

### Welcome

Webinar: Poison centre notifications: ensuring compliance for industrial use mixtures

14 November 2023

Heidi Rasikari Regulatory Officer European Chemicals Agency



### Programme



Time	Topic	Speaker
11:00	Introduction	Heidi Rasikari, ECHA
11:05	Industrial use only mixtures – what you need to know	Heidi Rasikari, ECHA
11:20	Status update on the CLP revision	Daniele Ape, ECHA
11:30	Support and guidance	Pedro Roselló Vilarroig, ECHA
11:40	Closing remarks	Pedro Roselló Vilarroig, ECHA
11:45-13:00	Webinar open for questions	All



### Live Q&A

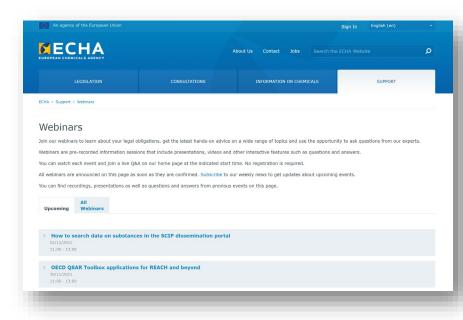
- Join Q&A at: slido.com Event code: # pc2023
- Send questions from 11:00 to 13:00 (EET, GMT +2)
- Only questions within scope
- Question not answered? Contact us: <a href="mailto:echa.europa.eu/contact">echa.europa.eu/contact</a>





### Material available

- Video recording
- Presentations
- Q&A (soon after the event)
   echa.europa.eu/webinars







# What you need to know about industrial use only mixtures

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#### Introduction

- 1 January 2021 compliance date for consumer and professional use mixtures passed
- Upcoming compliance date for industrial use: 1 January 2024
- Transition period ends 1 January 2025
- Over 5.3 million notifications for all use types so far





### Second compliance date

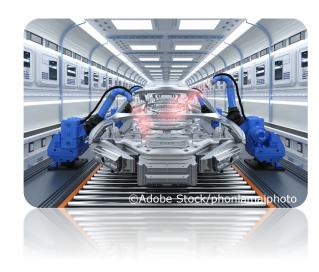
- Second compliance date: 1 January 2024
- Scope: Industrial use only mixtures
- Requirement: Notify mixtures hazardous to health or physical effects
- Starting January 2024: Notify all new mixtures (consumer, professional, and industrial) in harmonised format





### What is an industrial use <u>only</u> mixture?

- Must be used at industrial sites only.
   Can be supplied as:
  - Industrial end-use product
  - Mixture-in-mixture ('MiM') re-formulated into other industrial use only products
- Not the same as mixture for 'industrial use'
- Based on 'end-use': must not be available to consumer or professional users (as-supplied or reformulated)





### Transition period

- Existing 'national' notifications: Valid until 1 January 2025
- Starting 1 January 2025: Any 'national' notifications require submission in harmonised format
- Product changes: Before this time, changes may trigger a harmonised notification and unique formula identifier (UFI) on label (e.g., new toxicity data, classification, trade names)
- Discontinued products: No new submission required if product discontinued before transition period ends





### Relabelling 'old' products after 2025

- Duty holder responsibilities (1 January 2025):
  - Create UFI and ensure correct product labelling when placing on the market.
  - Consider relabelling products in warehouses (e.g., using stickers)
- Distributor guidelines
  - (1 January 2025):
    - No need to relabel products on shelves with UFI if they were CLP compliant when supplied



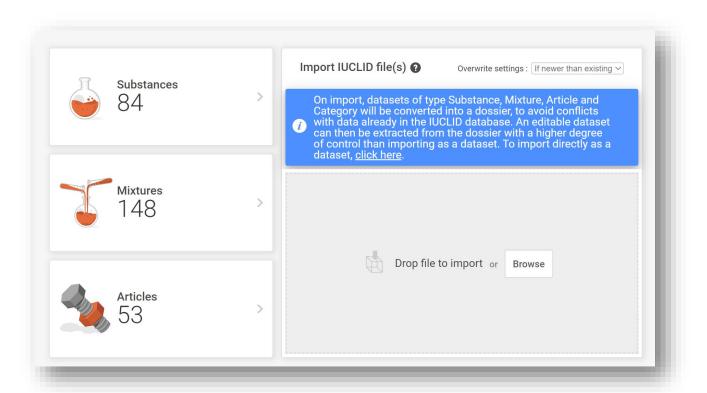
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### Importance of the unique formula identifier (UFI)

- Main principle: one UFI for one mixture composition
- Flexibility: one mixture composition can have multiple UFIs
- UFI:
  - Used by poison centres to identify a unique mixture composition
  - Used and re-used by industry to protect confidential information
- Correct management from generation to use in supply chain vital to assist poison centres









### **Limited submission – use is optional**

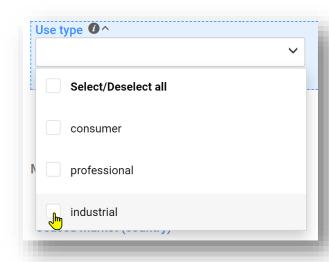
- 'Limited' compositional information from safety data sheet can be used
  - All other information must be provided
- Contact person must be available 24/7 to provide 'rapid access' to more information
  - In all relevant languages indicated in the dossier header

Submission type		
Limited submission (industrial use only) 🛂 ^		
Group submission		
Voluntary submission		



### **Use type**

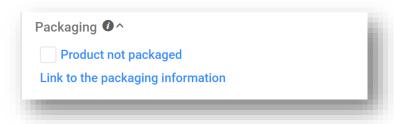
- Select 'Industrial' use type
  - Prevents downstream users from using mixture to reformulate consumer or professional products
- Available also for industrial mixtures 'with an end use not subject to notification'
  - Final mixture not classified or classified for environmental hazards only
  - Falls outside CLP scope e.g. cosmetic product





### **Packaging**

- Not strictly necessary to provide 'packaging' information
- Applies also to industrial mixtures



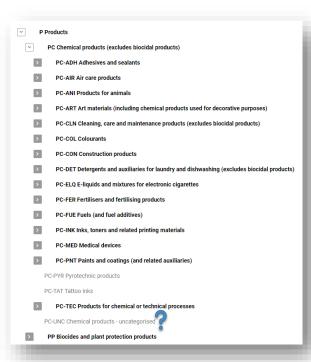


#### **Product category**

- One 'main intended use' per product record
- Select category with care if unsure, reach out to industry association or request an EuPCS change through: echa.europa.eu/contact

#### **Tips**

- Top-level categories should be covered so mixtures categorised as 'uncategorised' should be rare. Let ECHA know.
- Selecting 'for further formulation' should only be for industrial end-use products



#### Contact information considerations

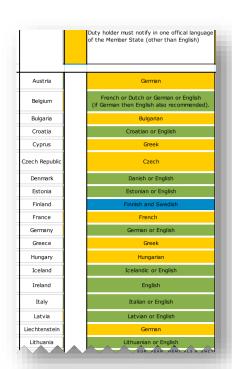
- Contact person (24/7) for rapid access in all relevant languages for limited submissions
- Different from emergency telephone number used in section 1.4 of safety data sheet
  - Some poison centres charge fees e.g. NPIC-Ireland
- Do not use contact details of appointed bodies in notification or safety data sheet





### Using ECHA submission portal

- Check Member State overview document fees, national requirements, languages
- National systems currently remain open for industrial use mixtures in a handful of countries
- Check languages some countries only accept in national language.
   <u>List of appointed bodies</u>
- Submitting to Northern Ireland?
  - Use UK national system <u>check guidance</u>



### Thank you

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## Status update on the CLP revision

Webinar: Poison centre

notifications: ensuring compliance

for industrial use mixtures

14 November 2023

Daniele Ape Regulatory Officer European Chemicals Agency



### Why a CLP revision?

- Part of <u>European Green Deal</u> and <u>Chemicals Strategy for Sustainability</u>
- Serves 'one substance, one assessment'
- Adaptation to technical and scientific progress
- Push and prioritise more harmonised classifications
- Better identify and classify hazardous chemicals
- Address legal gaps and high non-compliance





### CLP revision in two parts

# 1. Ordinary Legislative Procedure

Change in CLP "body" text

Co-decision via Parliament and Council

### 2. Delegated Act

Changing Annex I Hazard classes

Commission decision via consultation with competent authorities for REACH and CLP (CARACAL)

Published 30 March 2023
Entered into force 20 April 2023





### **Delegated Act (Annex I)**

#### Overview

New criteria for endocrine disruptors for human health and environment (ED HH & ED ENV)

- Category 1 (known/presumed)
- Category 2 (suspected)

Persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM)

No subcategories

Persistent, Bio-accumulative and Toxic (PBT), very Persistent, very Bioaccumulative (vPvB)

No subcategories



### **Delegated act**Application dates





# **Delegated act**Impact on poison centre notification system

- Scope expansion: new mixtures to notify and existing notifications to (potentially) update
- IUCLID format revision (not only related to poison centre notifications)
- IT tools adaptation (for industry and authorities)
- Validation assistant revision
- Guidance and practical guide





### **Delegated act**Adaptation timelines

- IUCLID format revision: new hazard classe records
  - IUCLID release April 2024
  - Test version available earlier
- Validation assistant revision
  - Updated rules together with format
  - Rules list not affected (descriptions remain the same): no new rules expected





### **Ordinary legislative procedure**

Considerations based on Commission draft proposal:

- Trialogue between Commission, Parliament and Council ongoing
- Expected entry into force earliest June 2024
- Focus on poison centre notifications





### Ordinary legislative procedure Distance sales

- Supplier in EU needed to ensure
   CLP requirements are met
  - Avoid obligations on consumer (e.g. direct online sales from non-EU vendor)
  - No addition of new operator (e.g. not an only representative like in REACH)
- Expected impact mainly on guidance and practical guide





### Ordinary legislative procedure Duty holder definition (1)

- Inclusion of distributors to cover potential information gaps in case of:
  - Distribution across borders
  - Re-labelling/rebranding

**Note:** No need for submission if information included in supplier's notification



### Ordinary legislative procedure Duty holder definition (2)

Duty holder definition - to be clarified:

- When distributor's notification is expected
- How to prove information has been provided to relevant appointed bodies

### Expected impact on:

- Guidance and practical guide
- Format (potential)
- Validation rules (potential)





### Ordinary legislative procedure ECHA role and access rights

- Further facilitate support for authorities
- More robust legal basis for ECHA's role in receiving and preprocessing notifications

**Note:** Final legal text and interpretation not available yet



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### Support and guidance

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#### **Guidance on Annex VIII**

- First support material after legal text
- Last update in 2022
- Next revision once CLP revision adopted
- Translated into all EU official languages



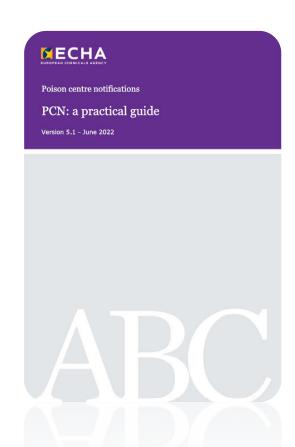


**Poison centre notifications:** 

a practical guide

 Replies to 80% of questions received

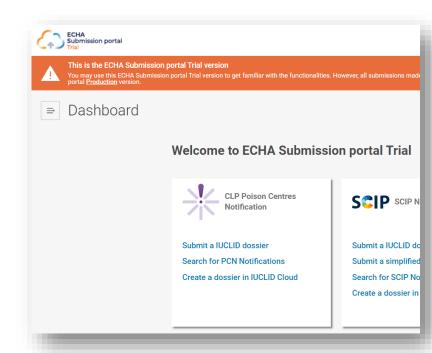
- Next update expected before end of 2023, only in English
- Translation later in 2024 following changes from IUCLID release and changes to CLP





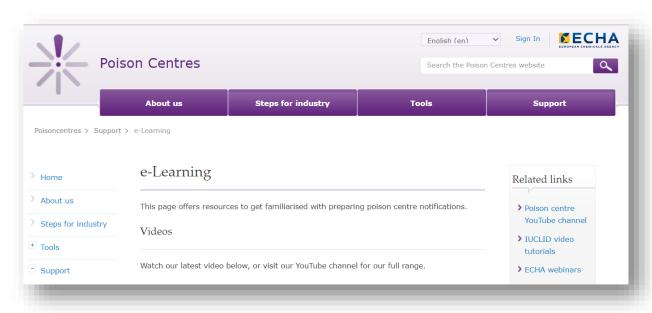
### **Trial environment**

- Sandbox concept
- Both for ECHA submission portal and cloud IUCLID
- IUCLID files from standalone can also be imported and submitted



#### Video tutorial

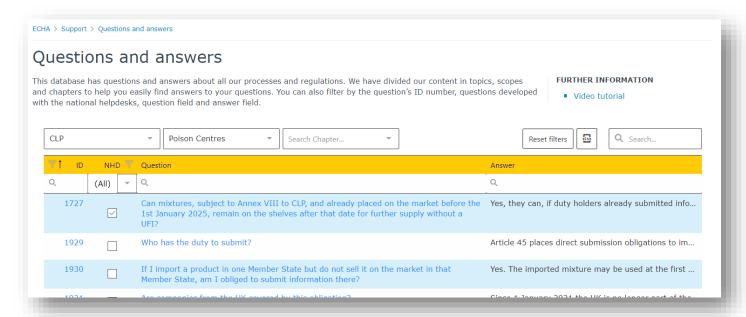
- Video covers whole submission process
- General submission case





## Questions and answers

- Moved to new platform in spring
- New revision ongoing: expected publication before end of the year





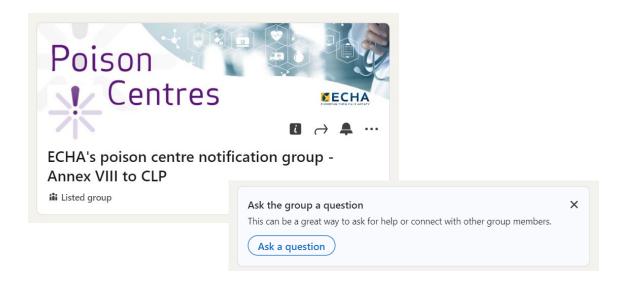
## National CLP helpdesks

- First point of contact for regulatory questions on poison centre notifications and CLP in general
- National Helpdesks ECHA (europa.eu)
- Advice harmonised through network of helpdesks, ECHA included



### LinkedIn

Place to ask and share experiences





## Take home messages

- Plenty of information available to prepare for compliance
- Most support material translated

### <u> Home - Poison Centres (europa.eu)</u>

 Contact your CLP national helpdesk for regulatory support



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# Closing remarks

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#### Remember

- Prepare on time
- Contact customer to confirm end use of mixture
- Contact supplier about notification intentions
- Know your appointed body
- UFI valuable for appointed bodies and poison centres to identify mixture in case of intoxication or accident



## Compliance date

- From 1 January 2024 new mixtures for industrial use only on the market need to be Annex VIII compliant
- Mixtures already on the market may benefit from transitional period
- From 1 January 2025 all mixtures need new notification and UFI placed on label





## Closing remarks

- Changes coming from CLP revision that impact scope and duty holders
- Follow our updates and stay informed
- Useful resources:
  - Web page on new hazard classes 2023
  - Videos and webinars
  - Subscribe to our news





### Live Q&A

- Join Q&A at: slido.com
   Event code: #pc2023
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