



UMC Utrecht

Implementation of CLP Annex VIII

EU harmonised product information for Poisons Centres

| | |
|-------------------|------|
| Pieter Brekelmans | NVIC |
| Ronald de Groot | NVIC |
| Thijs de Kort | RIVM |



Nationaal Vergiftigingen Informatie Centrum

[NVIC, UMC Utrecht]

Pieter Brekelmans, team productnotificatie NVIC

Ronald de Groot, team productnotificatie NVIC

Rijksinstituut voor Volksgezondheid en Milieu

[RIVM]

Thijs de Kort, REACH en CLP helpdesk



CLP Regulation (EC) 1272/2008

'from article 45 to Annex VIII'

- CLP article 45
 - NVIC is appointed body
(Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten, art 15h)
 - The appointed bodies shall have at their disposal all the information required (...) to carry out the tasks for which they are responsible.

- CLP Annex VIII
(Regulation (EU) 2017/542)
 - Specification of the product information to be notified
 - Introduction of a Poisons Centres Notification (PCN) format
 - ECHA responsible for the tools and guidance documents
 - Phased deadlines by 1 January:
 - *2020 products for consumer use*
 - *2021 products for professional use*
 - *2024 products for industrial use*
 - *2025 end of transition period*



European Chemicals Agency

'responsible for tools and guidance'



CLP – Annex VIII

We are here for you:

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

These include:

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



European Chemicals Agency

'timelines'



Timelines

2017

Finalising tools (Q1 2018)

- PCN format
- UFI generator
- EU PCS

Preparation of support material started

Feasibility study on notification portal

2018

Development of central portal starts, according to feasibility study outcome

Completion of guidance and support material

2019

Formats, tools, guidance, helpdesks and support material in place

Central portal ready, first version



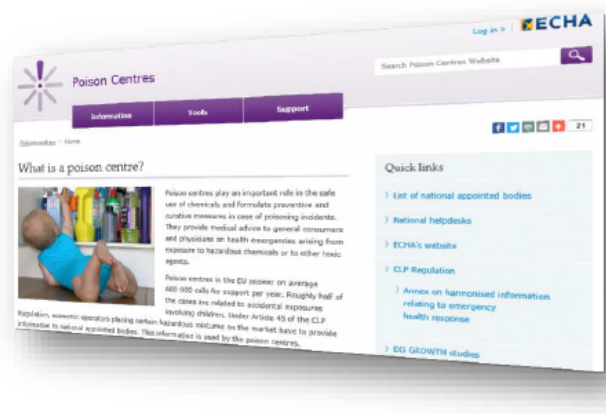
European Chemicals Agency

'status October 2017'



Where are we?

- Poison Centres website is live 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



UMC Utrecht
Nationaal Vergiftigingen Informatie Centrum

Guidance and support 'drafting guidance...'



Guidance phase 1

Phase 1: drafting (on-going)

- Active involvement of authorities and industry via working group
poisoncentres.echa.europa.eu/guidance
- Workshop planned early December
- First draft by end 2017

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 EU 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, that Directive was repealed by 1999/45/EC, which provides for a similar obligation. Already before that obligation, many Member States had in place a system for collecting information from companies placing chemical products on the market. This information was accessible to the Poison Centres, the bodies established in the Member States to provide medical 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 preventive and curative measures. The absence of harmonised information requirements has led to considerable variation in national notification systems, data formats and information requirements regarding the composition of hazardous mixtures 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 previous 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, Commission 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 chemical composition and the company responsible for the placing on the market of the mixture, the composition and hazardous ingredients and on the uses. The information is submitted in a specified format, which enables the appointed bodies 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 1.2.1) need to ensure the confidentiality of the information received.



Guidance and support

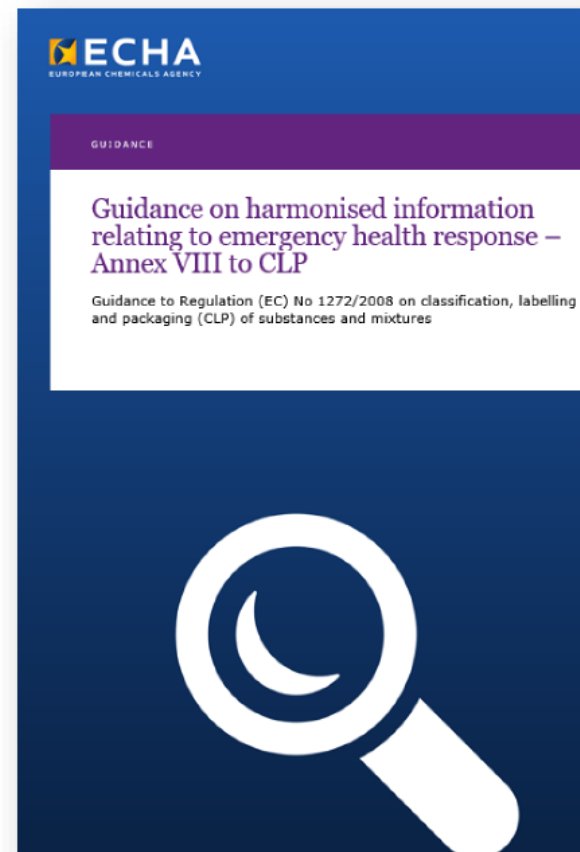
'... formalising guidance'



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
- Partner Expert Group



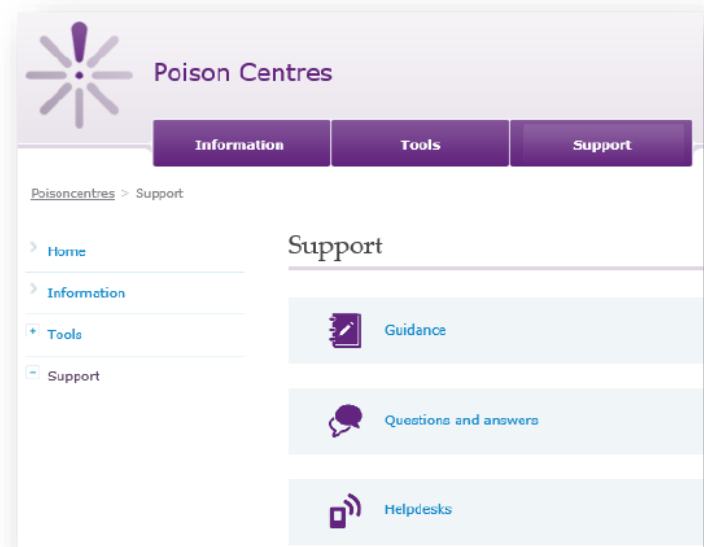
Guidance and support

'... and support'



Support - current status

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



EU Product Categorisation System

'PCS'



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



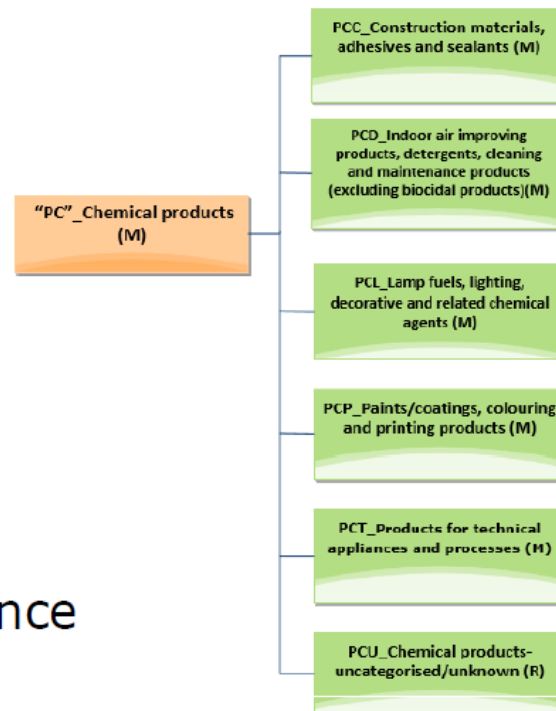
EU Product Categorisation System

'PCS'



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



Unique Formula Identifier

'UFI and UFI generator'



Unique Formula Identifier

New notification
requirement for
product label

Unique 16 character
code in 4 blocks



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



Unique Formula Identifier

'UFI and UFI generator'



Relevance of UFI for poison centres

QJA0

Search

About 1650 results (0.60 seconds)

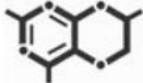
QJA0-K0KA-H00P-EEW2

QJA0-AGRT-ERKL-TT21--

(Showing top results only)


UFI: QJA0-K0KA-H00P-EEW2

•TRICHLORO X®
Contains: triclosan



63 Saint Mary Axe
London
EC2A 4AY
United Kingdom

Tel. +44.12312342




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



QJA0-K0KA-H00P-EEW2



Unique Formula Identifier

'UFI and UFI generator'



Current status

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

A screenshot of the 'Unique Formula Identifier Generator' web interface. The page title is 'Unique Formula Identifier Generator' with a language dropdown set to 'English'. There are three tabs: 'Create UFIs' (selected), 'Validate UFI', and 'Get a company key'. Below the tabs is a section for 'Company VAT number' which includes a dropdown menu with a downward arrow and an adjacent text input field.

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



IT tools

'Poisons Centre Notification (PCN) format'



Current status

- Draft PCN format and editor available
 - Structured electronic format defining harmonised information requirements
 - Current draft format from 2015 obsolete
- Final version by Q1 2018
 - Revise information requirements (e.g. include product category, support group submission)
 - Align with standardised formats through compatibility with the IUCLID XML format
 - Consider notification process and improve overall data quality by minimising redundancy



IT tools

'PCN portal feasibility study'



Objectives of the study

- Analysing various stakeholder needs
- Proposing a solution for the portal
- Producing a blueprint of a candidate architecture for the new system that fits into our IT architecture
- Defining the best approach for the delivery of the software
- Providing early estimates of development costs and efforts



IT tools

'PCN portal feasibility study'



Central portal features

- Collect and dispatch notifications from industry to appointed bodies
 - Secure transfer of information
 - Multilingual support
- Automated submission with agreed validations
 - Technical checks (e.g. virus scan)
 - Business checks and basic verification of key elements (e.g. trade name included in the notification)

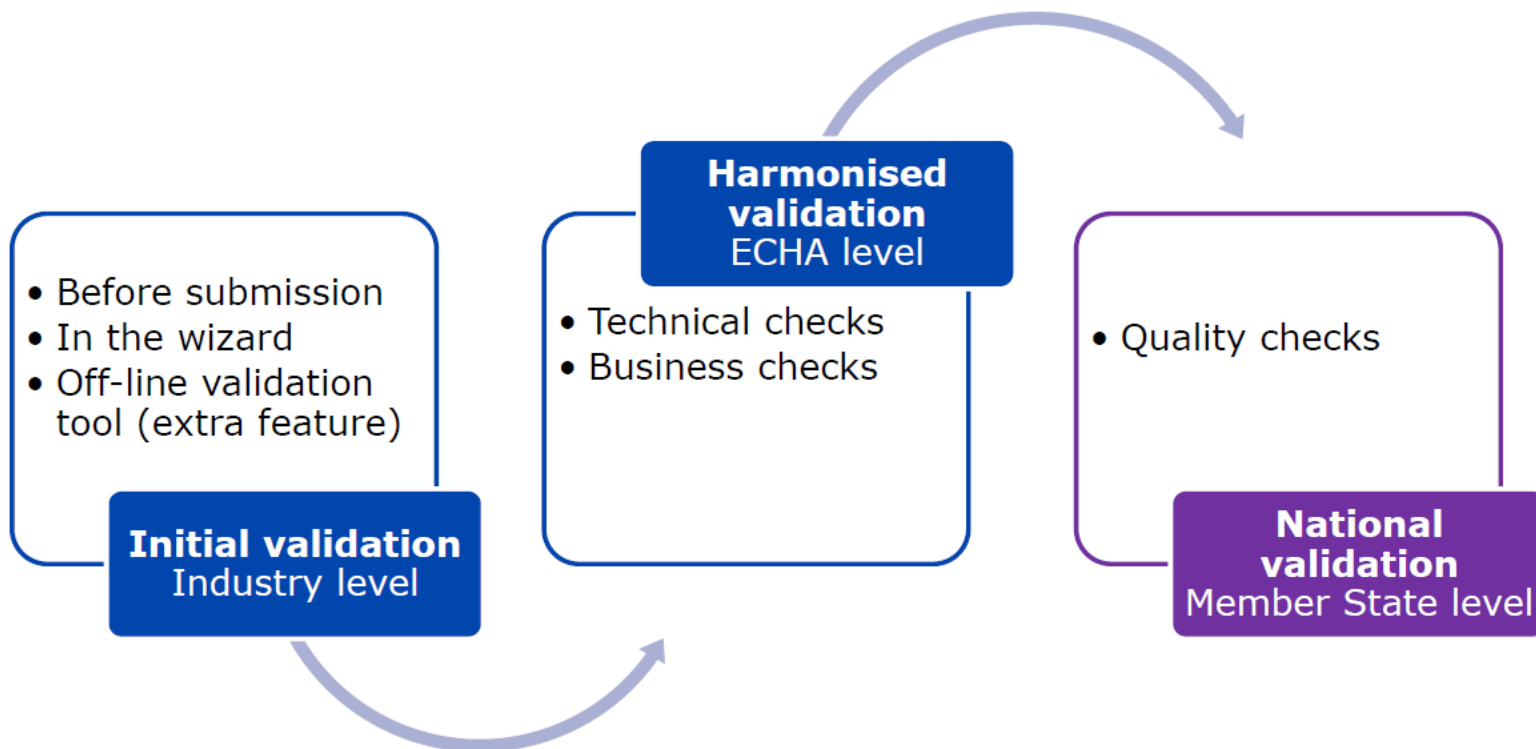


IT tools

'PCN portal feasibility study'



Three levels of validation

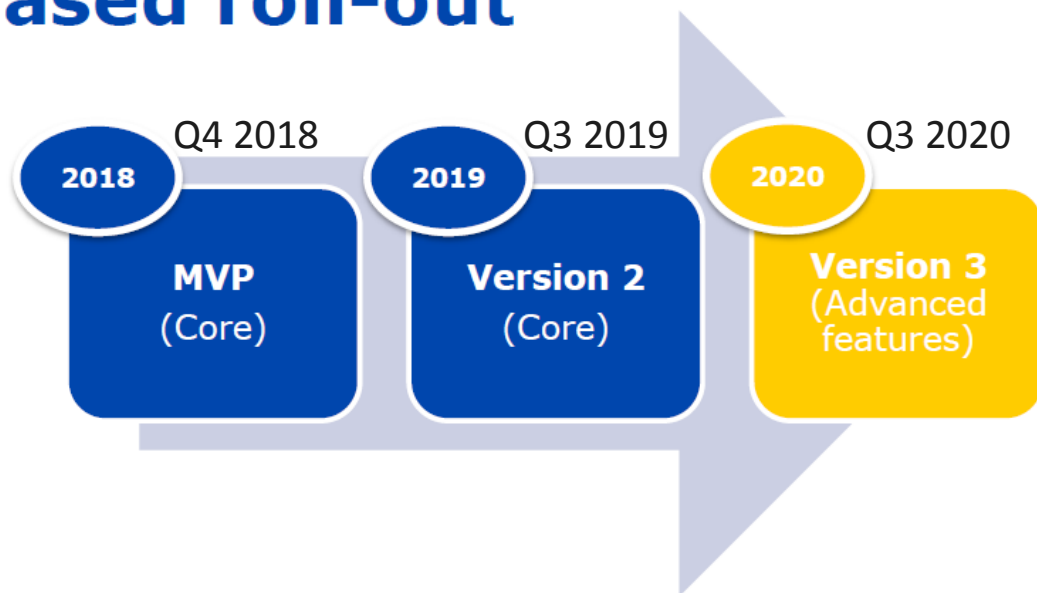


IT tools

'PCN portal feasibility study'



Phased roll-out



- Minimum Viable Product (MVP)
- Incremental product evolution



IT tools

'PCN portal feasibility study'



Core functionalities by 2019

Q4 2018

MVP

Multi-lingual and **secure** web tool for industry to **upload** and **submit** their notification files

A secure portal for **Member States** authorities **(AB/PC)** to **receive and download notifications**

Automated submission process that ensures submitted files conform to the format specifications.

Searchable central repository containing the full history of notified data where actors can retrieve their portion of the data.

Basic **User & Contact management** functions

and

Q3 2019

v2

On-line preparation of notification using a dedicated web UI that seamlessly integrates with the portal's submission process.

Exposing a **Web-service integration layer** that allows secure submission and retrieval of notified data from industry and MS IT systems respectively.

Performing **Automated checks** on submitted files to ensure minimum content compliance against a commonly agreed set of business checks.



Implementation of Annex VIII

'leftovers and national planning ...'

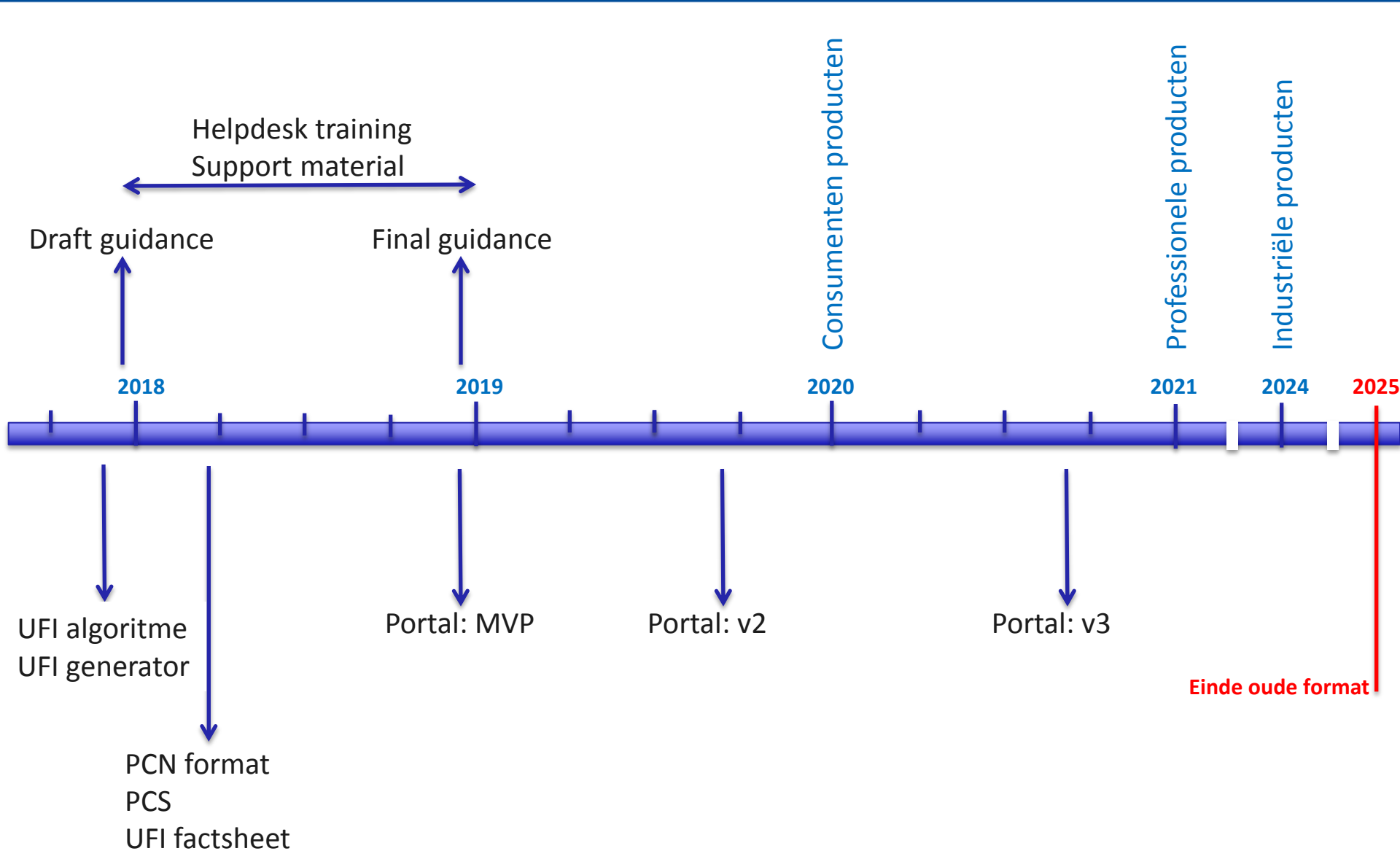
- (EC) Study on workability issues of Annex VIII (2018)
[might lead to adaptations of Annex VIII or Guidance]

- (NL) REACH en CLP helpdesk: vraagbaak voor nieuwe wetgeving (Q1 2018)

- (NL) national planning?
 - (NVIC) design/build a new database (2018 – 1-Jul-2019)?
[Start depends on final version of PCN format and finances]
 - (VWS) establish roadmap with NVIC and industry
 - (VWS) adaptation of national legislation on procedure?
 - (NVWA) communication plan
 -



| Actie | Huidige werkwijze | Toekomstige werkwijze (vanaf 1jan2020) |
|-----------------------|--|--|
| Registratie | Account bij NVIC | Account bij ECHA |
| Informatie Format | Vib.pdf + compositie.pdf | PCN.xml format [Incl. UFI en PCS] <ul style="list-style-type: none"> • Mbv PCN editor (standalone / webapplicatie ECHA) • Mbv eigen aangepaste SW met PCN • Mbv commerciële SW met PCN output |
| Notificatie | Upload via NVIC portaal (incl. technische checks) (beveiligde verbinding) | Upload via PCN portaal van ECHA (incl. technische/business checks met failure / warning / Ok procedure) (beveiligde verbinding) Download van ECHA naar NVIC (beveiligde verbinding) |
| Opslag | In NVIC producten database (incl. beschikbaar voor informatieverstrekking bij acute vergiftigingen) | In NVIC producten database (incl. beschikbaar voor informatieverstrekking bij acute vergiftigingen) |
| Inhoudelijke controle | <ul style="list-style-type: none"> - Steekproefsgewijs - Bij analyse belangrijke product groepen - Bij analyse vergiftiging | Idem |
| Handhaving | NVWA en ILT (ihkv REACH en CLP verplichtingen) | Idem? |





Rijksinstituut voor Volksgezondheid
en Milieu

*Ministerie van Volksgezondheid,
Welzijn en Sport*

REACH en CLP Helpdesk

Wat doen wij?



Nationale REACH en CLP Helpdesk

- Onderdeel RIVM, Centrum Veiligheid van Stoffen en Producten
- In opdracht van ministeries van I&W en VWS
- REACH en CLP Vraagbaak voor bedrijven
- Presentaties bij brancheverenigingen, bijeenkomsten, symposia
- Communicatie met Europees Chemicaliënagentschap (ECHA) en andere nationale helpdesken (EU)



Vraagbaak voor bedrijven

- www.chemischestoffengoedgeregeld.nl
- Jaarlijks ca. 650 vragen schriftelijk beantwoord
- Uitleg van CLP- en REACH-regelgeving
- Focus op midden- en kleinbedrijf
- Maandelijks spreekuur voor bedrijven
- Geen adviseursrol: bedrijven maken eigen keuzes





Rol van Helpdesk bij Productnotificatie

- NVIC is het orgaan waar productnotificaties worden ingediend
- Productnotificatie valt binnen CLP-verordening (Art. 45)
- Helpdesk beantwoordt inhoudelijke vragen over productnotificaties
 - Expertise van NVIC wordt ingezet waar nodig
 - Samenhang met overige regels in CLP-verordening
- Technische ondersteuning indiening buiten scope
- Voor specifieke handhavingsvragen wordt naar inspectie verwezen



Questions (left)?

