UMC Utrecht

Implementation of CLP Annex VIII

EU harmonised product information for Poisons Centres

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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'

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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'

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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'

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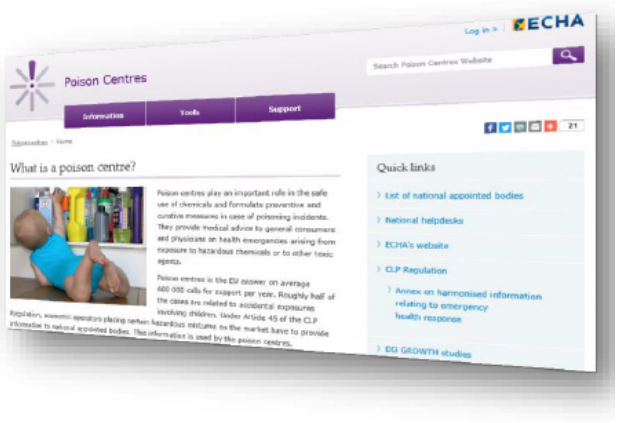
Where are we?

- 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

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Guidance and support

‘drafting guidance…’

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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

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Guidance and support

'… formalising guidance'

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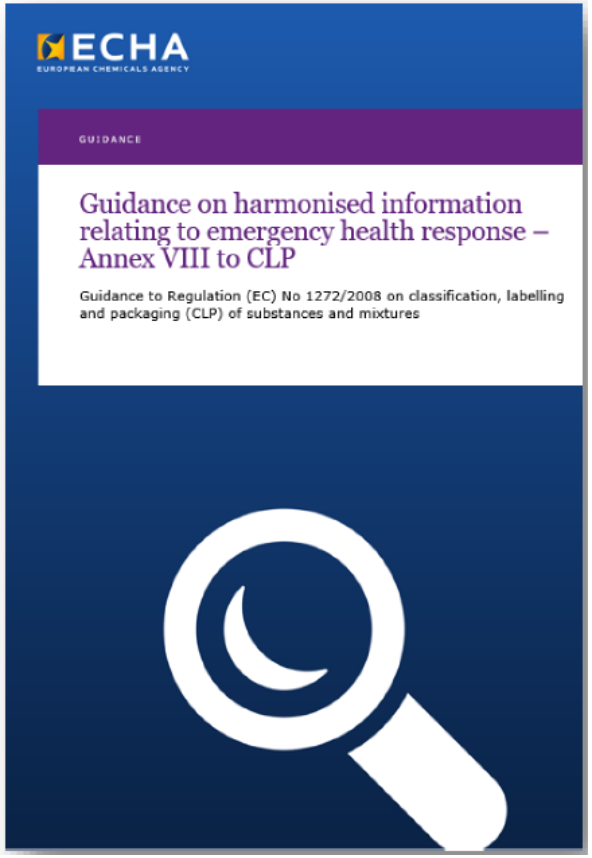
Guidance phase 2

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'

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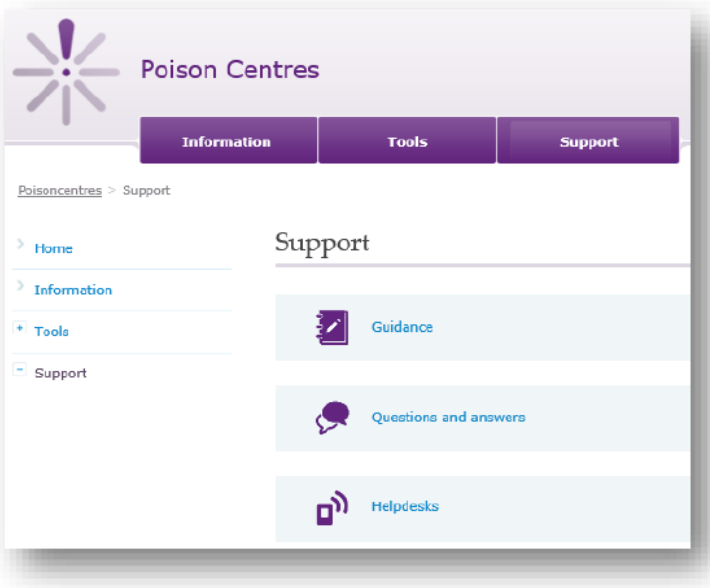
Support - current status

- 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'

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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'

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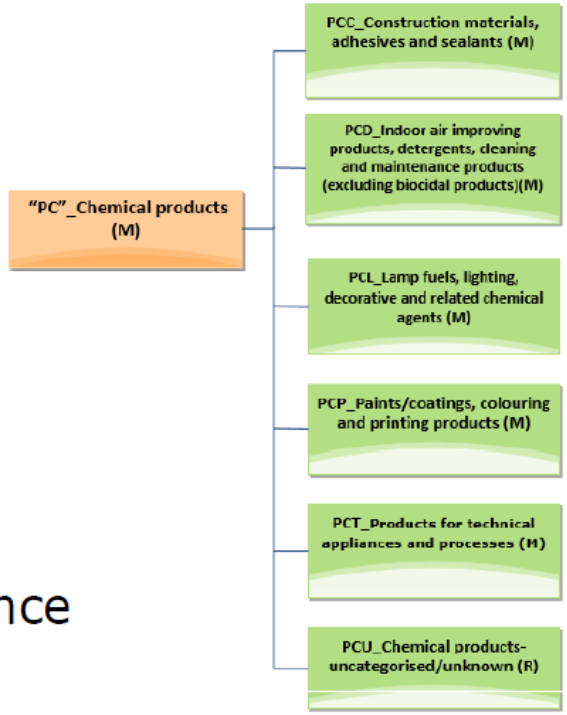
Current status

- 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’

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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'

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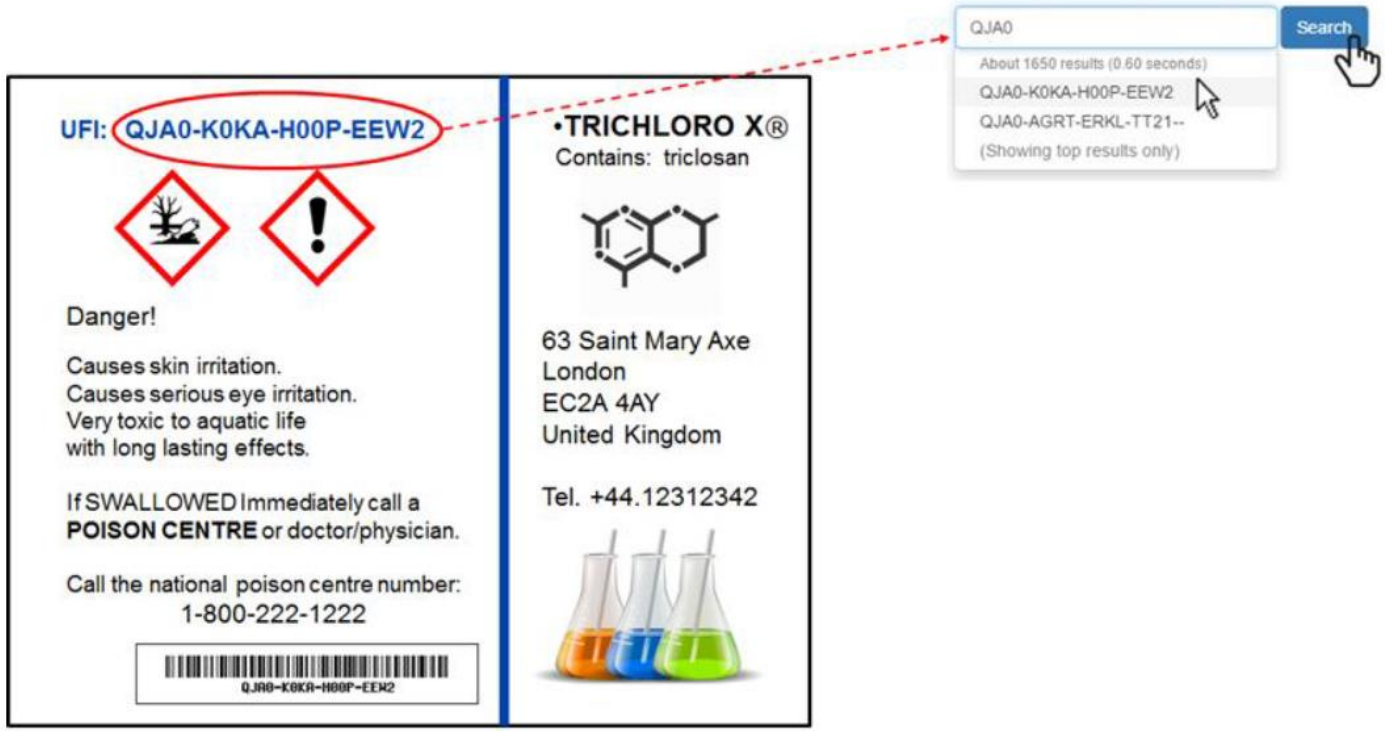
Relevance of UFI for poison centres



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Unique Formula Identifier

'UFI and UFI generator'

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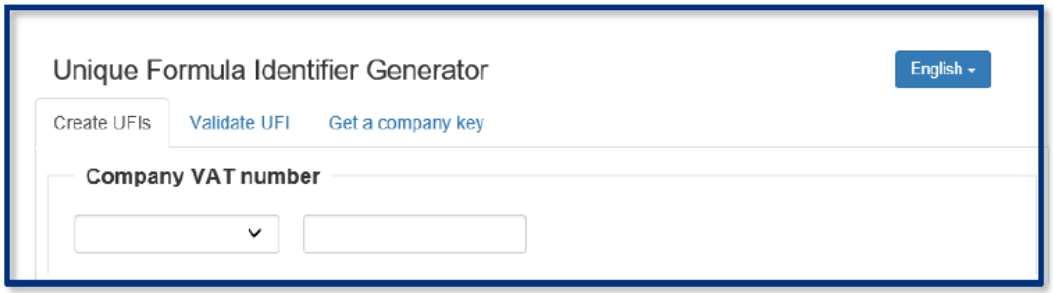
Current status

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



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

IT tools

'Poisons Centre Notification (PCN) format'

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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 feasability study'

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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 feasability study'

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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 feasability study'

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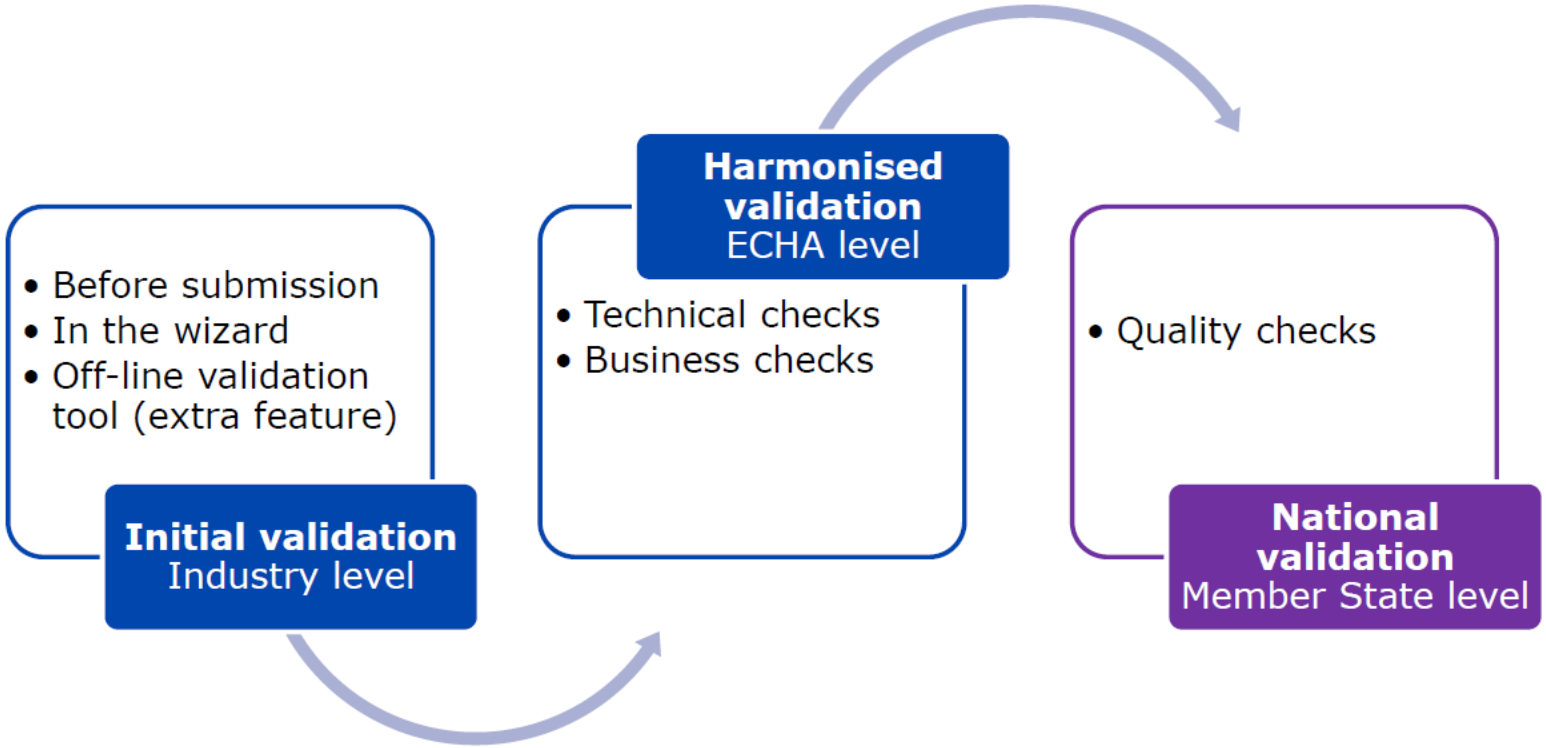
Three levels of validation



IT tools

'PCN portal feasability study'

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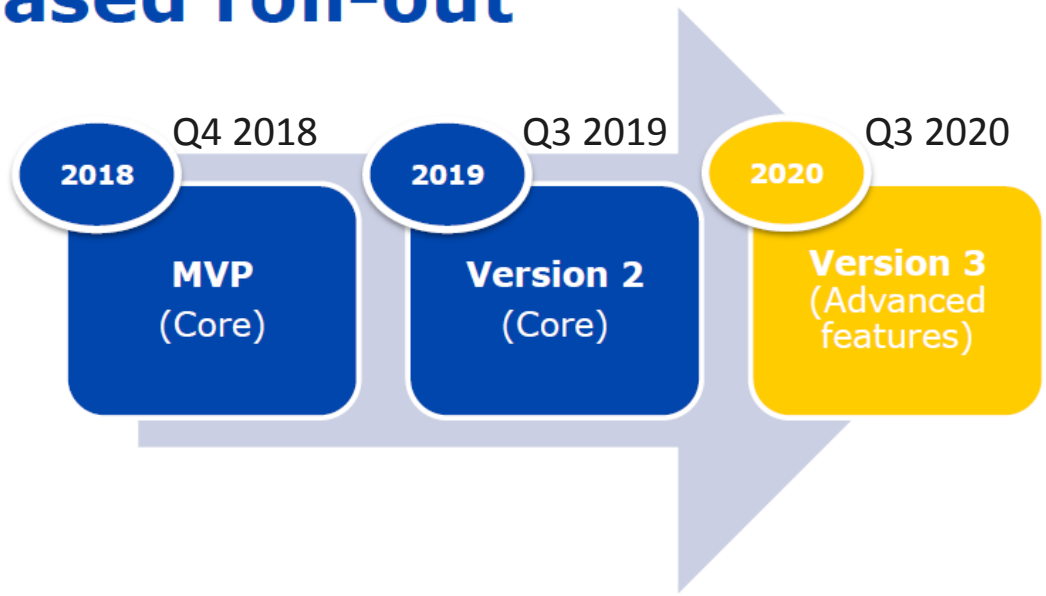
Phased roll-out



- Minimum Viable Product (MVP)
- Incremental product evolution

IT tools

'PCN portal feasability study'

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Core functionalities by 2019

Q4 2018 **MVP** and Q3 2019 **v2**

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

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

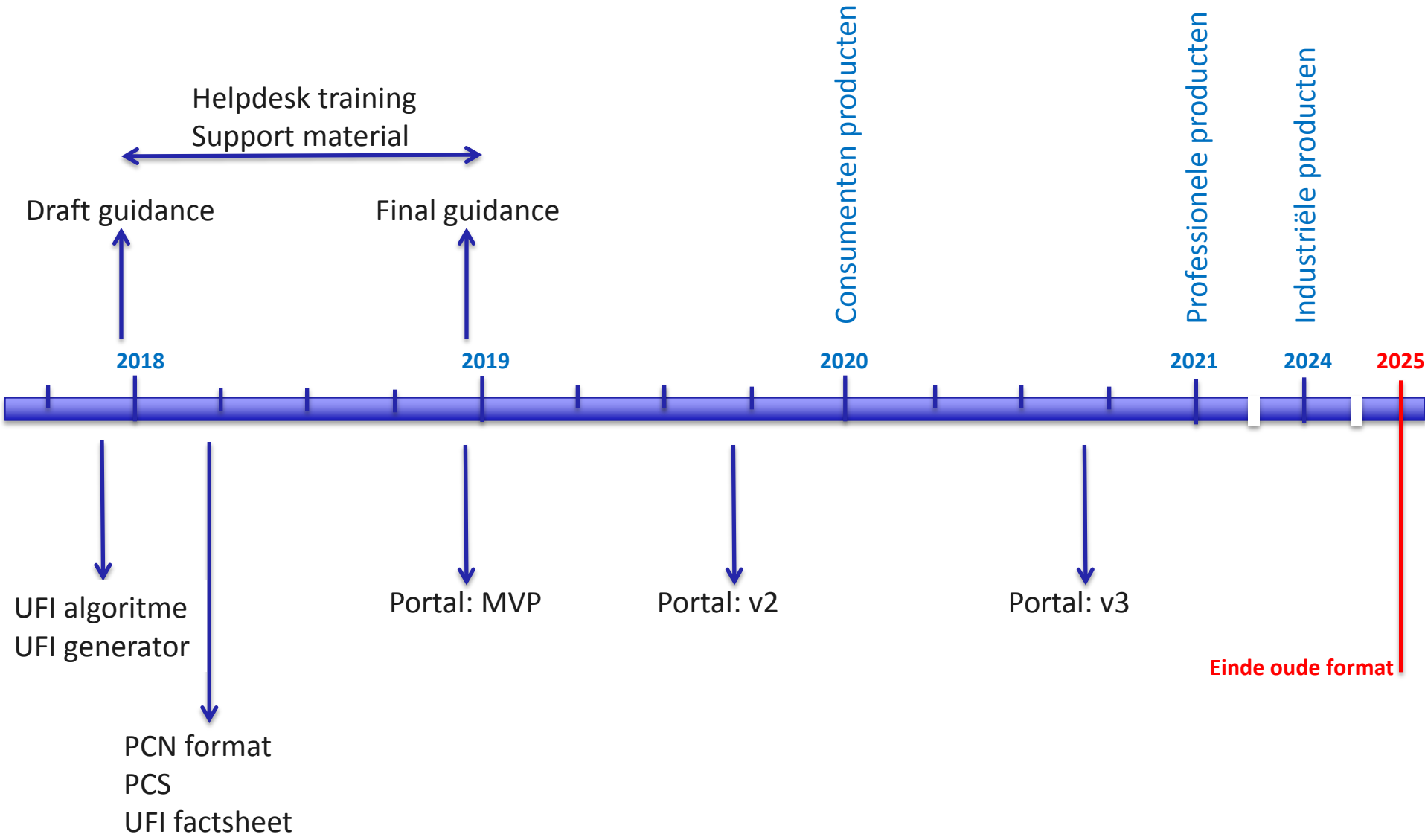
'leftovers and national planning …'

- (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] • 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	- Steekproefsgewijs - Bij analyse belangrijke product groepen - Bij analyse vergiftiging	Idem
Handhaving	NVWA en ILT (ihkv REACH en CLP verplichtingen)	Idem?


Helpdesk training
Support material
Draft guidance
Final guidance
Consumenten producten
Professionele producten
Industriële producten
2018
2019
2020
2021
2024
2025
UFI algoritme
UFI generator
PCN format
PCS
UFI factsheet
Portal: MVP
Portal: v2
Portal: v3
Einde oude format

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)?