

EU Poison Centres Notification portal – results of the feasibility study and upcoming developments

20 November 2017
8th BfR User Conference on Product Notifications
Berlin, Germany

Daniel Sompolski
Dossier Submission Unit
European Chemicals Agency

- 1. Format - how will industry prepare information?**
- 2. How will industry submit information?**
- 3. How will Member States (appointed bodies and poison centres) receive information?**
- 4. Questions and answers**

Preparing the notification

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

Submitting the notification

Poison Centres Notification (PCN) portal

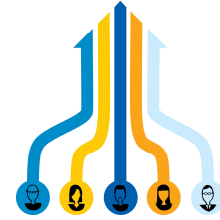


Feasibility study - objectives



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

Centralised submission system

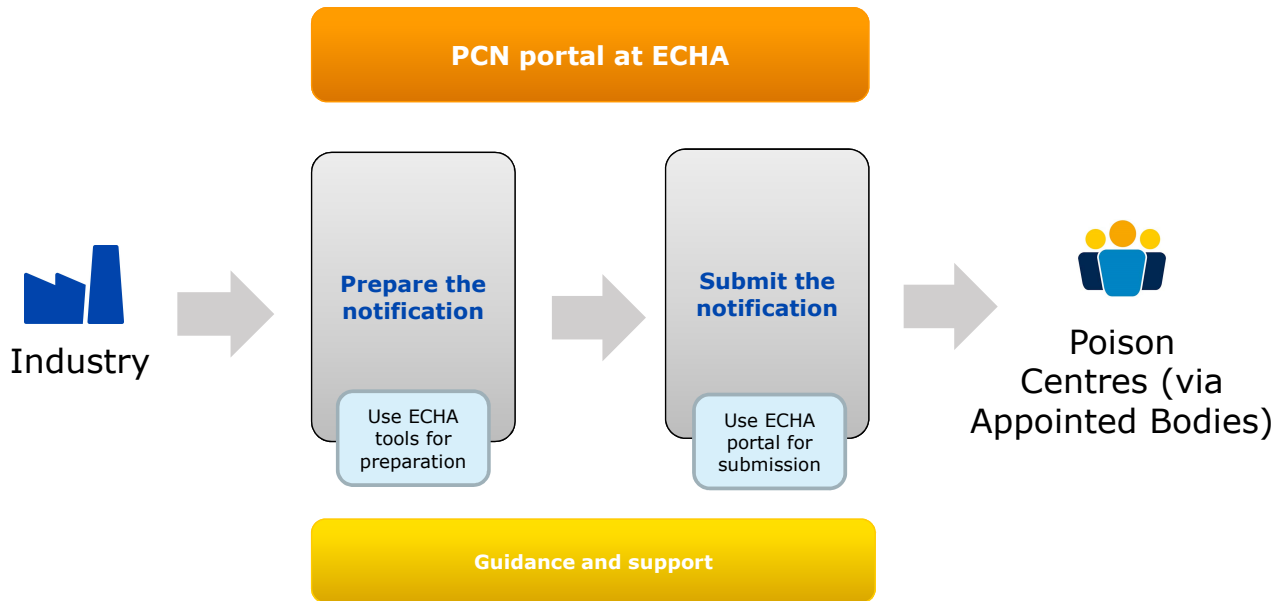


- Economies of scale
- Ensure high level of security
- Increase industry efficiency
- Facilitate exchange of information among Member States
- Leverage benefits of harmonised formats

Actors

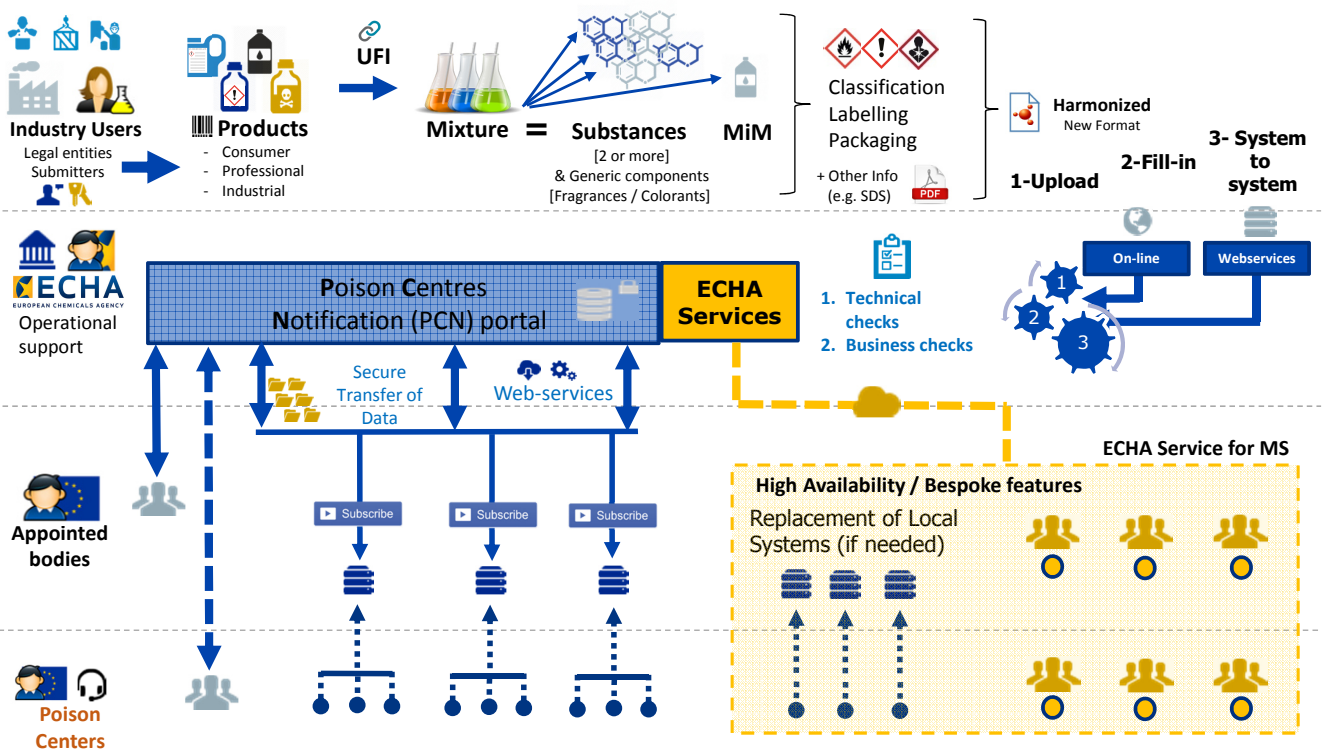


Feasibility study



echa.europa.eu

PCN portal



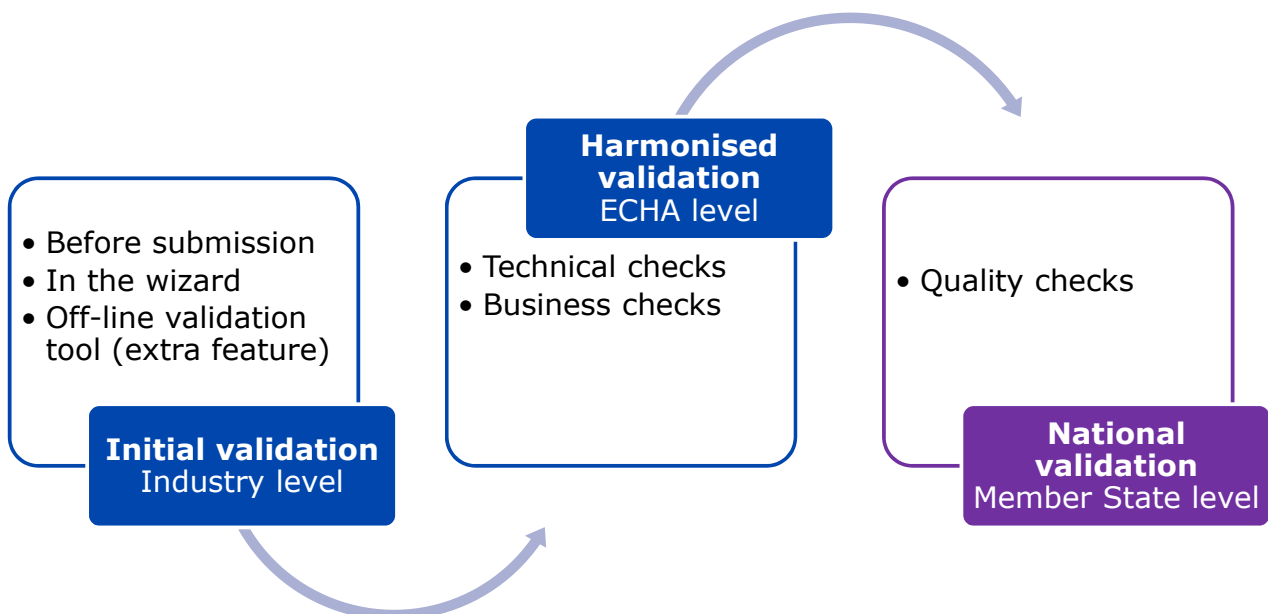
echa.europa.eu

Central portal features

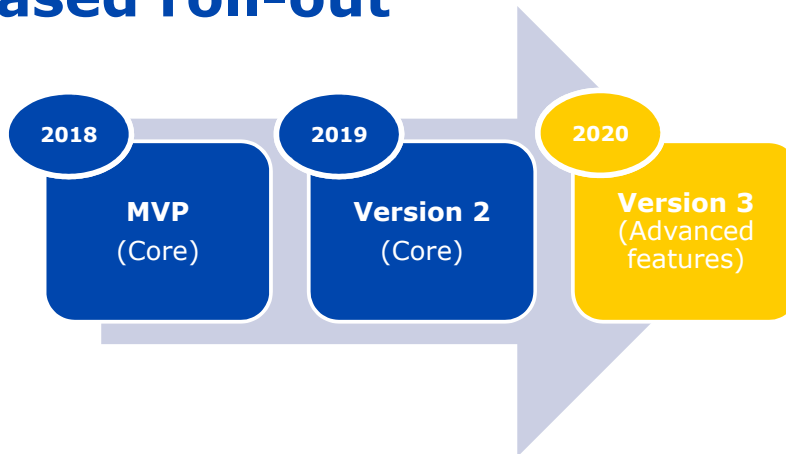
- Collect and dispatch notifications from industry to appointed bodies
 - Secure transfer of information
 - Multilingual support
- Automated submission with agreed validations
 - Technical checks (e.g. virus scan)
 - Business checks and basic verification of key elements (e.g. trade name included in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



Three levels of validation



Phased roll-out



- Minimum Viable Product (MVP)
- Incremental product evolution

Core functionalities by 2019

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

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.

In short

Core Features MVP	Core features V2	Adv. Features V3
<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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
<p>(search) ECHA Operational Dashboard</p> <p>(notification) ECHA Operational Dashboard</p>	<p>echa.europa.eu</p>	

15

Webinar

<https://www.youtube.com/watch?v=XlhPHC5L2dU&feature=youtu.be>

Proposing an architecture blueprint

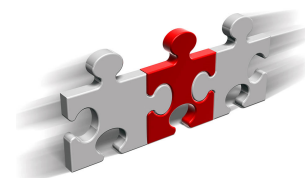
Main principles

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

Main constraints

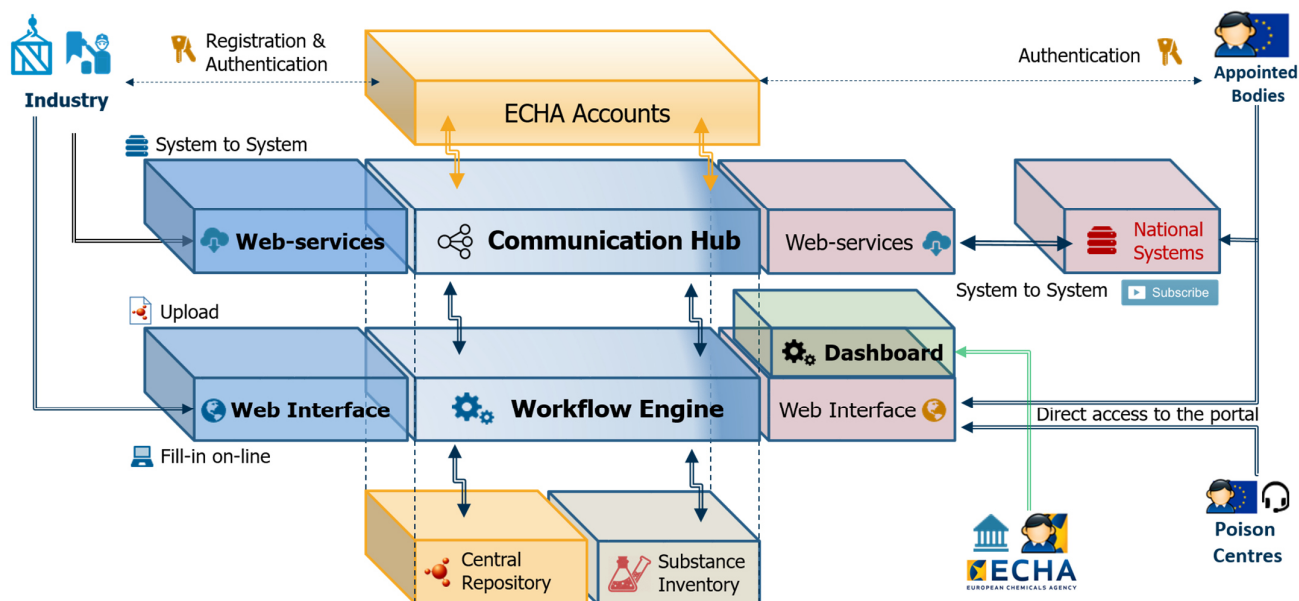
- Must fit our IT architecture
- Must be delivered within agreed timelines

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 ECHA 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.)

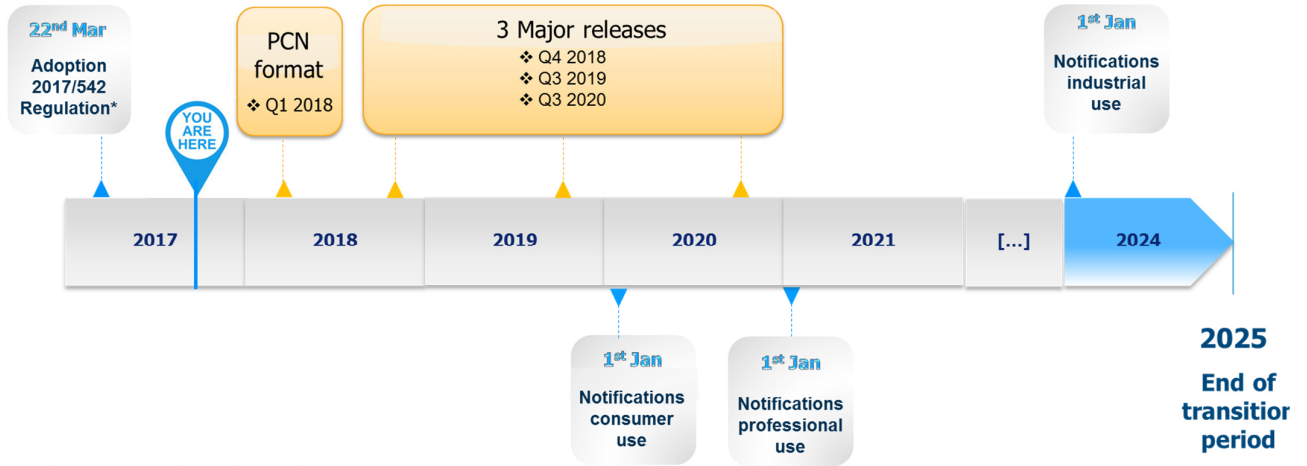
High level architecture



Related services

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

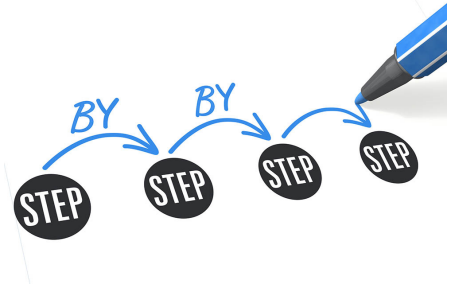
Project timelines



* Amendment to the CLP Regulation (EC) No 1272/2008 – Annex VIII

Next steps & getting ready





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
 - CARACAL 16 November 2017
 - ECHA Management Board decision 15 December 2017

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

Questions and answers



Thank you!

poisoncentres@echa.europa.eu
<https://poisoncentres.echa.europa.eu/>

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
[@EU_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook
[Facebook.com/EUECHA](https://www.facebook.com/EUECHA)