Introduction

Webinar: notifying hazardous mixtures for poison centres - what you need to know

3 and 10 October 2017

Heidi Rasikari

Agenda

11:00 – 11:05   **Introduction**
Heidi Rasikari, ECHA

11:05 – 11:15   **Poison centres project – where are we?**
Mercedes Viñas, ECHA

11:15 – 11:40   **Feasibility study outcome and next steps**
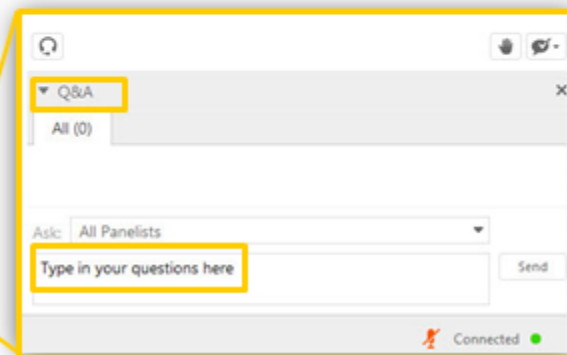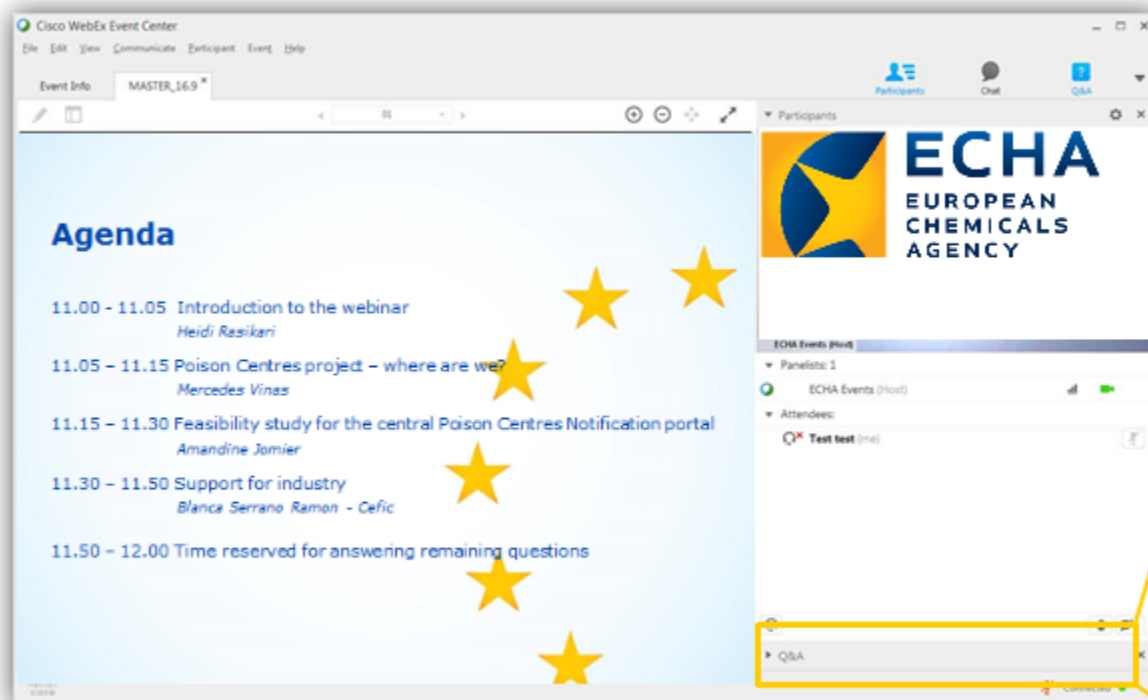Amandine Jomier, ECHA

11:40 – 12:00   **Support for industry**
Blanca Serrano Ramon, Cefic

12:00 – 13:00   Time reserved for answering remaining questions

Use the Q&A panel to:

- Send questions about the presentations

- Send messages if you have any technical difficulties

Q&A panel

- Submit your questions at any time in the Q&A panel - our panellists will answer as many as possible

- If your question is not answered by the end of the webinar - submit it to your national helpdesk or to our helpdesk
https://echa.europa.eu/contact

Recordings published

- On our YouTube channel YouTube.com/EUchemicals

- Webinar materials available on our website

Poison centres project: where are we?

Webinar: notifying hazardous mixtures for poison centres - what you need to know

3 and 10 October 2017

Mercedes Viñas

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

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

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
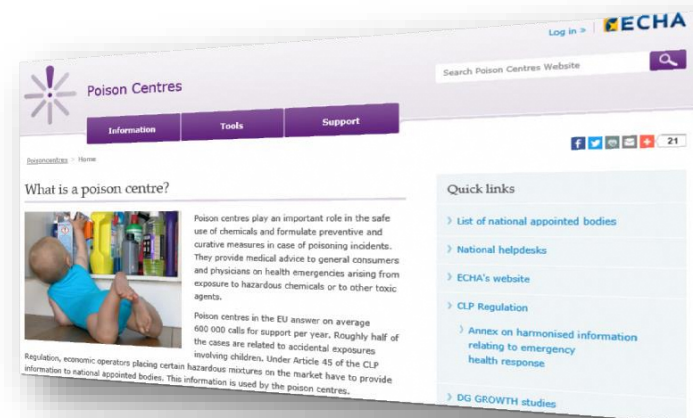
Completion of guidance and support material

2019

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

Central portal ready, first version

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

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

- Workshop planned early December

- First draft by end 2017

Guidance on harmonised information relating to emergency health responses
Draft (Internal) version 1.0 – Month 201x

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 necessary 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. Already based on 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 other medical staff, workers and the general public are able to contact the Poison Centres to get recommendations on medical treatment.
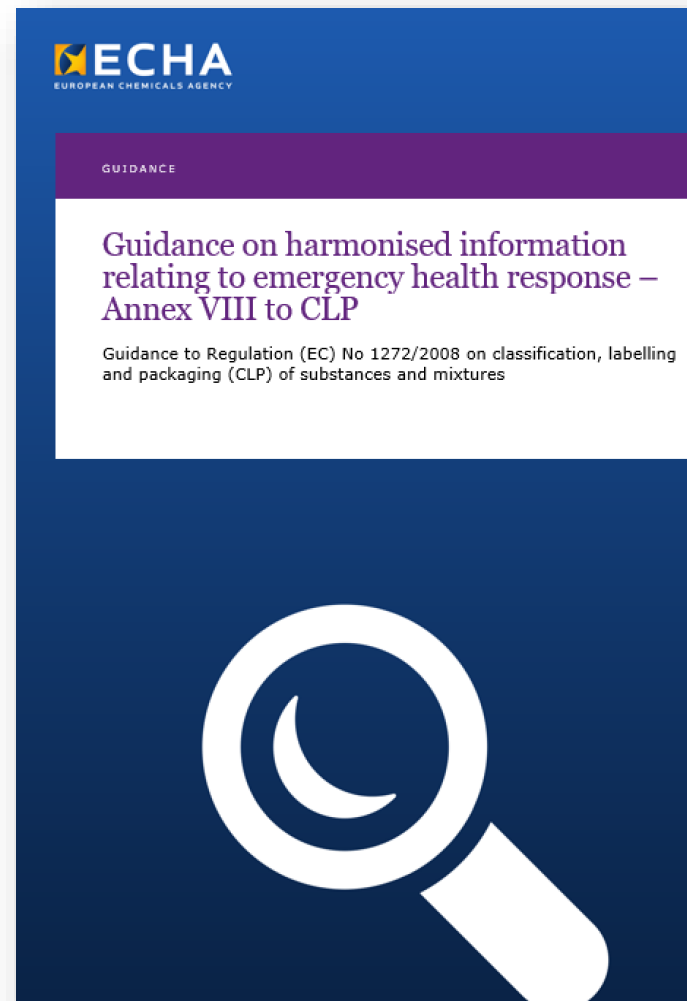
Article 45 of the CLP Regulation ((EC) No 1272/2008, which entered into force on 1 June 2017) requires the EU Member States to appoint bodies for receiving information on the composition of hazardous mixtures (e.g. detergents, paints, adhesives) to enable the formulation of preventive and curative measures. The absence of harmonised information requirements has led to considerable variation in the notification systems, data formats and information requirements regarding the required 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 multiple times 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 received 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, the CLP 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 classification of the mixture and of the company responsible for the placing on the market, as well as the composition and hazardous ingredients and on the uses. The information is submitted via electronic means in a specified format, which enables the appointed bodies to process the relevant information. Through a new unique formula identifier ("UFI", described in section 4 in detail), the Poison Centres, who are the end user of the submitted information, are able to identify exactly the product of concern and to suggest the appropriate medical treatment. The appointed bodies and Poison Centres (which are not necessarily the same entity, although in some Member States this may be the case, see section x) both have the 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

ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on harmonised information relating to emergency health response – Annex VIII to CLP

Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures

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
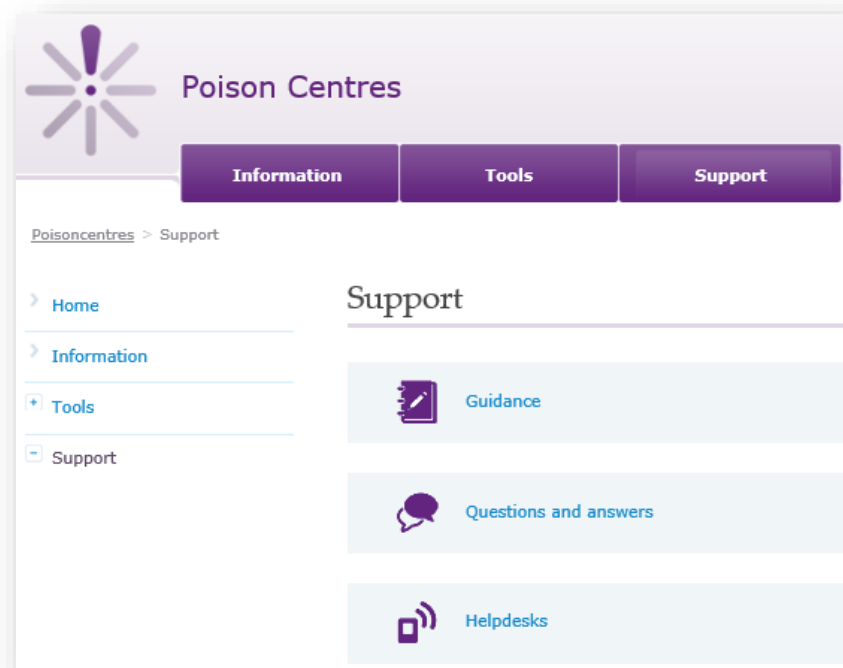
EU Product Categorisation System (EU PCS)

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

Intended use and end user
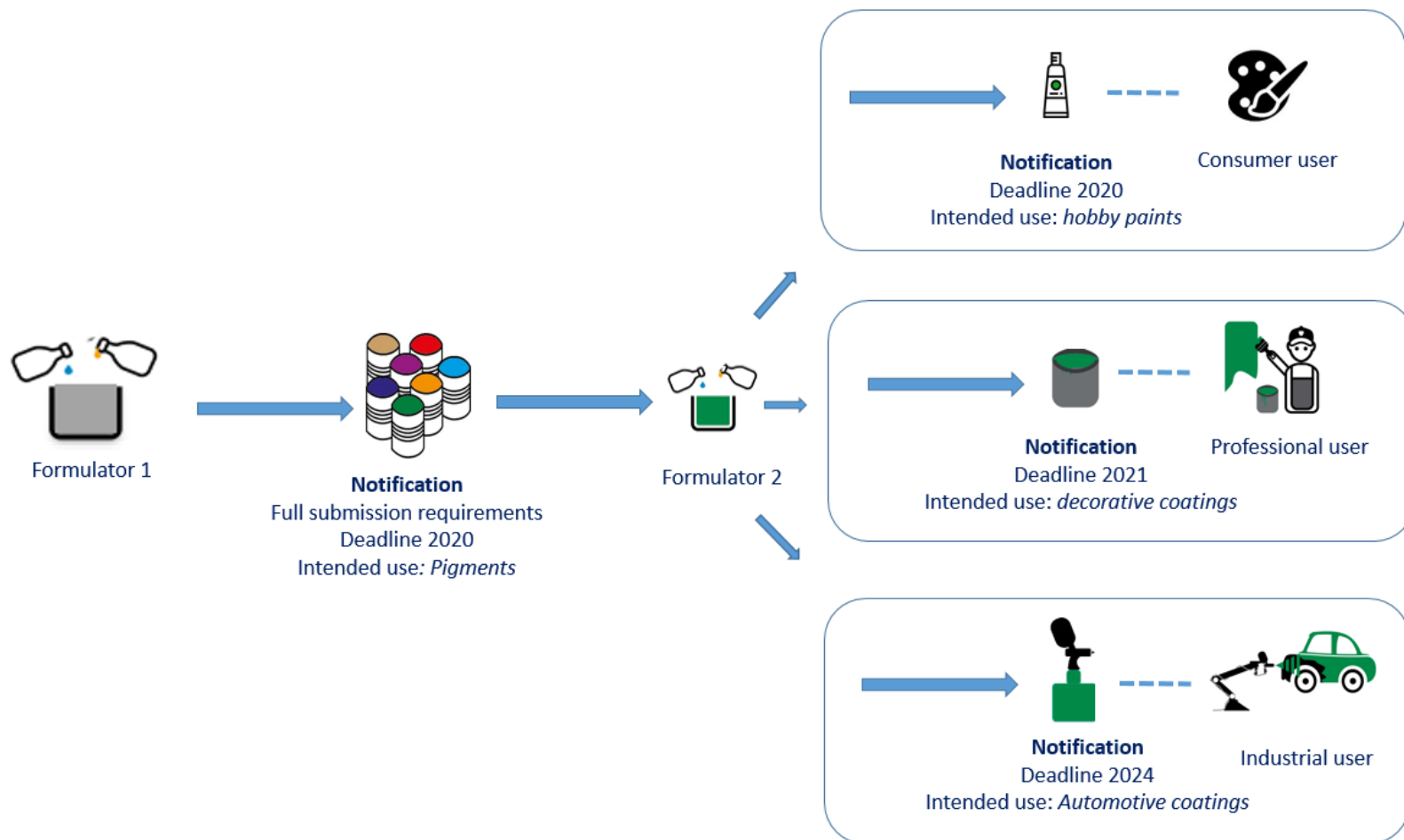
Current status

- 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

"PC"_Chemical products (M)

PCC_Construction materials, adhesives and sealants (M)

PCD_Indoor air improving products, detergents, cleaning and maintenance products (excluding biocidal products)(M)

PCL_Lamp fuels, lighting, decorative and related chemical agents (M)

PCP_Paints/coatings, colouring and printing products (M)

PCT_Products for technical appliances and processes (M)

PCU_Chemical products-uncategorised/unknown (R)

UFI generator

![ECHA - European Chemicals Agency]

Unique Formula Identifier

New notification requirement for product label

Unique 16 character code in 4 blocks

UFI: A300-N06Y-N00U-G73S
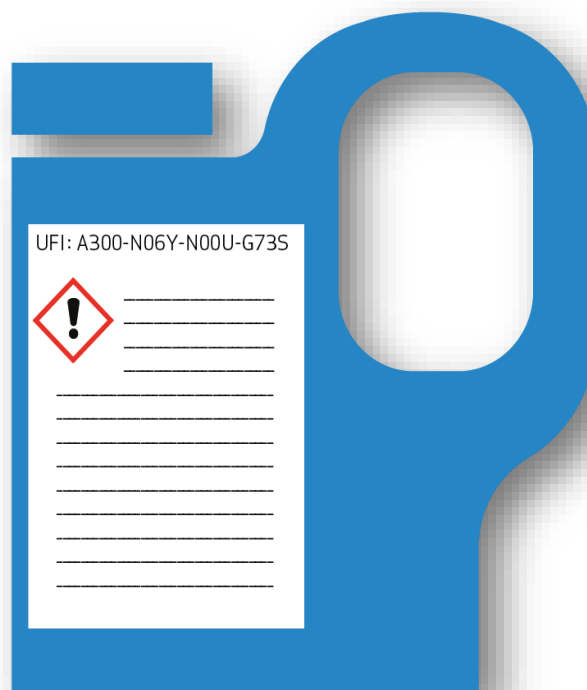
UFI code links the notified mixture information to a specific product on the market

Relevance of UFI for poison centres
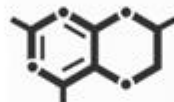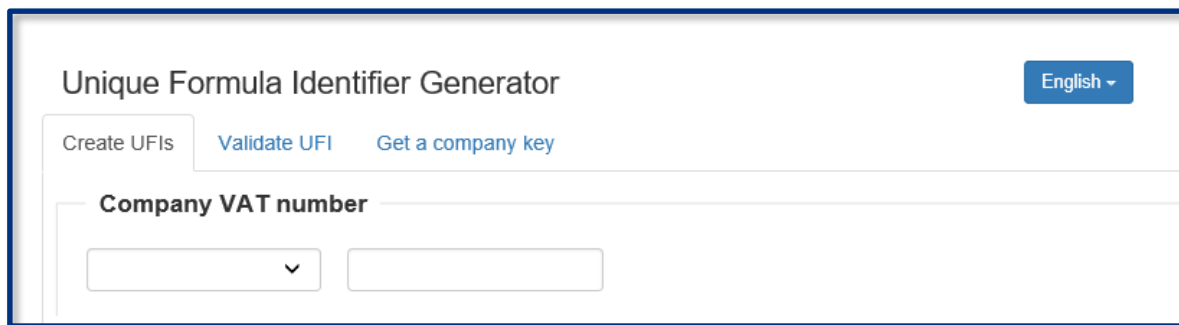
Current status

- 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

Poison Centres 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

Central notification portal

Centralised submission system

- Economies of scale
- Ensure high level of security
- Increase industry efficiency
- Facilitate exchange of information among Member States
- Leverage benefits of harmonised formats

Feasibility study for central poison centre notification portal: outcome and next steps

Webinar: notifying hazardous mixtures for poison centres - what you need to know

3 and 10 October 2017

Amandine Jomier

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

Actors

Industry — Notification → ECHA — Poison Centre Notification Portal → Appointed Bodies / Poison Centres

Additional stakeholders

European Commission

Competent Authorities

Enforcement Authorities
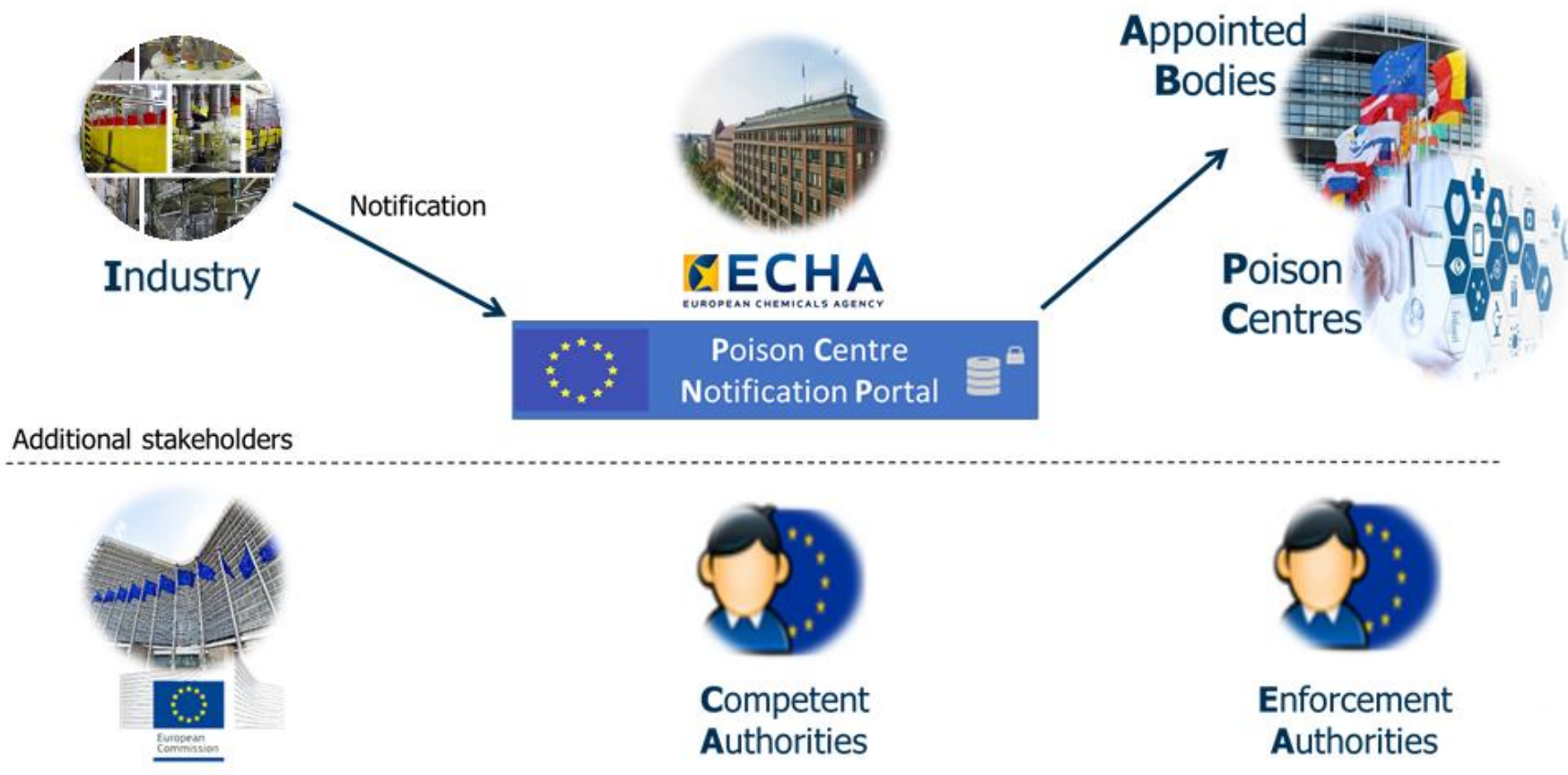
Central portal features

- 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)

Three levels of validation

Initial validation
Industry level

- Before submission
- In the wizard
- Off-line validation tool (extra feature)

Harmonised validation
ECHA level

- Technical checks
- Business checks

National validation
Member State level

- Quality checks

Phased roll-out

2018 — **MVP** (Core)

2019 — **Version 2** (Core)

2020 — **Version 3** (Advanced features)
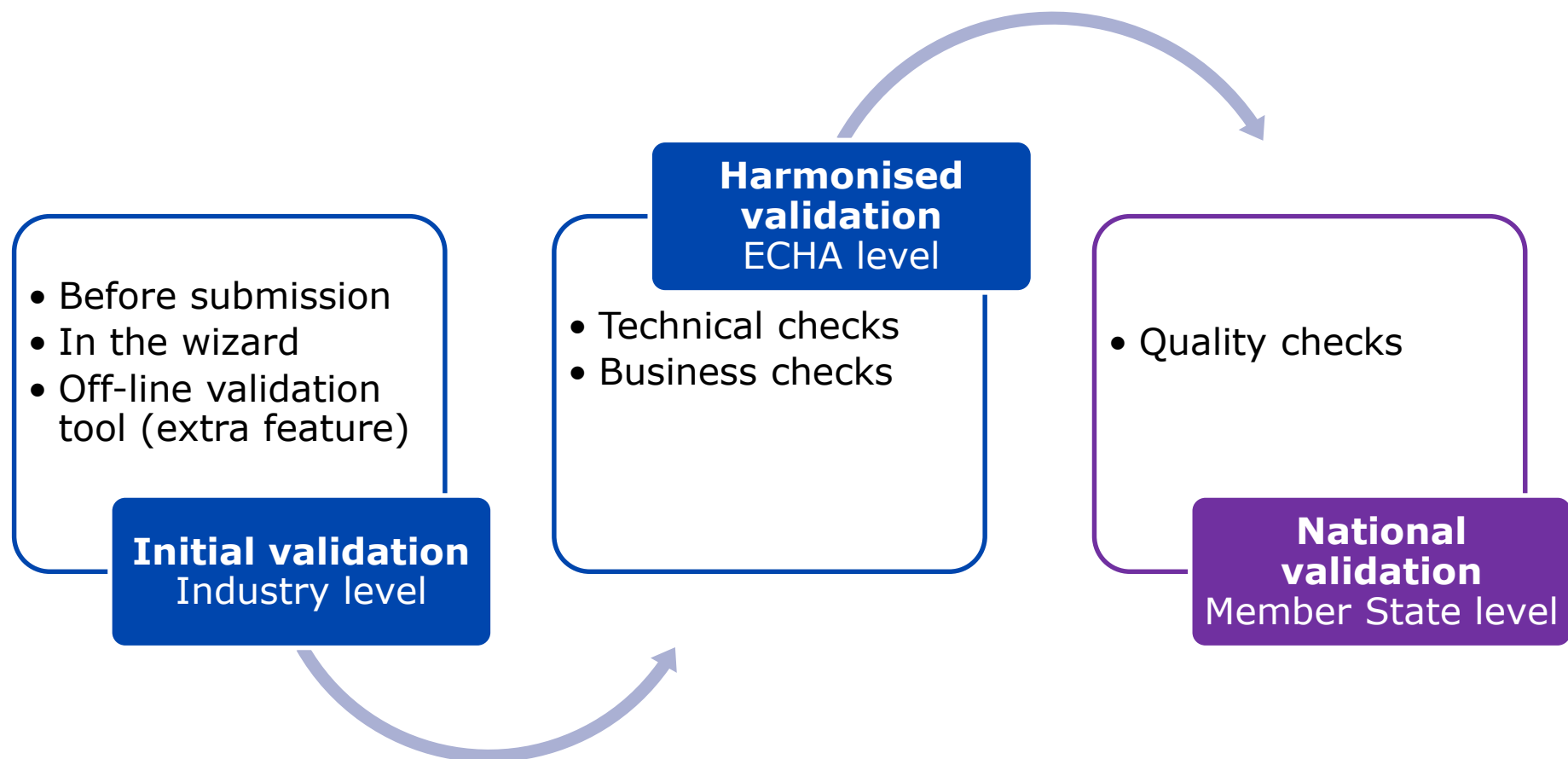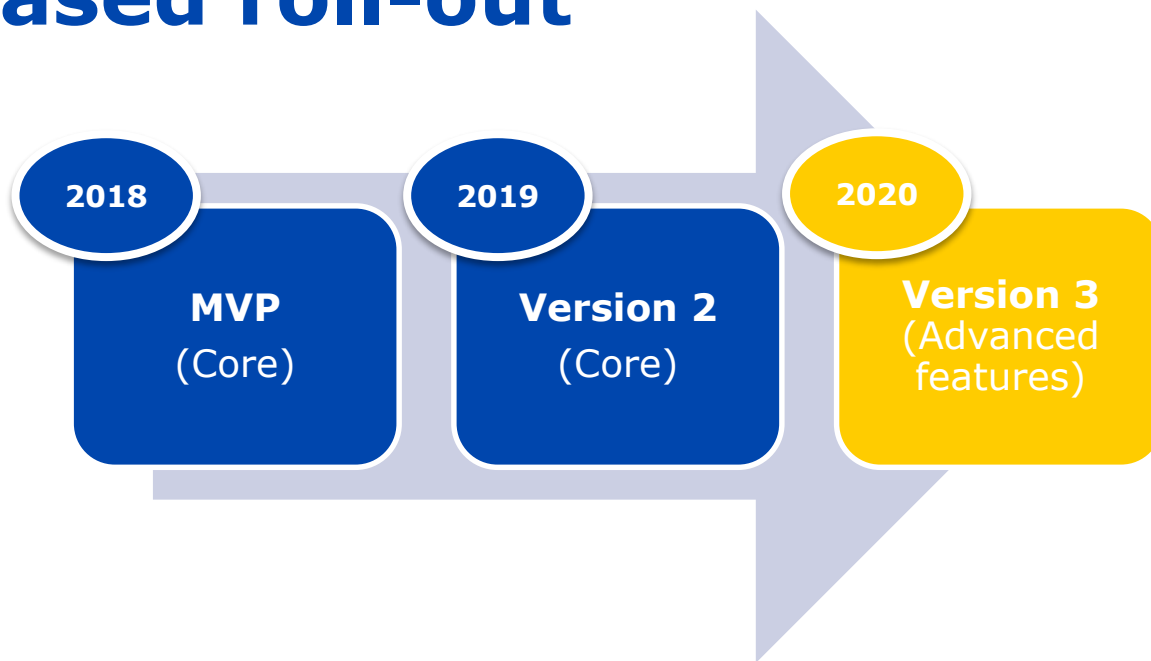
- Minimum Viable Product (MVP)
- Incremental product evolution

Core functionalities by 2019

MVP

and

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.

Features for all users

Mockups are for illustration purposes only. The portal may look different.

User registration and authentication

Registration ✎

Integration with

ECHA Accounts

Authentication

Simple sign-up procedure that gives access to existing ECHA services

Roles administration

Simplified authentication if actor is already known to ECHA

Home page – Menu – Search

MVP

Main menu tailored according to the user role

Interface available in 23 EU Languages

Search always available in the navigation bar

Powerful Search

Check status of the submitted notification

On-line help

- Contextual
- Field by field
- Available in all EU languages
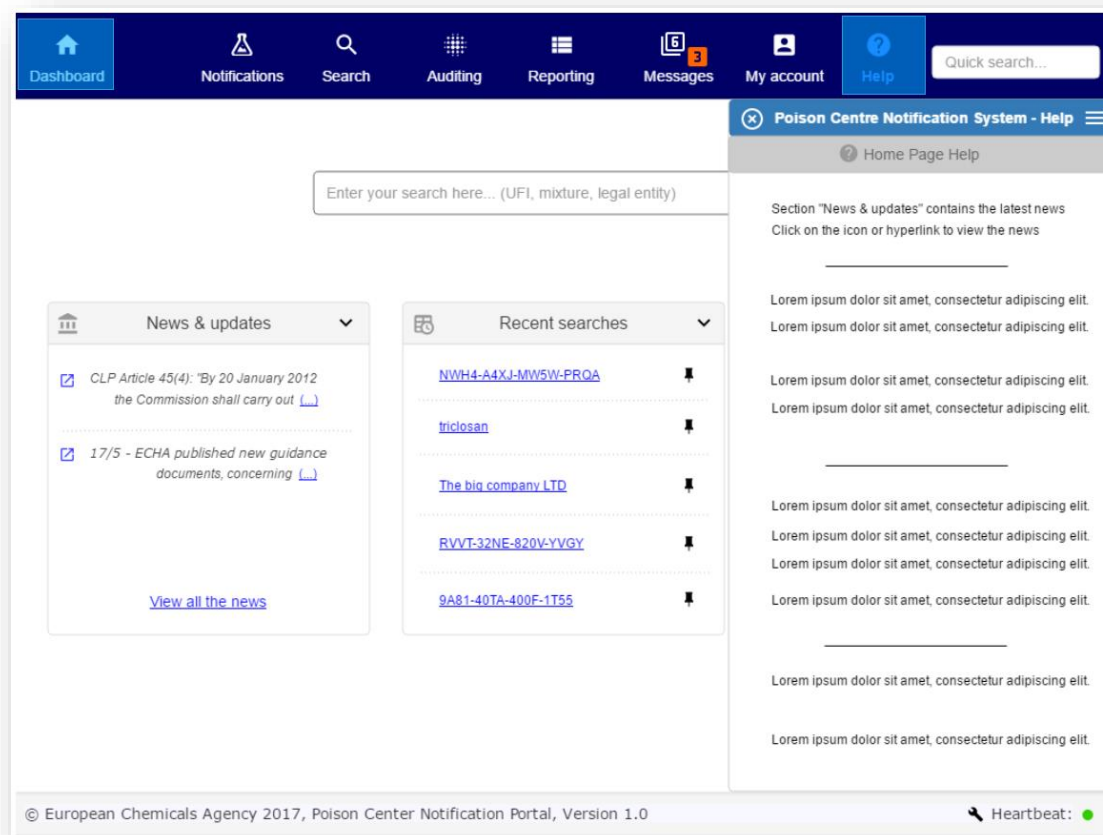
Manage notifications online

MVP

Search notifications

View notifications

Print content

Download

Message box

MVP

✓ Search, view and archive messages generated by the portal

✓ Configure email notification preferences

Advanced

✓ Users exchange messages securely within the portal

✓ Users create tasks in addition to messages
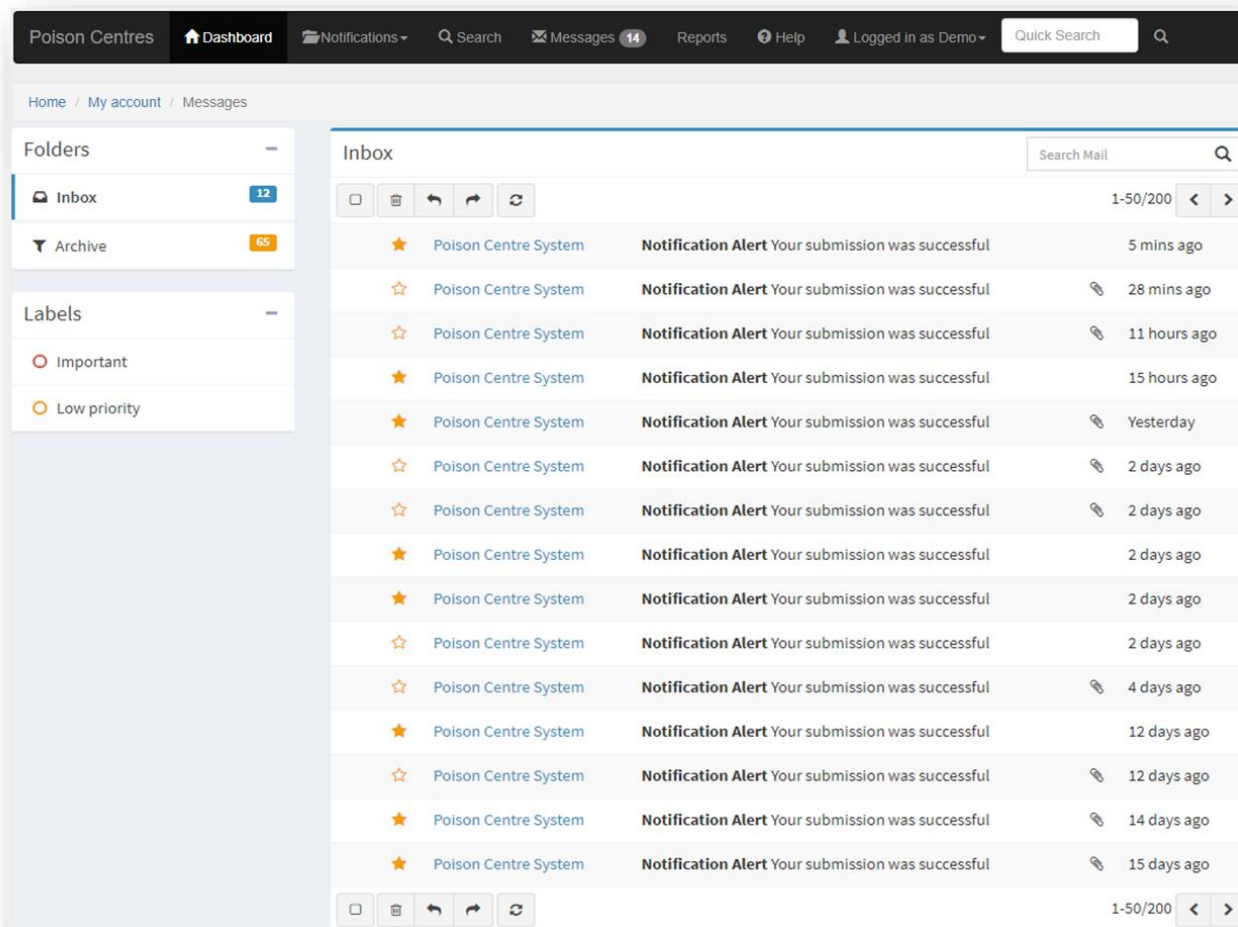
Audit functionality

✓ Comprehensive audit functionality where selected key business events and actions are logged

Industry features

- Support preparation, update and submission of notifications
- Provide support to validation of files prepared offline
- Manage contacts
- Support legal entity changes and transfer of assets

Upload and submit

✓ Initial notifications
✓ Update notifications

Single or Bulk

Prerequisite: files prepared off-line by Industry

📁 Notification Submission

Method   Import off-line notification file ▾

Upload notification

➕ Add files...   ⊕ Start upload   ⊘ Cancel upload

ce930600-9bae-11e7-abc4-cec278b6b50a.i6z   67.37 KB   ⊘ Cancel
Error The file uploaded contains a virus !

de9213700-9bae-11e7-abc4-cec278b6b5a.i6z   67.37 KB   ⊕ Start ⊘ Cancel

❓ Help with your submission

- ☑ The maximum notification file size for uploads in this demo is **999 KB** (default file size is unlimited).
- ☑ Only image files (**XML, I6Z**) are allowed (by default there is no file type restriction).
- ☑ Uploaded files will be deleted automatically after **5 minutes or less** (demo files are stored in memory).
- ☑ You can **drag & drop** files from your desktop on this webpage

Multi-market and multilingual support

✓ Multiple countries in one single notification

✓ Support to several languages in one notification

Online preparation and submission

✓ Fill-in and submit notification on-line

✓ Export, Import draft notification files

(Local file system)

Save and recall an online draft

Validation of files

✓ Validation of a notification file

System-to-system integration

v2

Submit notifications →

Update notifications →

Industry

Advanced

Retrieve notifications ←

MVP

Access via web →

Web-services

Poison Centre Notification Portal

Communication Hub
[Web-service Application]

Notification Processing Engine
[Back-end application]

Central repository

Contact management

MVP

Manage contacts

✓ Create Contacts
✓ Search Contacts
✓ Update contact

v2

Tracking dependency between contact records and notifications to avoid re-submission

Integration with our substance inventory

v2

- ✓ Provides a level of automation and assistance when the user provides or updates the mixtures components.

- ✓ User searches and retrieves the substance identity using:
  - EC
  - CAS
  - Chemical Name
  - Index Number (Annex VI)

Note: Business checks can also validate the correctness of the substance identifiers provided by industry

But also…

- Support to legal entity (LE) changes to be further analysed

LE changes triggered by:

✓ change in the legal entity ownership or structure (e.g. one company is acquired by another company)
✓ change in the business strategy (e.g. a company decides to sell its operations in one MS to a different legal entity)

Features for appointed bodies and poison centres

- Searchable access to notifications relevant to their territory
- Dispatch of notifications via system-to-system integrations
- Support to notification review or invoicing
- Dedicated services

Receive notifications

Communication Hub
[Web-service Application]

Notification Processing Engine
[Back-end application]

Central repository

Subscribe

Secure Transfer of Data

National Systems

Appointed Bodies

Authorities Web interface

Poison Centres
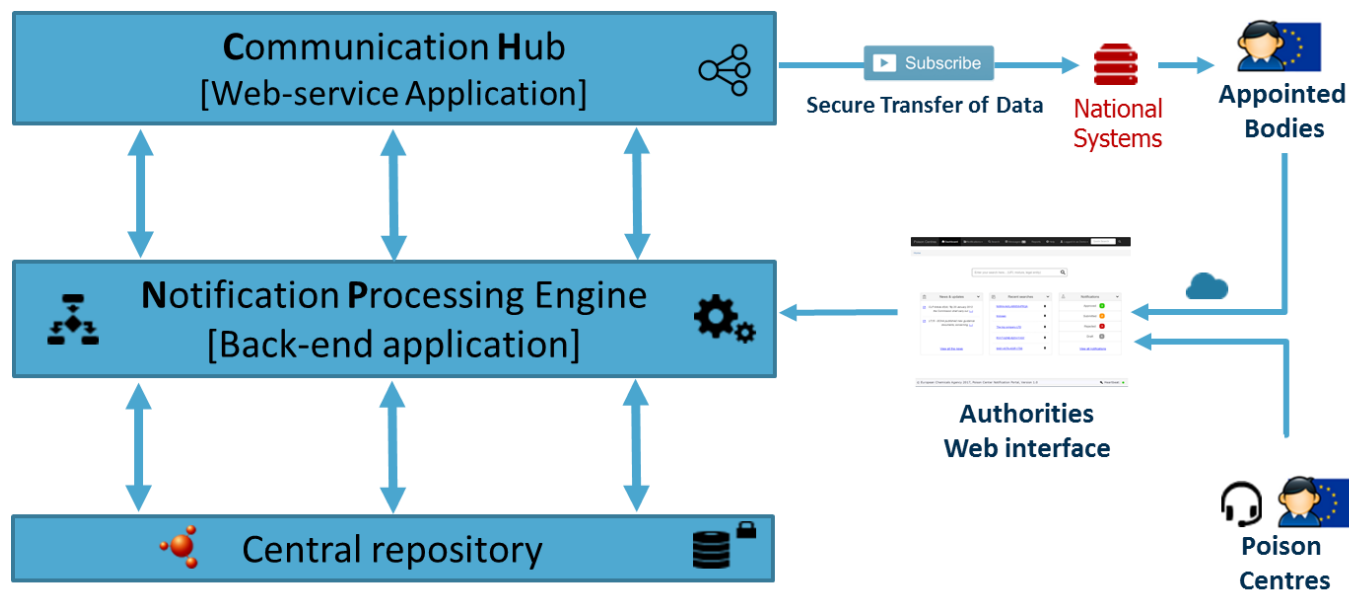
MVP

Through web interface:
- Search
- View
- Download

v2

via Web-services

Support to notification review

- Quality checks performed at national level
- PCN portal could support communication

v2	Record notification review status e.g. 'initiated' vs 'completed'
v2	Provide remarks (rationale) and send request to Industry
Advanced	Annotate(flag) problematic notification data

Support to invoicing

- Invoicing at national level
- PCN portal could:
  - Provide indication to industry on fee per Member State
  - Provide reports to Member States to support their national invoicing process

v2 **Advanced**

ECHA services to Member States (ideas captured)

- Dedicated environment with increased availability

🔍 Support for **advanced search** capabilities

📊 Additional **reporting capabilities** or data analytic services

📋 Support for **recording** emergency health **incident data**

💧 **Support** for notification **quality check** at national level (e.g. national-level workflow orchestration)

v2 **?**

Advanced **?**

In short

Core Features MVP	Core features V2	Adv. Features V3
▪ **User registration and authentication (via ECHA Accounts)** ▪ **Home page and search functionalities** ▪ **Upload, submit and update notification files prepared off-line** ▪ **Manage notifications (Search/View/Download/Print)** ▪ **Manage message box** ▪ **Multi-market and multilingualism** ▪ **Audit logs** ▪ **Basic contact management** ▪ **Dispatch of notifications** ▪ **Notification workflow processes (including technical checks)** ▪ **ECHA Operational Dashboard (search, view and manage processes)**	▪ **Online help** ▪ **Prepare, update and submit notifications online** ▪ **Tracking dependency between contact records and notifications** ▪ **Validation of files before submission** ▪ **Industry system integration** ▪ **MS system integration** ▪ **Support for the review of notifications and invoicing performed at national level** ▪ **Dedicated services to Member States (core or advanced)** ▪ **Integration with ECHA substance inventory** ▪ **Enhanced notification workflow processes (Business checks)**	▪ **Save and recall online notification draft** ▪ **Support to Legal Entity Changes** ▪ **Validation of notifications via web-services** ▪ **Additional and enhanced features for all users** ▪ **Sending of internal messages and tasks between users**

Proposing an architecture blueprint

Main principles

- Reuse proven existing solutions where possible
- Favour standards over custom solutions
- Clear separation of concerns between components

Main constraints

- Must fit our IT architecture
- Must be delivered within agreed timelines

Key conclusions reached

- Using standardised formats: making PCN format compatible with IUCLID XML
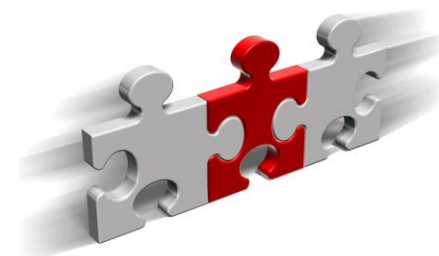
- Re-using "ECHA Accounts" concept for sign-up, authentication and administration of users and parties

- Integrating with our substance repositories as reference sources to support notification file preparation and validation

- Re-using our reporting platform to support the compilation of advanced reports and statistics

- Relying on other existing infrastructure elements

  (secure VPN, virus scanning services, email services, etc.)

High level architecture
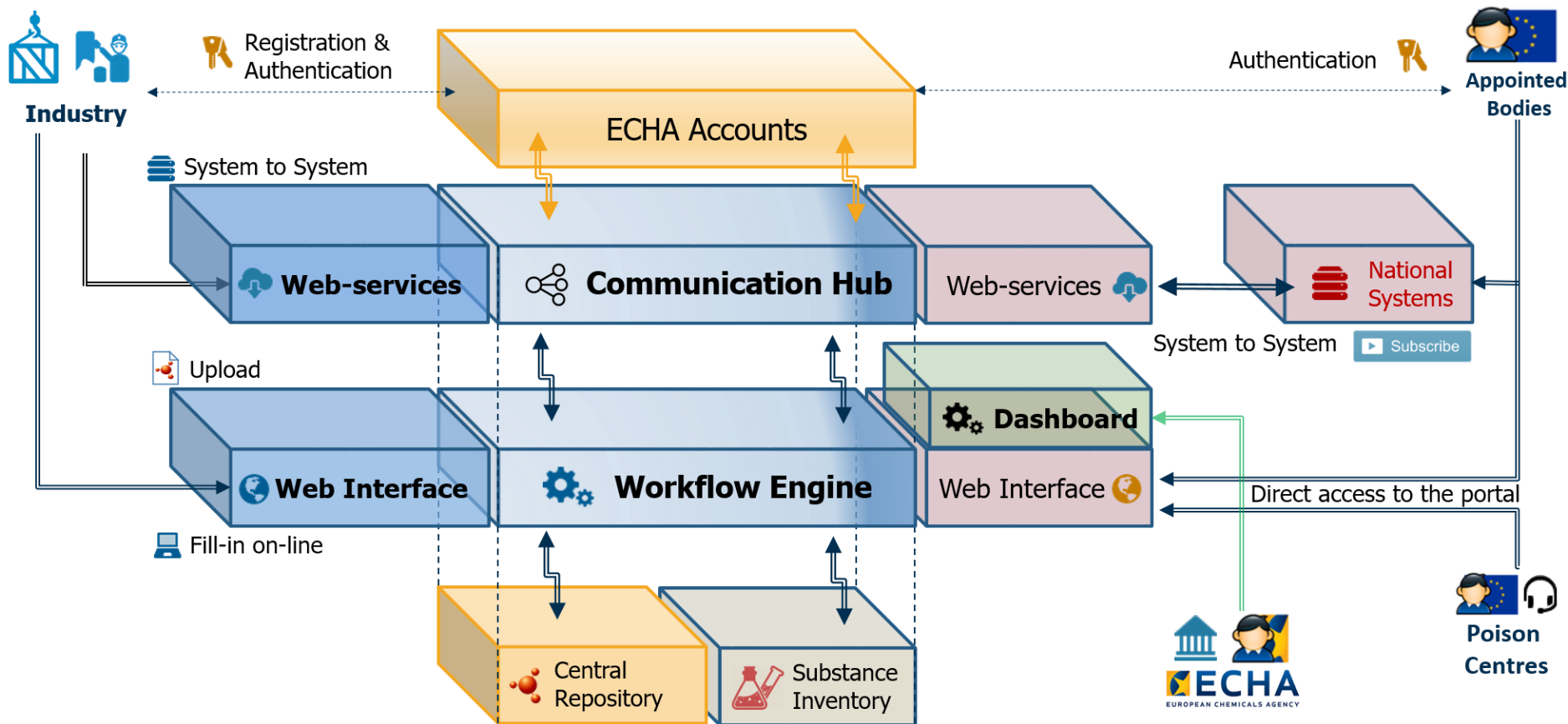
Related services

- Training
- Communication and awareness raising
- Helpdesk support to industry together with MS
- Support to MS on the implementation

Project timelines

22nd Mar
Adoption 2017/542 Regulation*

YOU ARE HERE

PCN format
❖ Q1 2018

3 Major releases
❖ Q4 2018
❖ Q3 2019
❖ Q3 2020

1st Jan
Notifications industrial use

| 2017 | 2018 | 2019 | 2020 | 2021 | […] | 2024 |

1st Jan
Notifications consumer use

1st Jan
Notifications professional use

2025
End of transition period

* Amedment to the CLP Regulation (EC) No 1272/2008 – Annex VIII
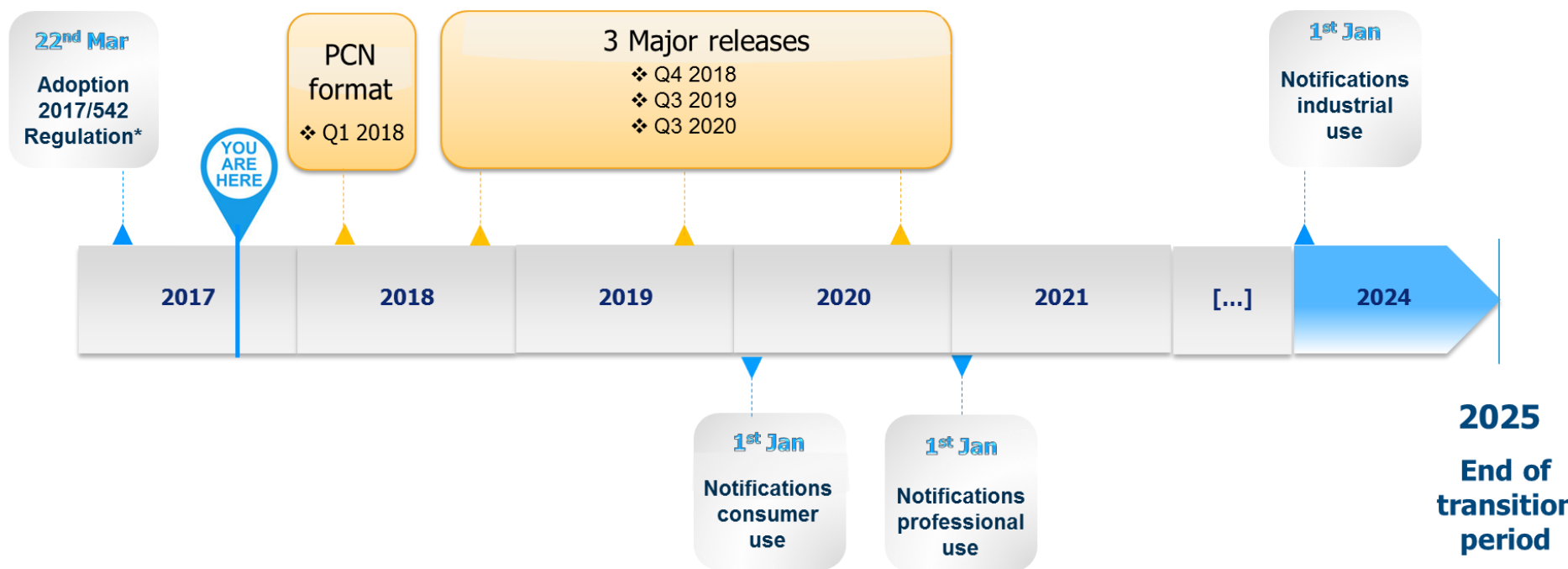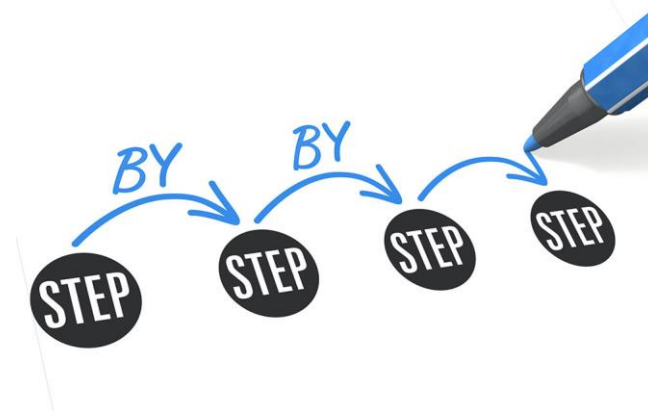
Next steps

- Continue and refine analysis needs for various stakeholders
- Finalisation of notification format
  - Revised information requirements and process aspects need to be taken on board
- Develop validations
- Continue analysis of architecture and security model
- Decisions
  - Meeting of the Member States Competent Authorities (Oct.)
  - Caracal (Nov.)
  - ECHA Management Board decision (Dec.)

Get ready

Member states

- Decide on options to receive and manage notifications

- Adapt or develop internal database infrastructure accordingly

All: industry, appointed bodies & poison centres

- Support business analysis and express your needs
  - Make sure we develop what you need

- Build capacity to support next year's development phase and test features

Thank you!

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