures classified for human health or physical effects

Does NOT include mixtures:

- classified only for environmental effects/gases under pressure/or explosives
- used in scientific research & development
- not covered by CLP Regulation

Who has to submit information?

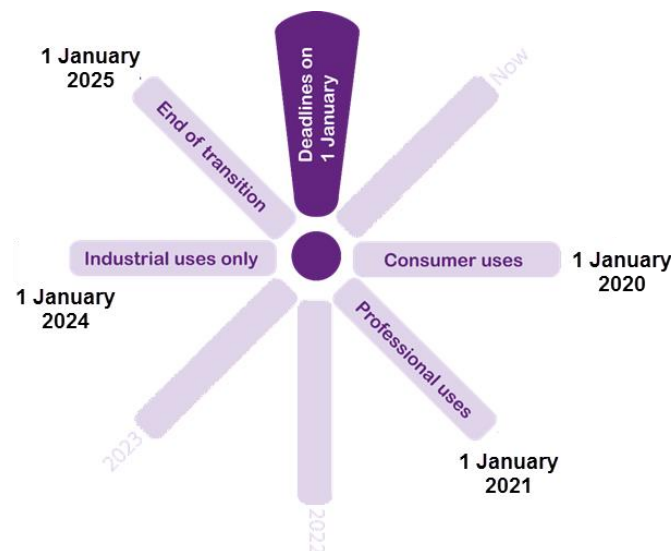
- Importers and downstream users placing hazardous mixtures on the market.



**Distributors are not considered duty holders – Member States challenging the role of distributors 'placing on the market' – open issue discussions ongoing*

Timelines for compliance

- Notifications must comply with the harmonised requirements according to the use type of the mixture
 - 1 January 2020: consumer uses
 - 1 January 2021: professional uses
 - 1 January 2024: industrial use only
- Transition period for existing products ends 1 January 2025
 - unless change made to existing notification between relevant deadline and end of transition period



Harmonised requirements in a nutshell



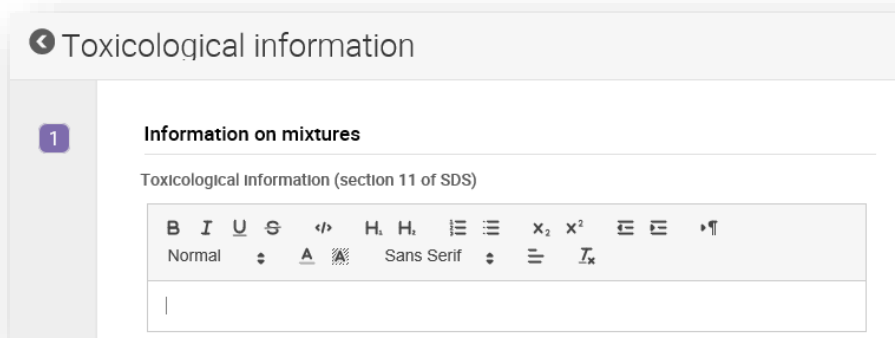
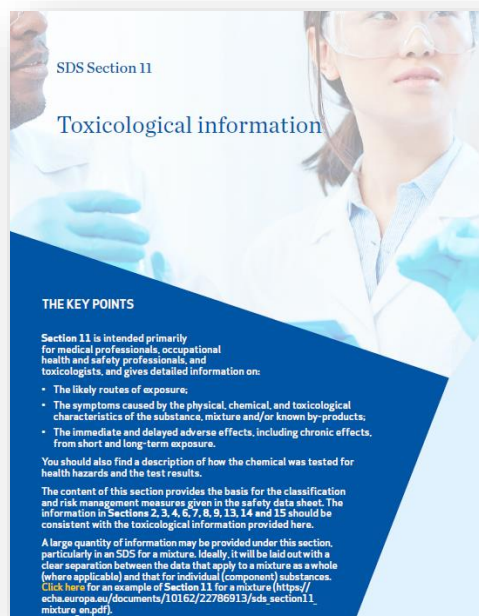
- **Submission format** – Poison Centre Notification (PCN) format, IUCLID compatible, structured fields for information
- **Submitter details** – name, address... - consistent with the label
- **Mixture information** - C&L, tox info, composition, pH, physical state
- **Product information** - trade name, packaging, uses, colour
- **Unique formula identifier** – e.g. YV9K-3J9A-G209-C2T7,
UFI makes a link between the product and the submitted mixture information

**Beyond the safety data
sheet – adapting existing or
including new data**



Review toxicological information

- Toxicological information from SDS section 11
 - Free text in all required languages
 - Check quality - no references to other sections





Obtain the full composition


- Hazardous components
- Non-hazardous components
 - not normally detailed in the SDS
 - establish improved information exchange in supply chain
- Check the formulation of any mixtures in mixtures (MiMs)
 - Best case scenario – report information on all substances
 - In other cases, possible to use the UFI notified by your MiM supplier, provided you also list all the known components

Assign concentrations to all components

<https://poisoncentres.echa.europa.eu/components-of-major-concern>

- Exact concentrations or concentration ranges allowed
- If ranges are used, check the maximum width allowed (see Tables 1 & 2 of Annex VIII)
- Components that are not classified for physical and health effects need only be declared at concentrations $\geq 1\%$

Declaring concentrations under Annex VIII to CLP Regulation



Annex VIII to the CLP Regulation has provisions on the information provided on the concentration of mixture components (substances or mixture in mixtures). Different provisions apply to hazardous components considered of major concern and to other hazardous components and components not classified as hazardous. This distinction is defined in section 3.4 of Part B of Annex VIII. The submitter is required to provide the concentration or concentration range of each component according to the hazard class.

Suggested reading

- [Annex VIII to the CLP on harmonised information relating to emergency health response](#)

Components of major concern

Other hazardous and non-hazardous components

Changes in composition and the effect on the UFI



Consider exceptions...

- Perfumes, fragrances and colouring agents may be generically identified (GPIs) ***if***
 - They are not classified for any health hazard
 - Function and total concentration provided
 - Total concentration within thresholds
- Some submissions can contain limited compositional information ***if***
 - Mixture has industrial use only
 - 24/7 phone service provided

Review product information

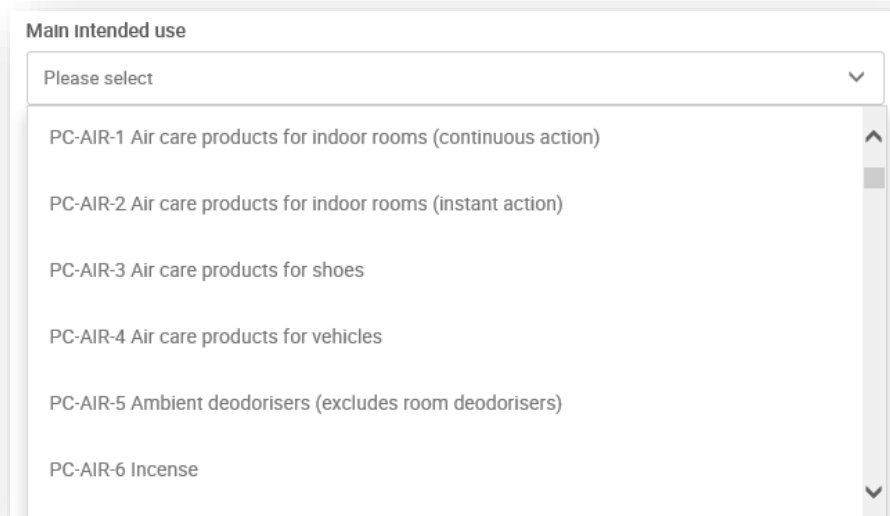
- Additional mapping may be required:
 - 33 packaging types available
 - 14 colours available
- Assess the use type(s) down the supply chain
 - Consumer
 - Professional
 - Industrial
- Select a product category according to the European product categorisation system



Assign product category

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

- Based on a single main intended use
- Select from 250 categories
- Descriptions/examples available
- Advice when more than one use



Main intended use

Please select

- PC-AIR-1 Air care products for indoor rooms (continuous action)
- PC-AIR-2 Air care products for indoor rooms (instant action)
- PC-AIR-3 Air care products for shoes
- PC-AIR-4 Air care products for vehicles
- PC-AIR-5 Ambient deodorisers (excludes room deodorisers)
- PC-AIR-6 Incense

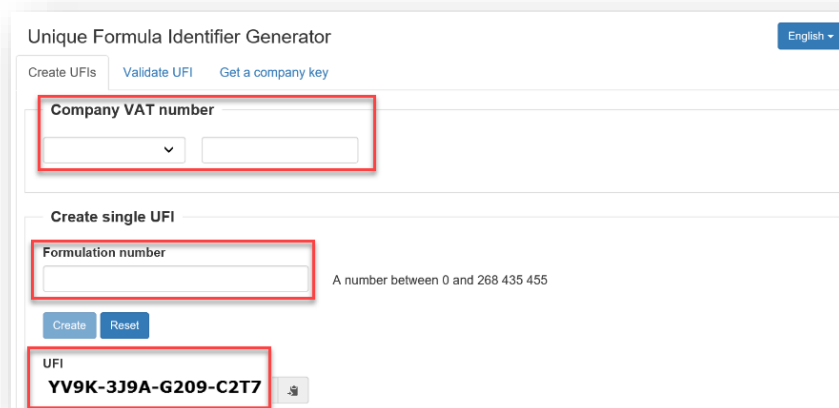
echa.europa.eu



Generate and assign UFIs

poisoncentres.echa.europa.eu/ufi-generator

- A single UFI can only be assigned to **one** mixture composition
- To generate a UFI you need:
 - company VAT number
 - formulation number between 0 - 268 435 455
- Additional mapping of internal formulation codes/names (i.e. letters or special characters) may be required
- UFI generator tool available or you can implement a UFI generating algorithm in your own systems



The screenshot shows the 'Unique Formula Identifier Generator' web interface. It has a header with 'English' and three tabs: 'Create UFIs', 'Validate UFI', and 'Get a company key'. The 'Create UFIs' tab is active. Below the tabs, there is a 'Company VAT number' field with a dropdown arrow, highlighted by a red box. Below that, there is a 'Create single UFI' section with a 'Formulation number' field, also highlighted by a red box. To the right of this field is the text 'A number between 0 and 268 435 455'. Below the 'Formulation number' field are 'Create' and 'Reset' buttons. At the bottom, there is a 'UFI' field containing the text 'YV9K-3J9A-G209-C2T7', highlighted by a red box.

Plan the relabelling of your products

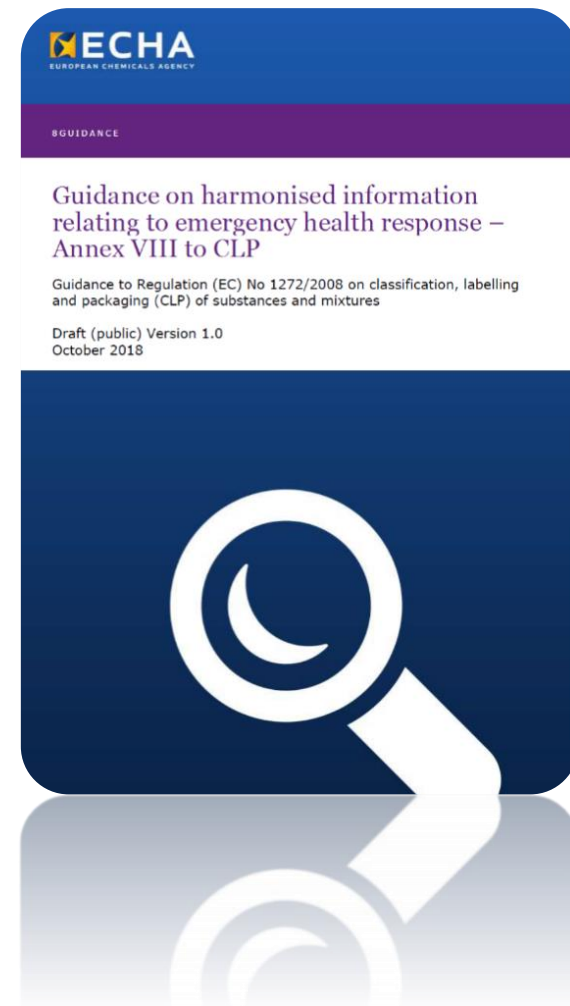
- The UFI is always to be included in the notification **as well as** on the label/packaging
- No rules on placement - redesign of label to incorporate this new element
- If the product is not packaged or has an industrial use only, the UFI can be included in section 1.1 of the SDS
- Printing of UFIs on the label should be planned to coincide with the submission of information



Follow guidance

poisoncentres.echa.europa.eu/guidance

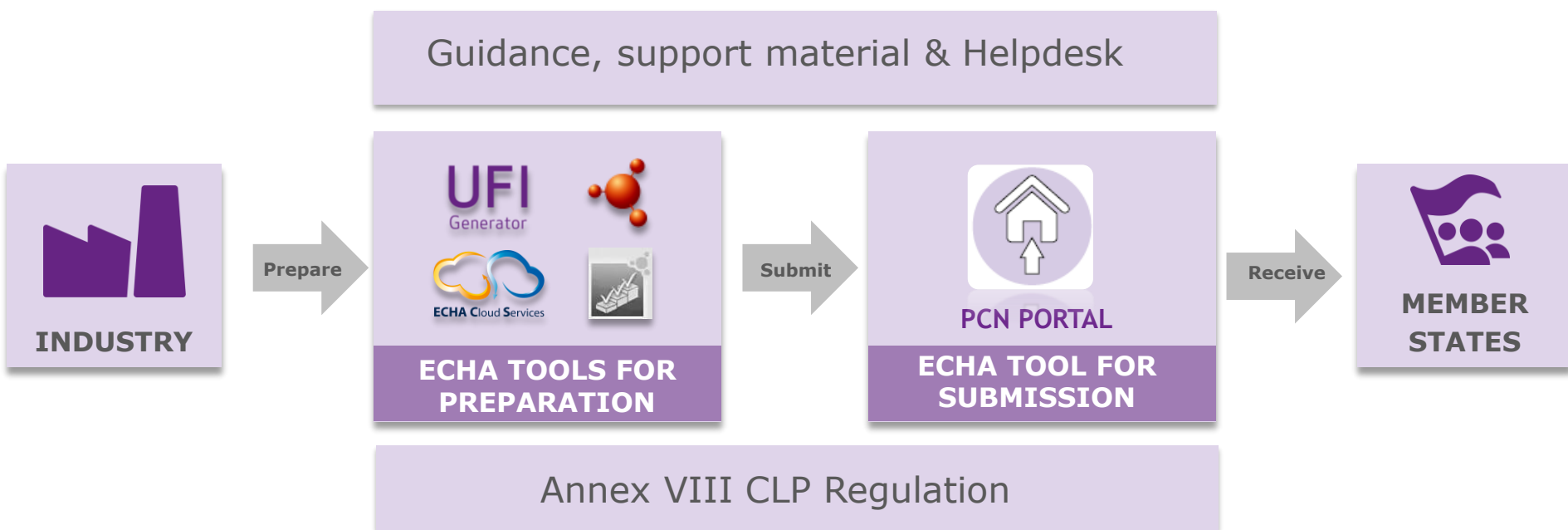
- Draft version in last consultation step with Member States and EU Commission ongoing
- **Open issue** role of distributor → Under discussion: waiting for the outcome
- Expected publication of first final version early 2019
- Translations following outcome of ongoing discussion on distributors' role

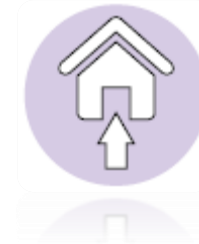


Dossier preparation and submission tools



Tools for preparation and submission





Ways to prepare and submit 1/3

Online preparation in the PCN portal

- Guided dossier preparation tool for manual entering of data
- User friendly interface with step by step instructions and help
- ECHA Cloud service available to store dossier
- Dossier can be validated before submission to the PCN portal



Ways to prepare and submit 2/3

Offline preparation using IUCLID

- Additional option for companies preferring to enter data manually
- A new PCN user interface developed in IUCLID 6
- IUCLID dossier can be submitted to the PCN portal or to national submission systems
- Dossier validated before submission

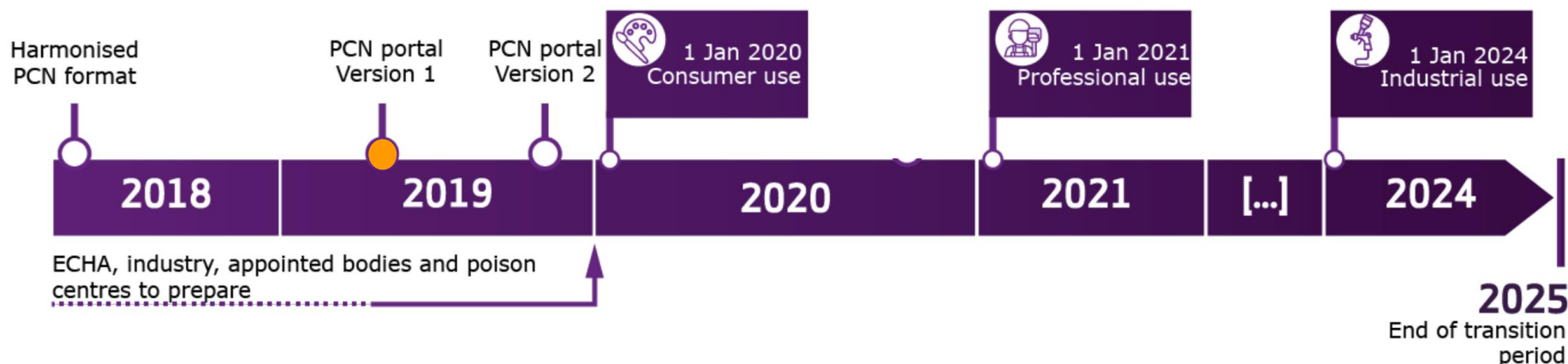


Ways to prepare and submit 3/3

System-to-system (S2S)

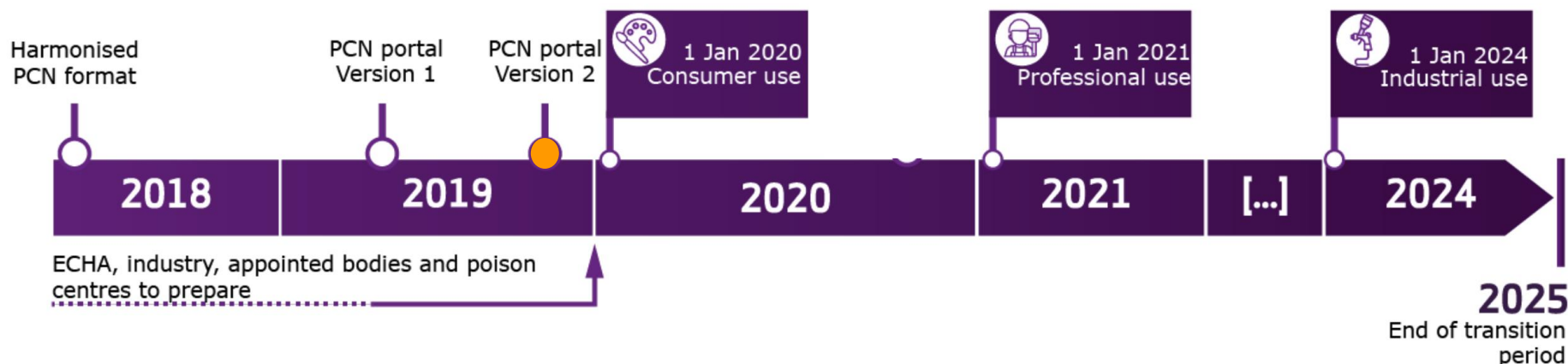
- Most advanced dossier preparation and submission method
- Companies can directly prepare dossiers in PCN format in their own systems
- Submission occurs through automatic transfer to the PCN portal
- Supports companies with large portfolios
- Validations only possible after submission

PCN portal development – version 1



- Version 1 April 2019
- Features for industry
 - Online dossier preparation tool
 - Submission and search functionality
- Features for Member States
 - Secure mechanism to download notifications (security model in place)

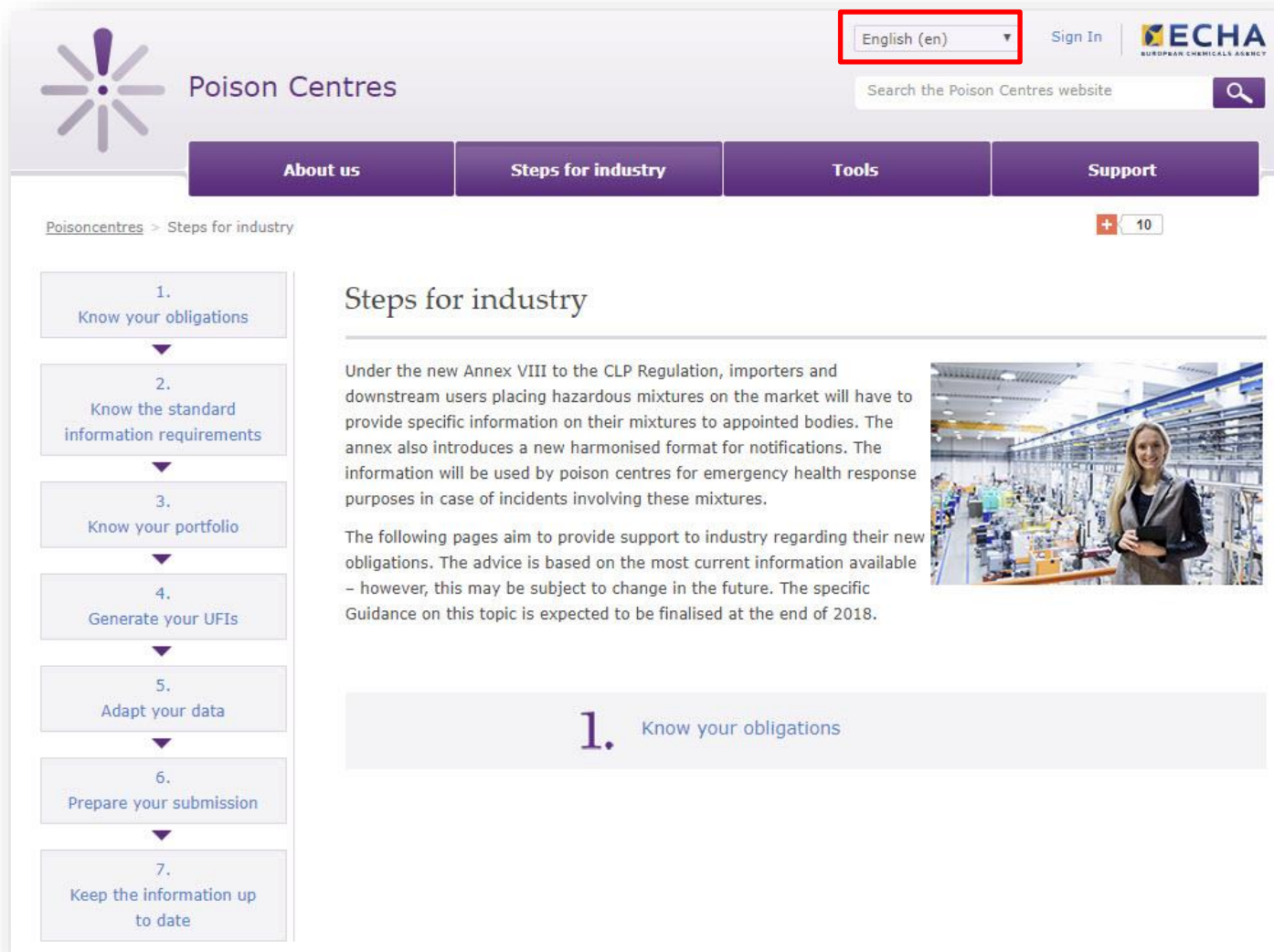
PCN portal development - version 2




- Version 2 November 2019
- Features for industry
 - S2S automated submission
 - Improved user interface – multilingualism, online help...
- Features for Member States
 - S2S automated receival in own database
 - Searchable database available for all MS to search notifications

Need support?

poisoncentres.echa.europa.eu/steps-for-industry




The screenshot shows the 'Poison Centres' website interface. At the top, there is a navigation bar with a language dropdown menu set to 'English (en)', a 'Sign In' link, and the ECHA logo. Below the navigation bar is a search bar with the placeholder text 'Search the Poison Centres website'. The main content area is titled 'Poison Centres' and features a sidebar with a vertical list of steps: 1. Know your obligations, 2. Know the standard information requirements, 3. Know your portfolio, 4. Generate your UFI's, 5. Adapt your data, 6. Prepare your submission, and 7. Keep the information up to date. The 'Steps for industry' section is highlighted, and the first step, '1. Know your obligations', is expanded. The expanded content includes a paragraph explaining the requirements under Annex VIII to the CLP Regulation and a photograph of a woman in a laboratory setting.

English (en) Sign In 

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Poison Centres

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Steps for industry

1. Know your obligations

2. Know the standard information requirements

3. Know your portfolio

4. Generate your UFI's


5. Adapt your data

6. Prepare your submission

7. Keep the information up to date

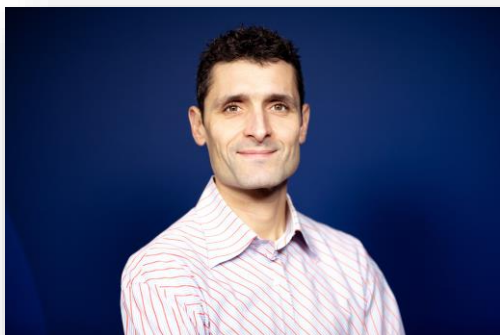
Under the new Annex VIII to the CLP Regulation, importers and downstream users placing hazardous mixtures on the market will have to provide specific information on their mixtures to appointed bodies. The annex also introduces a new harmonised format for notifications. The information will be used by poison centres for emergency health response purposes in case of incidents involving these mixtures.

The following pages aim to provide support to industry regarding their new obligations. The advice is based on the most current information available – however, this may be subject to change in the future. The specific Guidance on this topic is expected to be finalised at the end of 2018.



1. Know your obligations

Q&A session



Daniele Ape



Daniel
Sompolski



Heidi Rasikari

The webinar has ended

Thank you for joining us

We continue to answer your questions via the Q&A panel until:

13:00 Helsinki time

If you don't receive an answer by then, contact us:

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