

## Preparation of notifications for poison centres according to Annex VIII CLP

20 November 2017  
8<sup>th</sup> BfR User Conference on Product Notifications  
Berlin, Germany

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## CLP – Annex VIII

- New Annex published in March 2017
- Obligation for **importers and downstream users** placing hazardous mixtures on the market to notify national appointed bodies
- Phased deadlines by 1 January
  - 2020 for consumer use
  - 2021 for professional use
  - 2024 for industrial use
  - 2025 marks end of transition period
  - Before placing on the market (no data, no market)

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2017/542  
of 22 March 2017

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding in Annex on harmonised information relating to emergency health response

(text with EEA relevance)

- 1. What companies will need to notify?**
- 2. Poison centres project – where are we?**
- 3. Getting ready – how can industry prepare?**
- 4. Questions and answers**

**What companies will need  
to notify?**



## What companies will need to notify?



Unique Formula Identifier (UFI)

[echa.europa.eu](http://echa.europa.eu)

## Unique Formula Identifier

New notification  
requirement for  
product label

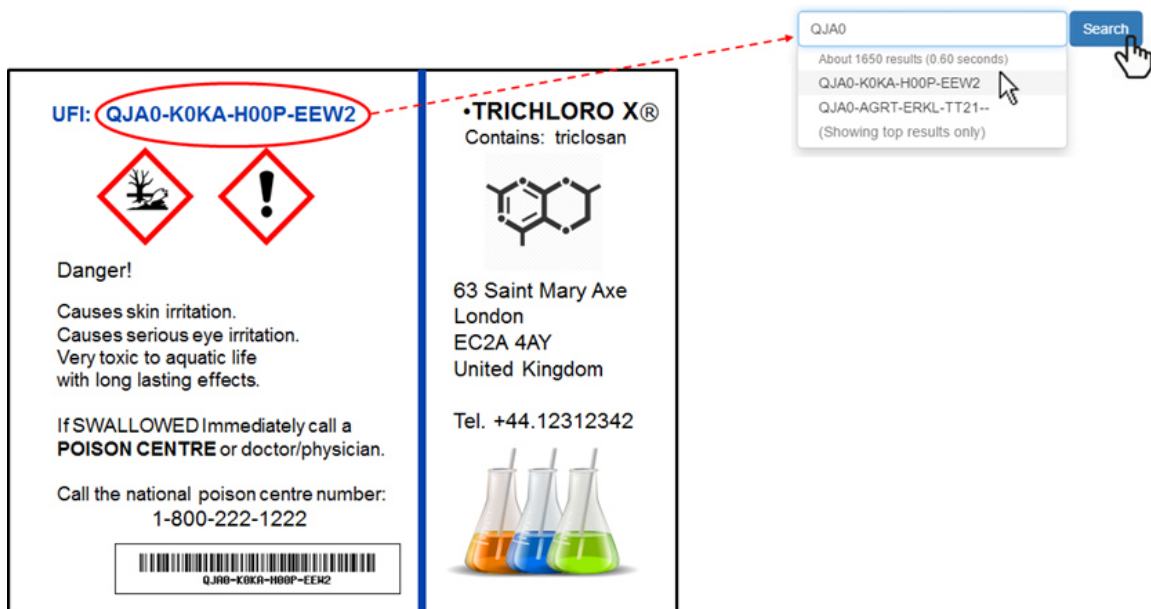
Unique 16 character  
code in 4 blocks



UFI code links the  
notified mixture  
**composition**  
information to a  
specific product  
on the market

[echa.europa.eu](http://echa.europa.eu)

## Relevance of UFI for poison centres



UFI: **QJA0-K0KA-H00P-EEW2**

**•TRICHLORO X®**  
Contains: triclosan

**Danger!**  
Causes skin irritation.  
Causes serious eye irritation.  
Very toxic to aquatic life with long lasting effects.

If SWALLOWED Immediately call a **POISON CENTRE** or doctor/physician.

Call the national poison centre number:  
1-800-222-1222

63 Saint Mary Axe  
London  
EC2A 4AY  
United Kingdom

Tel. +44.12312342

QJA0

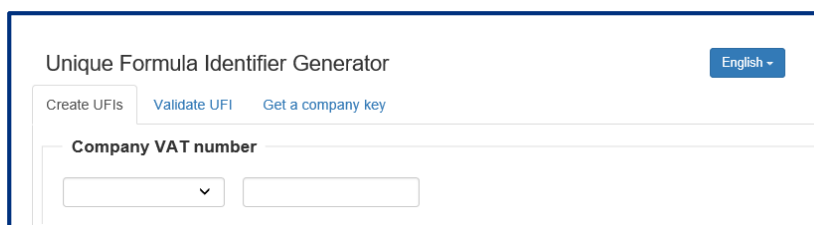
About 1650 results (0.60 seconds)  
QJA0-K0KA-H00P-EEW2  
QJA0-AGRT-ERKL-TT21--  
(Showing top results only)

echa.europa.eu

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## Current status

- Final version of UFI Generator and algorithm (with developers guide) available [poisoncentres.echa.europa.eu/](https://poisoncentres.echa.europa.eu/)



Unique Formula Identifier Generator English ▾

Create UFIs [Validate UFI](#) [Get a company key](#)

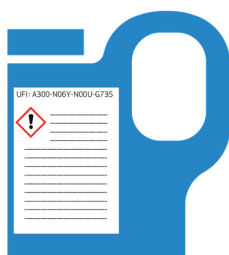
Company VAT number

- Single or multiple generation of UFIs
- Available in all EU languages

echa.europa.eu

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## What companies will need to notify?



Unique Formula Identifier (UFI)



Details of the submitter

[echa.europa.eu](http://echa.europa.eu)

## Details of the submitter



Details of the submitter

- Company name
- Address
- Phone number
- Email address
  
- Information consistent with the label

[echa.europa.eu](http://echa.europa.eu)

## What companies will need to notify?



Unique Formula Identifier (UFI)



Details of the submitter



Details of product

[echa.europa.eu](http://echa.europa.eu)

## Details of the product



- Trade name
- Physical state
- Colour
- pH
- Packaging type and size
- Use (consumer, professional, industrial)

[echa.europa.eu](http://echa.europa.eu)

## What companies will need to notify?



Unique Formula Identifier (UFI)



Details of the submitter



Details of product



Product category

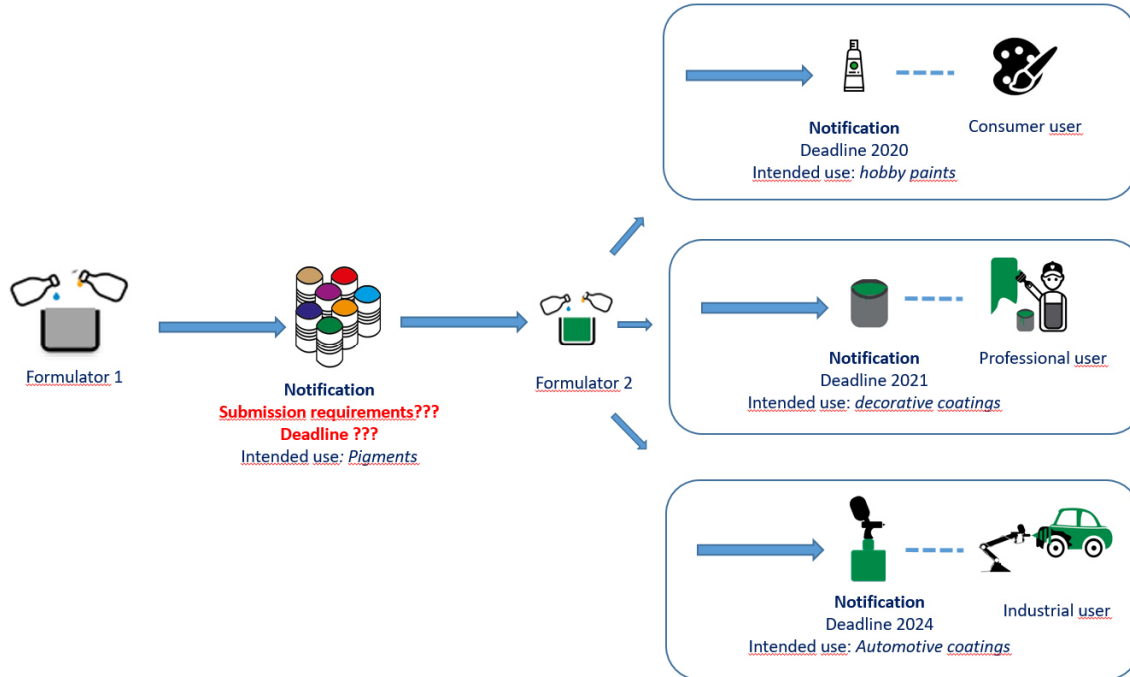
[echa.europa.eu](http://echa.europa.eu)



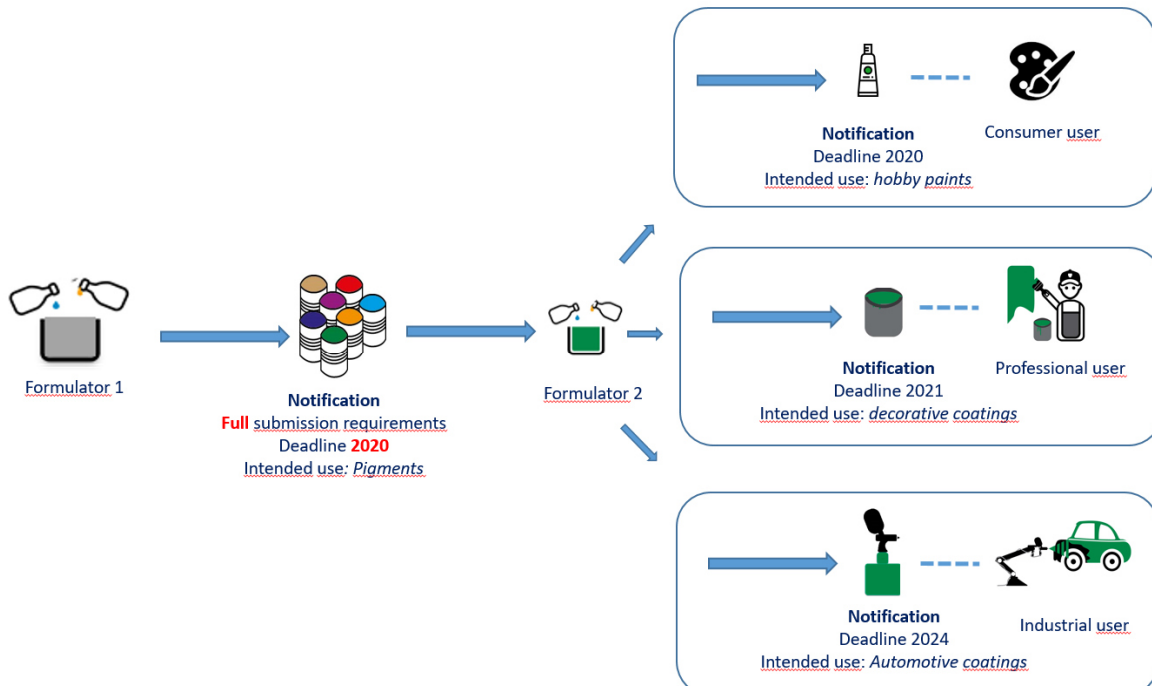
## Product categorisation - key principles and purpose

- Product category mandatory in industry notifications
- Single selection based on main intended use
- Supports appointed bodies at EU level
  - reporting/statistical analysis of poisoning incidents
  - identification of risks & proposing risk management measures
- Used by poison centres e.g. for 'backtracking' and registering cases in incidents

## Intended use and end user



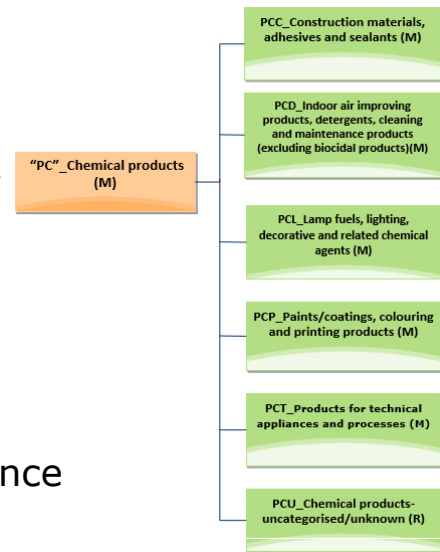
## Intended use and end user



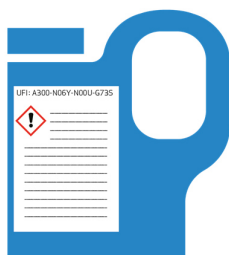


## Current status

- Draft EU PCS published in March 2017 →
- Final version 1.0 by December 2017
- Active participation from working group
- Development of practical EU PCS manual
- Process for EU PCS update and maintenance currently being developed



## What companies will need to notify?



Unique Formula Identifier (UFI)



Details of the submitter



Details of product



Product category



Toxicological information

SDS Section 11

## Toxicological information

**THE KEY POINTS**

Section 11 is intended primarily for medical professionals, occupational health and safety professionals, and toxicologists, and gives detailed information on:

- The likely routes of exposure;
- The symptoms caused by the physical, chemical, and toxicological characteristics of the substance, mixture and/or known by-products;
- The immediate and delayed adverse effects, including chronic effects, from short and long-term exposure.

You should also find a description of how the chemical was tested for health hazards and the test results.

The content of this section provides the basis for the classification and risk management measures given in the safety data sheet. The information in Sections 2, 3, 4, 6, 7, 8, 9, 13, 14 and 15 should be consistent with the toxicological information provided here.

A large quantity of information may be provided under this section, particularly in an SDS for a mixture. Ideally, it will be laid out with a clear separation between the data that apply to a mixture as a whole (where applicable) and that for individual (component) substances. [Click here](https://echa.europa.eu/documents/10162/22786913/sds_section11_mixture_en.pdf) for an example of Section 11 for a mixture (https://echa.europa.eu/documents/10162/22786913/sds\_section11\_mixture\_en.pdf).

**SECTION 11: Toxicological information**

**11.1 Information on toxicological effects**

**Acute toxicity**

Practical experience / human evidence: No data available

**Animal data:**

Effect dose / concentration	Species	Method	Symptoms / delayed effects	Remark
Acute oral toxicity LD50: >2000 mg/kg bw	Rat female	OECD 423	No adverse effect observed	Direct derivation of an ATE because of robust data
Acute dermal toxicity LD50: >2000 mg/kg bw	Rat	OECD 402	No adverse effect observed	Direct derivation of an ATE because of robust data
Acute inhalation toxicity (vapour)	Rat male	OECD 403	No adverse effect observed	Direct derivation of an ATE because of robust data

Other information: No data available

Assessment / Classification: Based on available data, the classification criteria are not met

**Skin corrosion/irritation**

Practical experience / human evidence: No data available

Acid / Alkali reserve (buffer capacity for mixtures with extreme pH values)

Acidic reserve [g NaOH/100 g product]: not applicable

Alkaline reserve [g H2SO4/100 g product]: not applicable

**Animal data:**

Exposure time	Observation time	Species	Method	Result / evaluation	Remark
24 hours	72 hours	Albino rabbit	OECD 404	erythema Scores: 2,3. reversible	

In-vitro skin test: data lacking

Other information: No data available

Assessment / Classification: Causes skin irritation

**Serious eye damage/irritation**

Practical experience / human evidence: No data available

**Animal data:**

Species	Method	Result/Evaluation	Remark
Albino rabbit	OECD 405	Conjunctival redness Scores: >= 2 Chemosis Scores: 1.5 Corneal opacity Scores: 1.7	

Other information: No data available

Assessment / Classification: Causes eye irritation

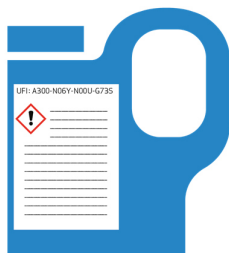
**Sensitisation to the respiratory tract**

Practical experience / human evidence: No data available

Other information: No data available

Assessment / Classification: Not classifiable due to data lacking

## What companies will need to notify?



Unique Formula Identifier (UFI)



Details of the submitter



Details of product



Product category



Toxicological information



Hazard classification  
Label elements



# Hazard classification

## Label elements

- Classification of the mixture (health and physical hazards)
- Hazard pictogram codes
- Signal words
- Hazard statement codes
- Precautionary statement codes

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## What companies will need to notify?



Unique Formula Identifier (UFI)



Full chemical composition

Component A - 60%  
Component B - 30%  
Component C - 10%



Details of the submitter



Details of product



Product category

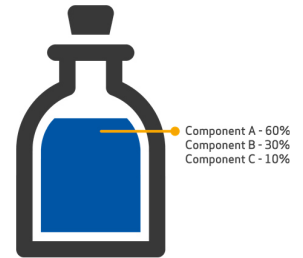


Toxicological information



Hazard classification  
Label elements

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## Full chemical composition

- More information than normally present in SDS – need for more information exchange in supply chain
- All components must be indicated, also non-hazardous
- Exact concentrations or ranges
- Classification of components
- Generic components possible for perfumes, fragrances and colouring agents
- Mixtures in mixtures (MiM) possible via UFI to protect CBI
- UFI linked to the mixture **composition**, not product/mixture
- New UFI (and new label) needed when:
  - adding, substituting or deleting a component
  - variation in concentration beyond the range specified
  - supplier changes UFI and it has impact on MiM

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## Annex VIII and ECHA's role





## Annex VIII and ECHA's role

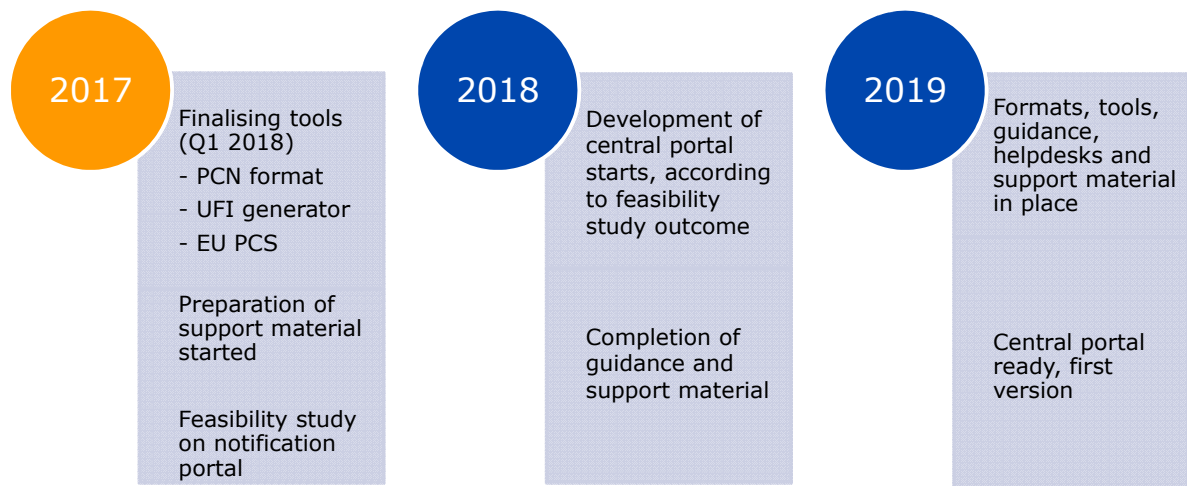
ECHA is here for you:

- Technical and scientific guidance and support
- Tools to facilitate submission of information

These include:

- Unique Formula Identifiers (UFI) generator
- Product categorisation system (PCS)
- Poison centres notification (PCN) format
- **Development of a central notification portal?**
- Guidance and support material

## Timelines



## Where are we?

- Poison Centres website is live [poisoncentres.echa.europa.eu](http://poisoncentres.echa.europa.eu)

- Outcome of the feasibility study on central notification portal

- ECHA/Stakeholder working groups in operation



Guidance

EU product  
categorisation  
system

IT tools

[echa.europa.eu](http://echa.europa.eu)

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## Guidance and support



# Guidance phase 1

## Phase 1: drafting (on-going)

- Active involvement of authorities and industry via working group  
[poisoncentres.echa.europa.eu/guidance](http://poisoncentres.echa.europa.eu/guidance)
- Workshop on 5 Dec 2017
- First draft early 2018

### 1. Introduction

#### 1.1 General introduction

A large number of chemical mixtures are used in the EU on a daily basis. The general public and workers regularly come into contact with them, both in their private life and in the occupational environments.

Chemical products are in general considered to be safe when they are used properly. Nevertheless, unintentional exposure to chemicals can occur, for example due to inappropriate use or accidents. When this happens, immediate access to relevant information on the chemical product is crucial to medical staff and those who provide emergency response.

#### 1.2 Legal background

Already since 1988, Council Directive 88/379/EEC required Member States to appoint a body for receiving information on dangerous preparations in order to meet any medical demand by formulating preventative and curative measures. This Directive was repealed by 1999/45/EC, which provided for a similar obligation. Many Member States had in place a system for collecting information from companies placing chemical products on the market. This information is accessible to the Poison Centres, the bodies established in the Member States to provide advice on health emergencies. Depending on the Member State, physicians and medical staff, workers and the general public are able to contact the Poison Centres to get recommendations on medical treatment.

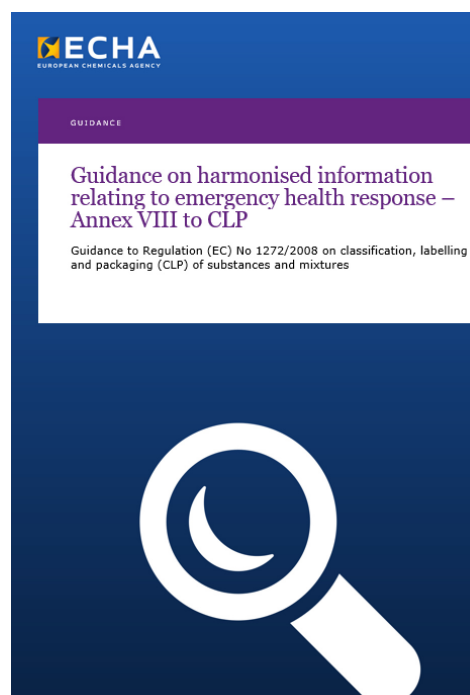
Article 45 of the CLP Regulation ((EC) No 1272/2008, which entered into force on 1 June 2017) requires the EU Member States to appoint a body for receiving information on the composition of hazardous mixtures (e.g. detergents, paints, adhesives) to enable the formulation of preventative and curative measures. The introduction of harmonised information requirements has led to considerable variation in information systems, data formats and information requirements regarding the information in each Member State. Thus importers and downstream users placing mixtures on the market in different Member States have needed to submit similar information in different formats. This diversity has led to inconsistencies in the information available to medical personnel and the general public in cases of poisoning incidents in different Member States.

The European Commission has a mandate to address these shortcomings and a review was carried out in consultation with stakeholders and with the support of the European Association of Poison Centres and Clinical Toxicology (EAPCCT). Following the review as foreseen in Article 45 of the CLP Regulation (EU) 2017/542 was adopted. The Regulation entered into force on 12 April 2017, adding to the CLP Regulation an annex (Annex VIII) to harmonise, in terms of format and content, the information relating to emergency health response that certain operators placing hazardous mixtures on the EU market are required to notify to the bodies appointed by each Member State (from now on called the "appointed bodies"). This information includes, for example, the composition and hazardous ingredients and on the uses. The information is submitted in a specified format, which enables the appointed bodies (the Poison Centres, who are the end user of the information) to be able to identify exactly the product of concern and to suggest the appropriate treatment. The appointed bodies and Poison Centres (which are not necessarily, although in some Member States this may be the case, see section 2.1) need to ensure the confidentiality of the information received.

# Guidance phase 2

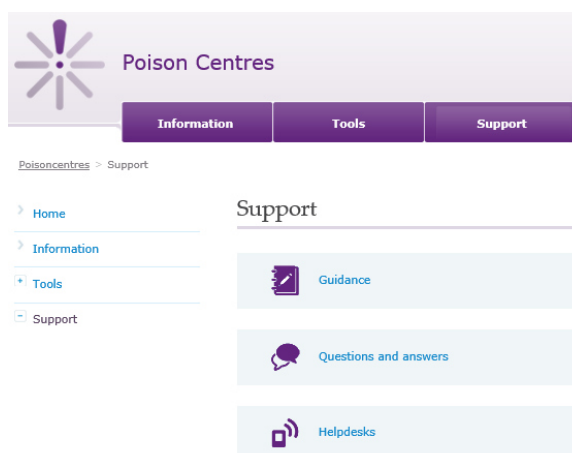
## Phase 2: formal consultation with our partners

- Launch in Q1 2018
- Active participation of our accredited stakeholders
- Final Guidance v1.0 by end 2018



## Support - current status

- >50 Q&As published  
visit our support page
- Targeted support for  
companies  
under development
- Training for national  
Helpdesks  
coming in 2018
- UFI factsheet  
coming soon



**Get ready**  
**How can industry prepare?**





## Know your obligations



- Are you importer or downstream user?
- Mixture hazardous? Exemptions?
- Deadlines? Transition period?
- Which countries?

## Familiarise yourself with required information



- Full chemical composition
  - enhanced communication in supply chain needed?
- UFI generation
  - mapping company internal codes of mixtures
  - planning re-labelling activities – can be done before the due time for notification
- Product categorisation according to PCS
- Section 11 of SDS
  - improving quality or relevancy?
  - language

## Know your portfolio



- Uses: consumer, professional or industrial?  
Note: consider uses downstream, not only your own
- Limited submission for industrial uses?
- Group submission for product 'families'?
- CBI important? Prepare to provide UFI to your customer (also possible for non-hazardous mixtures)
- Assign concentration (exact or ranges) to components of your mixtures

## Get prepared



- Data management system needed?
- Process for monitoring and change management?
- Resources implication
- Redesign of labels
- Decision on preferred way of preparing information
- Decision on preferred way of submitting information

## This is all done for...



## Questions and answers



Thank you!

[poisoncentres@echa.europa.eu](mailto:poisoncentres@echa.europa.eu)  
<https://poisoncentres.echa.europa.eu/>

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