



Poison Centre Notification System

Feasibility Study Report

Contract:	Specific Contract No 63 (ECHA/2017/160)
File location:	
Ref.:	PCN.Feasibility Study Report.v1.docx

Status information

Security classification:	Restricted communication	State :	FINAL
Current version number:	v1.1	Date of first issue :	31/7/2017
Prepared by:	Trasys	Date:	9/10/2017
Verified by:	Trasys	Date:	9/10/2017
Approved by:	Trasys	Date:	9/10/2017

## Circulation / distribution list

Name	Organization	I/A
ECHA internals	ECHA	
Trasys project team members	Trasys	

(I = for information, A = for action)

## Table of Contents

<b>1 EXECUTIVE SUMMARY</b>	<b>6</b>
<b>2 INTRODUCTION</b>	<b>8</b>
2.1 Background	8
2.2 Problem statement	8
2.3 Actors <sup>9</sup>	
2.3.1 Industry	9
2.3.2 Appointed Bodies and Poison Centres	10
2.3.3 ECHA	11
2.3.4 Additional stakeholders	11
<b>3 OBJECTIVES OF THIS STUDY</b>	<b>12</b>
<b>4 METHODOLOGY</b>	<b>13</b>
<b>5 SOLUTION SPACE</b>	<b>16</b>
<b>6 FUNCTIONAL AREAS AND FEATURES</b>	<b>17</b>
6.1 Common functionalities	17
6.1.1 Sign up / authenticate and manage users	17
6.1.2 Manage message box	17
6.1.3 Manage notifications on-line	17
6.1.4 Display on-line help	18
6.2 Industry	18
6.2.1 Fill-in and submit a notification on-line	18
6.2.2 Upload and submit notification files that were prepared offline	19
6.2.3 Update a notification	19
6.2.4 Industry system integration	19
6.2.5 Validate a notification file	20
6.2.6 Manage contacts	20
6.2.7 Change Submitter Legal Entity	20
6.3 Appointed Bodies and Poison Centres	20
6.3.1 Review notification	20
6.3.2 MS system integration	21
6.4 ECHA	21
6.4.1 Provide operational support	21
6.5 System	21
6.5.1 Perform notification workflow processes	21
6.5.2 Provide integration with ECHA substance inventories	22
6.5.3 Provide multilingual User Interface	22
6.5.4 Provide audit functionality	22

6.6 Provide dedicated services for Member States	22
<b>7 NON-FUNCTIONAL REQUIREMENTS</b>	<b>24</b>
<b>8 MINIMUM VIABLE PRODUCT AND PRODUCT BACKLOG</b>	<b>30</b>
<b>9 ARCHITECTURE OF THE NOTIFICATION PORTAL</b>	<b>35</b>
9.1 Founding principles	35
9.1.1 ECHA Enterprise Architecture	35
9.1.2 IUCLID format and software reuse	35
9.1.3 Notifications must be stored	35
9.1.4 An incremental delivery approach must be possible	36
9.2 Information and application architecture	36
9.2.1 ECHA Services to MSs	37
9.3 System Architecture	38
9.3.1 ECHA Services to MSs	39
<b>10 DESCRIPTION OF THE BUILDING BLOCKS</b>	<b>41</b>
10.1 Notification Format	41
10.2 Online Notification Preparation Tool	42
10.3 Web Services Communication Hubs	43
10.3.1 ECHA Services to MSs	43
10.4 Portal User Interfaces	43
10.4.1 ECHA Services to MSs	44
10.5 Notification Processing and Access Back-end application and Data Storage	44
10.5.1 Data storage	44
10.5.2 Notification Processing and Access Back-end application	44
10.5.3 ECHA Services to MSs	45
10.6 Notification Validation Tool	45
<b>11 RELATED SERVICES</b>	<b>47</b>
<b>12 SYSTEM IMPLEMENTATION COSTS</b>	<b>49</b>
12.1 Estimation methodology	49
12.2 Cost Projection	49
12.2.1 ECHA Profiles	50
<b>13 SERVICE AND SUPPORT COSTS</b>	<b>51</b>
13.1 Service Desk Organisation	51
13.2 Identifying the PCN Portal service desk staffing needs	51
13.3 Open Issues	53

---

<b>14 SUGGESTED IMPLEMENTATION PLAN</b>	<b>54</b>
14.1 Project Timeline	54
14.2 MVP Implementation Plan	55
<b>15 ELEMENTS FOR THE EX-ANTE EVALUATION</b>	<b>56</b>
15.1 Cost savings for Industry and Appointed bodies	56
15.2 Quality of information and data integrity	56
15.3 Notification submission and preparation process	57
15.4 Security and accessibility	57
<b>16 CONCLUSIONS</b>	<b>59</b>
16.1 Open Issues	59
16.2 Next Steps	62
<b>17 APPENDIX 1: REFERENCES AND RELATED DOCUMENTS</b>	<b>63</b>
<b>18 APPENDIX 2: IT USER GROUP PARTICIPANTS</b>	<b>64</b>

## 1 EXECUTIVE SUMMARY

Annex VIII to CLP Regulation lays out the harmonised information requirements and format for notifying hazardous mixtures for poison centres. The study investigated leveraging further benefits of harmonisation of data and their format.

This feasibility study recommends the implementation of a **central notification portal** which will, in short, simplify the process of submission of information for industry in addition to harmonising the information received by the Member States appointed bodies and their poison centres.

From the industry perspective, the central notification portal would:

- Increase efficiency and reduce the costs for compiling and submitting the information by offering a unique user interface as one-stop shop which will reduce the number of interactions with the Member States appointed bodies and thus reduce administrative burden (e.g. in terms of identification of the submitter);
- Offer various tools for preparation of notifications depending on the size of the company and of their portfolio (e.g. online editor, system-to-system integration or upload of files prepared offline); Increase the security of data by reducing the number of channels of data transmission;
- Facilitate the notification of mixtures containing 'mixtures in mixtures' (MiM) by enabling linking notifications submitted via the portal through UFI, and therefore allowing notifying without the need to disclose business confidential information across the supply chain;
- Reduce the potential for errors by offering validation mechanism and tools;
- Support multilingualism by allowing the preparation and submission of the information by industry in their preferred language while ensuring the availability of that information to the appointed bodies and poison centres in their preferred language.

From Member States appointed bodies and their poison centres perspective, the central notification portal would:

- Reduce the need for IT development work at each Member State level and thus reduce the overall cost (economies of scale);
- Facilitate the exchange of information between Member States, e.g. in case of mixtures notified in one Member State but marketed in another Member State as part of another mixture (MiM);
- Enable the building of common criteria for assessing the completeness and the quality of the information submitted;
- Support secure transfer of information from industry to appointed bodies;
- Facilitate provision of data from appointed bodies to poison centres;
- Provide a searchable access to database of notifications relevant for Member State territory;
- Support Member States with the tasks performed at national level (e.g. invoicing, communication with industry or quality assessment);
- Allow future enhancements to the portal accommodating Member States specific needs under CLP.

Given the very tight development time of one year, it is recommended to go for a staggered approach starting with a first version of the portal (referred as **Minimum Viable Product** or **MVP**), and followed by subsequent releases increasing the features and business value to all stakeholders.

The MVP will support entering into operation by enabling the core notification process and a secure access of Member States to the notified data. It will provide:

- a multi-lingual web user interface for Industry to upload and submit their notification files (according to the final format that will be published by ECHA) and
- a multi-lingual web user interface for Member States appointed bodies and their poison centres to extract or download these notifications in a secure manner.

The release to follow (version 2) shall aim to complement the initial scope with a number of key features which high business values have been acknowledged during this study. The release of the MVP is planned for the end of 2018 and will be followed with the major release of version 2 in 2019. Therefore, all features that have been identified as 'core' would be developed and implemented before the first deadline of 2020. Other releases providing additional features are foreseen in the following years.

This phase-approach will allow gradual product evolution by setting a stable architectural foundations that will allow a gradual extension of the functional scope. It will also allow in-time delivery by providing in the earliest possible time, the essential tools to support notifications in the scope of the first regulatory deadline.

The recommended central notification portal will reuse elements of the current ECHA enterprise architecture, leveraging existing capabilities already in place where this is deemed necessary. It is worth noting that IUCLID will be considered as a core element of the final solution.

The study is meant to serve as support to the decision-making process by the relevant authorities on whether ECHA should develop this portal, and what is the best approach and related timelines.

## 2 INTRODUCTION

### 2.1 Background

Article 45 of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances (“The CLP Regulation”) requires each EU Member State to appoint and setup a national authority or body “responsible for receiving information on dangerous mixtures in order to formulate appropriate emergency measures”. Further to this, Article 45 requires the Commission to review the possibility of harmonising the information received by way of Article 45 by 20 January 2012. This was later complemented by a cost and benefit analysis and establishing a common format in March 2015. As a result of various consultations with stakeholders, an amending regulation was put forward which included a new Annex VIII to the CLP Regulation. The new Annex published on 22 March 2017, lays out the harmonised information requirements and implies that Member States appointed bodies and their poison centres build or adapt their notification systems in order to securely receive relevant information in a new harmonised format.

Importers and downstream users placing hazardous mixtures on the market must notify hazardous mixtures according to new requirements according to the phased deadlines of 1 January in a stepwise manner depending on the end use of the mixture:

- ▶ **2020** for mixtures intended for consumer use;
- ▶ **2021** for mixtures intended for professional use, and
- ▶ **2024** for mixtures intended for industrial use.

Importers and downstream users having already submitted the information to Appointed Bodies in accordance with Article 45(1) before the dates of applicability, will be required to comply with Annex VIII by **2025** (the end of the transition period). Appointed Bodies receive data on the identity and hazards of chemical products placed on the market in order to meet demands for emergency health response, for instance, by formulating preventative and curative measures in the event of a poisoning incident.

Under this amendment to the CLP Regulation, ECHA has a number of new tasks going beyond provision of scientific guidance, but also comprising technical aspects such as provision of the harmonised format, the tools and the technical support to facilitate the preparation and submission of the information.

### 2.2 Problem statement

The amending Regulation implies that all Appointed Bodies and/or Poison Centres of EU Member States build or adapt their notification systems in order to receive through a secure channel the information in the newly developed harmonised format. It also means that the Industry operating in different Member States will have to submit the same information multiple times and in different languages to each of these Member States. Therefore, the Commission had requested ECHA to explore the possibility to set up a central notification portal where companies that need to submit notifications to different Member States can carry out a single notification that will then be made available to the relevant Appointed Bodies in the appropriate languages. As the format of the notifications is harmonised, having a centralised submission system seemed a natural next step for an increased efficiency by all operators. It will leverage the benefits of harmonisation by enabling



the building of common criteria for assessing the completeness and the quality of the information submitted and facilitating the exchange of information between Member States, for example in the event of mixture in mixture that is notified in a different Member State than the final mixture.

The central notification portal is not a regulatory requirement, but the option is assessed on the premise that it can lead to simplification of the submission process for industry, increase security of data, motivate harmonisation of equivalent national processes and, as a consequence, positively impact quality and availability of the submitted data in the EU at reduced net costs (economies of scale). The central notification portal will aim to address current issues and challenges faced at national levels:

- *Harmonisation of submission processes and channels.* DG Grow studies (see R[1]) presented the existence of various submission procedures and channels across the Member States for the Industry to submit their notifications. Those channels include e.g. e-mails, web forms, offline tools, and even traditional mail or hard copies. For companies that are marketing their products in different Member States, this implies adapting to a specific submission process each time and submitting the same information multiple times and in different languages.
- *Development of robust validation layer.* Conventional submission channels (e-mail, post) may lack automated validation mechanisms on the notification. This can result in Member States receiving incomplete or incorrect data that may be identified only after subsequent manual quality checks.
- *Traceability of updates.* Current systems may not support the traceability of updates of notifications and updates of products. This causes challenges to Poison Centres while identifying the mixture of concern.
- *Linking the information on Mixture-in-Mixture (MiM).* Large amount of mixtures notified are composed of other mixtures (a.k.a. MiM) that may be or have been notified separately to the appointed bodies. Existing national databases may be missing the link between a mixture and its MiM components, in particular for mixtures and MiM notified in different Member States.
- *Need for enhanced security measures.* In various MSs until now, the information requirements do not comprise of confidential business information (e.g. only information from safety data sheet), thus notification process allows for submitting that information via non-secure channels (e.g. non-encrypted e-mail). This may cause the disclosure of confidential business information, given that Annex VIII of CLP requires provision of e.g. full composition of the mixture by the industry.

The aim of this study is to assess the feasibility of ECHA building this central notification portal including the impact in terms of resources, as well as to what extent can the above mentioned issues be addressed by this portal. The study is meant to serve as support to the decision-making process by the relevant authorities on whether ECHA should develop this portal, and what is the best approach and related timelines.

## 2.3 Actors

This section identifies the different actors that would play a role in the central notification portal and therefore are referred to throughout the study.

### 2.3.1 Industry

Industry actors, namely importers and downstream users, who must comply with the new regulation requirements, may comprise both large and SME actors ranging from extensive to modest product portfolios.

Industry actors may also be defined by their market presence, for example, some companies currently operate in only one specific territory where others operate in several territories across the EU. An additional characteristic of Industry actors includes the end user (or users) of the product for which they are notifying, e.g. for use by consumer, professional or industrial users. Their main interest is to have an efficient notification process that prevents manual entering of the information in different systems as this is resource intensive and prone to errors. It should be noted that other issues have been identified by the Industry, however, as they are related more to workability of the amended Regulation and not to the central portal, they are not addressed in this study.

From the industry perspective, the central notification portal would:

- Increase efficiency and reduce the costs for compiling and submitting the information by offering a unique user interface as one-stop shop which will reduce the number of interactions with the Member States appointed bodies and thus reduce administrative burden (e.g. in terms of identification of the submitter);
- Offer various tools for preparation of notifications depending on the size of the company and of their portfolio (e.g. online editor, system-to-system integration or upload of files prepared offline); Increase the security of data by reducing the number of channels of data transmission;
- Facilitate the notification of mixtures containing 'mixtures in mixtures' (MiM) by enabling linking notifications submitted via the portal through UFI, and therefore allowing notifying without the need to disclose business confidential information across the supply chain;
- Reduce the potential for errors by offering validation mechanism and tools;
- Support multilingualism by allowing the preparation and submission of the information by industry in their preferred language while ensuring the availability of that information to the appointed bodies and poison centres in their preferred language.

### 2.3.2 Appointed Bodies and Poison Centres

Appointed Bodies are the legal authorities appointed by the Member States for receiving information on hazardous mixtures from the Industry and making it available to Poison Centres. Poison Centres aim to have immediate access to relevant information in order to provide medical advice (to the general public or physicians) in the event of a poisoning incident.

With reference to the Poison Centres and the dispatching/exchange of notification data with the Appointed Bodies, various scenarios exist throughout the Member States:

- the Appointed Body may overlap with the Poison Centre role (e.g. same entity);
- the Poison Centre is a single entity serving the whole country;
- numerous Poison Centres are established to serve the needs of specific regions;
- instances where no official Poison Centre has been established.

From Member States appointed bodies and their poison centres perspective, the central notification portal would:

- Reduce the need for IT development work at each Member State level and thus reduce the overall cost (economies of scale);
- Facilitate the exchange of information between Member States, e.g. in case of mixtures notified in one Member State but marketed in another Member State as part of another mixture (MiM);
- Enable the building of common criteria for assessing the completeness and the quality of the information submitted;
- Support secure transfer of information from industry to appointed bodies;
- Facilitate provision of data from appointed bodies to poison centres;
- Provide a searchable access to database of notifications relevant for Member State territory;
- Support Member States with the tasks performed at national level (e.g. invoicing, communication with industry or quality assessment);
- Allow future enhancements to the portal accommodating Member States specific needs under CLP.

### 2.3.3 ECHA

The role of ECHA, as foreseen by the amended CLP Regulation, is the provision of formats and tools to facilitate the preparation and the submission of notifications in the harmonised format. ECHA has accumulated experience in the development and running of submissions systems for industry as well as platforms for Member States.

### 2.3.4 Additional stakeholders

Additional stakeholders have been identified as potential actors; however their relevant requirements have not been analysed in this study. It is advised to consider them in the future:

- EU Commission;
- National Competent Authorities;
- Enforcement authorities. Enforcement of the obligation to notify will be a key element in the coming years. Enforcement authorities may need access to the central portal or find alternative ways to get the information. Preliminary discussions have been held with these authorities in the context of the ECHA Forum, however they are not elaborated in this study.

### 3 OBJECTIVES OF THIS STUDY

The objectives of this feasibility study are to:

- ❖ Identify and validate high-level use cases from the different actors to better understand the key requirements that a portal should deliver;
- ❖ Identify and clarify ECHA's business and architectural requirements including terms of retention and accessibility of data, modularity of the targeted solution, reusability;
- ❖ Produce a blueprint of a candidate architecture for the to-be system in a modular nature that enables an incremental implementation plan;
- ❖ Produce reliable cost estimates in terms of financial and human resources for the development, implementation and operation costs of the target solution;
- ❖ Identify and estimate additional costs contributing to the TCO (Total Cost of Ownership) (e.g. non-technical tasks like user support, communication, etc.);
- ❖ Suggest a possible implementation plan (phased approach; multiannual).

## 4 METHODOLOGY

The project methodology/approach has been built around the following steps as described in the graph below:



Figure 4-1: Methodology / Approach

### 1. Define scope

This phase served to define the scope of the study, deliverables and the outcome.

### 2. Preparatory phase and review of existing material

The following sources were reviewed in the preparatory phase during the feasibility study:

- European Commission (DG GROW) studies<sup>1</sup> (see **R[1]**) for understanding:
  - the initial rationale behind harmonisation;
  - the proposed XML schema (assumptions, limitations, etc.);
  - existing practices in Member States for submitting notifications (processes, information requested, IT systems);
  - number of companies and submissions expected at EU level.
- Proceedings of the workshop organised jointly by the Commission and ECHA (23/1/2017) on the implementation of the Commission Regulation (EU) 2017/542, harmonising the information relating to emergency health response. Reflecting on key points/topics discussed mainly related to the Notification Portal and the expectations surrounding the feasibility study.
- Leveraging on existing knowledge, best-practices and lessons learned from other submissions systems like the Cosmetic Products Notification Portal (CPNP) and other ECHA hosted systems (REACH-IT, R4BP, ePIC).

### 3. Consultation with the project stakeholders

This phase served to consult with the project stakeholders for gathering and identifying the requirements was performed via the following methods:

#### Regular IT User group meetings

---

<sup>1</sup> Study on the costs and benefits of the harmonisation of the information to submitted to Poison Centres [ISBN:978-92-79-35803-6]

An IT User group has been set up to assist ECHA in defining the scope for the development of the IT tools that would support the notification process including the central portal. Regular meetings via web conferences have been established to facilitate the exchange of ideas from April to September, 2017. Additionally, a dedicated 'forum' space was also set up in S-CIRCABC in which group members were encouraged to provide their feedback or initiate discussions on certain topics of interest. The group is coordinated by ECHA and consists of (see [Appendix 2: IT User Group participants](#) for the detailed list):

- ECHA representatives from different Directorates including business, IT and support functions;
- Member State Appointed Bodies (8);
- Poison Centres (5);
- Industry Associations (7): both from downstream users and chemical producers;
- Other individual stakeholders and observers (11), which are closely following the work of the group but not actively contributing.

The main objectives of the User group meetings are:

- 1) Discussing business and IT needs and possible implementation approaches;
- 2) Elaborating/prioritising/reviewing user requirements;
- 3) Addressing open issues and endorsing the way forward.

The following list presents an overview of the topics discussed during the User group meetings:

- Notification identification schemes (selected case studies presented by MSs);
- High-level overview of supported business processes;
- Types of validations foreseen (specific examples also presented by MSs);
- Notification handling across multiple market areas;
- Positioning of the PCN portal in ECHA IT architecture context;
- Non-functional requirements (availability, security, capacity).

### [ECHA hosted workshop](#)

An ECHA hosted workshop for the IT User group (and related experts) was organised in June 2017 with the aim of agreeing on the final set of requirements for the development of a PCN Portal. During the workshop, the potential high-level features and functionalities of the portal were presented and dedicated breakout sessions took place on a number of selected topics targeted by the IT user group. These topics included:

- IT security and confidentiality of data;
- Industry users: portal's basic functionalities and integration needs;
- Authority users: portal's basic functionalities and integration needs;
- UFI/TFI concept – data model and key entities involved in the portal;
- ECHA services for Appointed Bodies / Poison Centres.

More details on those topics can be found in the Workshop report.

### Targeted missions and meetings

A series of on-site missions, in house face-to-face and teleconference discussions have been held with a variety of stakeholders ranging from small to large companies, various Industry sectors and operating on local and multinational markets. In addition, similar contacts were held Member State stakeholders were represented in terms of differing levels of complexity of national systems, resources, as well as different levels of willingness to rely solely on a central harmonised notification system. Contacts with Member States included both Appointed Bodies and Poison Centres.

The objectives of these meetings were to gain an understanding of the:

- specific needs, data and requirements (and future expectations) regarding the new harmonised notification system and the supporting tools;
- current working practices and processes, what is currently working, or not, and how the central portal would impact;
- challenges and opportunities from the central portal.

## **4. Requirements analysis**

This phase served to collate and analyse the identified requirements for the implementation of the EU PCN Portal. The outcome was used to provide a list of use cases deemed necessary for the implementation of the recommended solution grouped by functional area. Each use case aims to contain a description of the main interaction flows and foreseen exceptions. This list of use cases will be used to define the architecture and will be taken into account for the preparation of the implementation plan. Mock ups for the most important use cases will be made. Acceptance criteria are included for each requirement, meaning, add a measurement against which it can be tested has been added.

## **5. Conclusion & way forward**

This phase is considered the final one and will serve to draft the study – conclusions, propose an implementation plan, estimate the costs, list the benefits and provide the way forward.

## 5 SOLUTION SPACE

The basic principles of the portal are to support Industry users with preparing online or in their own system the notification files in the harmonised format, and submitting those files to the relevant Member States through the portal via a multi-lingual web user interface (UI) or via web services. From the authority user perspective, Appointed Bodies need to access the submitted notifications online or via web-services. They can connect to the centralised system or synchronise with their own local systems. The portal should provide a searchable central repository containing the full history of notified data where actors can retrieve their portion of the data. More details on the features and functionalities that the portal must or should support are described per actor in the following section [§6 Functional Areas and Features](#).

Analysis of the harmonised PCN format immediately pointed out the similarities between the notification content and the content of existing IUCLID documents, thereby initiating and finally recommending an alignment of efforts towards a unified IUCLID based format. Discussions around IUCLID lead to the realisation that the basic idea around submission of a notification, closely resembles existing processes supported by ECHA IT, like the submission of REACH/CLP dossiers in REACH-IT. Further analysis indicated a number of steps that are fairly common during any kind of electronic “dossier” submission, e.g. archiving the incoming files, virus scanning them and format checking them, etc.

Further analogies were noted between the requirement for the EU PCN portal to support preparation of notifications online and REACH-IT’s Online Dossiers module, which provides such a web-based user interface to support preparation of dossiers for submission to REACH-IT. Additional possibilities and opportunities can emerge by reusing cloud based IUCLID instances for either Industry preparing notifications or Appointed Bodies that require a system to evaluate received notifications.

ECHA Accounts system that is responsible for identity management both for user and legal entities is used by both REACH-IT and R4BP and all other ECHA IT systems to cover for authentication and authorization needs. The same will hold true for the EU PCN Portal.

Further discussions around cooperation between Member States e.g. to share the load of performing quality checks and verifications on the received data emerged, suggesting that a cooperative solution could benefit to the overall process on top of a submission system. R4BP implements a submission pipeline for BPR processes. Its overall collaboration model (between Industry and Authority sides, the separate applications serving each side backed by processed data from the same pipeline, internal messaging, etc.) was also analysed and used as a model to cover similar functionalities and needs in the context of the EU PCN Portal.

ECHA’s Data Integration Platform can further assist in producing better quality notifications by providing access to ECHA’s substance inventories and therefore supporting the preparation of notifications online with offering pre-validated options for mixture components.

By referring to all these analogies, the target architecture emerged as a combination of existing and new components, maximising reuse of existing already expended effort on other IT systems, while still addressing the specific needs stated as goals of the portal.



## 6 FUNCTIONAL AREAS AND FEATURES

The following sections describe the functional areas and features of the portal grouped by system actor.

### 6.1 Common functionalities

#### 6.1.1 Sign up / authenticate and manage users

The users access the portal in a secured manner through ECHA Accounts. The portal integrates with ECHA accounts in order to provide authentication, authorisation and sign up services to Industry, Appointed Bodies and Poison Centres. The Legal Entity Manager signs up by encoding the details of the new Legal Entity or by importing the new Legal Entity's details. After an email confirmation, the Legal Entity Manager user can sign-in to create new users and assign the appropriate roles.

The following features are foreseen:

- Sign up new Legal Entity;
- Sign up new user;
- Authenticate user;
- Manage user roles.

#### 6.1.2 Manage message box

The user is informed of key events by generated messages. Messages can be informative or an invitation for action from the user. The user accesses the message box available in the portal in order to search and view the content of the messages. The option to archive a message is also provided. The user can also configure the email notification preferences in order to be informed when new system messages are available in the portal's message box.

Additionally, the system can also allow the exchange of messages between selected actors.

The following features are foreseen:

- Search messages;
- View messages;
- Archive messages;
- Configure email notification preferences;
- Send ad-hoc messages.

#### 6.1.3 Manage notifications on-line

The user retrieves a notification via the portal. The user searches for the notification using a set of criteria. The portal provides the user with a result set of notifications satisfying the provided criteria. The user can print

selected notifications and also download a selected number of notifications at once. After selecting a notification from the result set, the user can view its details. In case a MiM is included in the mixture composition, the user can click on the MiM details and the portal will display the corresponding notification.

The following features are foreseen:

- Search notifications;
- View notifications;
- Download notifications;
- Print notifications.

#### 6.1.4 Display on-line help

The user, at any point of the submission process, invokes the help utility. Depending on the page/view he is currently in, the relevant help text is displayed in a separate window. The user will be able to easily browse the help content structure, search for specific terms and view related topics.

The following features are foreseen:

- Browse on-line help topics  
(Topics are structured in a hierarchical tree structure)
- Search for specific text in the on-line help library;
- Display related help topics;
- Display context-sensitive help  
e.g. when user selects the on-line help, the relevant text appropriate to the page he is currently in will be presented (e.g. description of the field he is editing, clarifications on any warnings/errors displayed etc.);
- Provide multi-lingual help content.

## 6.2 Industry

### 6.2.1 Fill-in and submit a notification on-line

The Industry user fills-in the notification online. The portal provides the user with some validation indications (e.g. that all the mandatory fields are provided). At any time during the online preparation process, the user can save the notification as a draft, either online or by exporting it locally, to resume editing later. The user can resume the online preparation by accessing the draft notification online or by re-importing the previously exported file. At the end of the preparation process, the user confirms and submits the notification. Upon completion of the previous step the portal performs its automatic validations and in case of errors informs the user accordingly.

The following features are foreseen:

- Fill-in, validate pre-submission and submit a notification online;

- Save and recall an online notification draft;
- Export/Import a draft notification file.

### 6.2.2 Upload and submit notification files that were prepared offline

The Industry user prepares one or more notifications offline and saves the files locally. After accessing the relevant section of the portal the Industry user selects the single or bulk submission option and uploads the notification files to the portal. After uploading the notification file, the portal performs a series of validations and in case of error informs the user accordingly. After confirming the submission, the user receives a system message with a confirmation message containing additional notification details including possible validation errors or warnings.

### 6.2.3 Update a notification

The Industry user accesses the portal in order to submit a notification update. The user prepares the notification update offline and subsequently uploads it (single or bulk file upload is permitted). Alternatively, the user searches and retrieves an existing notification from the portal. The user reviews the notification content and clicks on the update option in order to modify the content online. The user amends the notification and confirms the submission. The portal performs a series of validations and in case of error informs the user accordingly. Upon successful completion of the previous step, the portal starts the processing of the notification performing a series of validations and, in case of errors, informs the user accordingly.

The following sub-features are foreseen:

- Update notification online;
- Upload and submit updated notification file(s) (single or bulk).

### 6.2.4 Industry system integration

The Industry system connects to the dedicated web-services and authenticates with the correct credentials. The system interacts with the portal in order to submit initial notifications or subsequent notification updates over a secure channel, providing the appropriate request parameters (based on the interface specification). Upon completion of the previous process the web-service acknowledges safe receipt of the notification or responds accordingly in case of errors. Using the same method of interaction, previously submitted notifications can be retrieved from the portal to be imported back to the Industry system.

The following features are foreseen:

- Submit initial notification via web service;
- Update a notification via web service;
- Retrieve notifications into local systems via web-services.

### 6.2.5 Validate a notification file

The Industry user would like to check whether notification files prepared offline are error-free and ready to be submitted through the portal. Before submitting the notifications, the Industry user runs the assessment check by selecting the notification validation tool. Upon completion of the validation steps, the user receives a comprehensive list with potential problems and validation errors. Industry systems can also connect and use the web-service validation interface in order to check for errors in the notifications prepared offline.

### 6.2.6 Manage contacts

While preparing or updating the notifications, the Industry user needs to create and assign contacts with different roles. The user accesses a dedicated module of contacts management in order to create, search or update contact records linked to his own Legal Entity. Upon completion of the previous step, the user returns to the portal in order to continue the process, selects the role and assigns the contact.

Updating a contact does not require resubmission of a notification file. The portal will communicate the changes to the relevant Appointed Bodies.

The following features are foreseen:

- Manage contact records;
- Update already assigned contact.

### 6.2.7 Change Submitter Legal Entity

The Industry user needs to change the notification submitter due to a Legal Entity change. Such an event may be triggered by a change in the Legal Entity ownership/structure (e.g. one company is acquired by another company), or a change in the business strategy (e.g. a company decides to sell its operations in one MS to a different Legal Entity). All the Legal Entities involved in the change are already signed up through ECHA Accounts. The user accesses the portal and changes the assets ownership through a guided step-by-step Legal Entity change process. At the end of the process the portal changes the ownership and transfers the final assets to one or more Legal Entities. A thorough analysis is required in the context of the Poisson Centre to clarify any open points related to Legal Entity Change functionality.

## 6.3 Appointed Bodies and Poison Centres

### 6.3.1 Review notification

The Appointed Body user needs to review the content of the notification submitted by the Industry. The user retrieves and reviews the submitted notification online. During the revision process the user may annotate and flag the problematic fields. Upon completion of the notification review and quality checks, the user may make a request to the submitter for additional clarification through the portal indicating where the problems

are. The user may also record the notification review status by indicating in the portal if a quality check has been initiated or completed.

The following features are foreseen:

- Record notification review status (e.g. not reviewed, ongoing review, review completed);
- Request clarification;
- Annotate notification fields.

### 6.3.2 MS system integration

The Appointed Body system needs to interact with the portal in order to retrieve the Industry-submitted notifications into their local systems via web-services. The Appointed Body system connects to the dedicated web-services at predefined intervals and authenticates with the correct credentials. The Appointed Body system provides in its request the appropriate parameters (based on the interface specification), in order to retrieve the notifications into the local systems over a secure channel.

## 6.4 ECHA

### 6.4.1 Provide operational support

The ECHA user provides operational support in relation with a specific notification submission, or another key event, performed by the Industry or the Authority actors through the portal. The request of support is received via the dedicated service desk. Using the administration dashboard, the user searches and retrieves a list of notification specific processes or business events performed by the Industry user requesting assistance. Depending on the situation, the user is allowed to view the logs and details of the process, having the ability to terminate (in case of mistakes) or resume again the processes.

The following features are foreseen:

- Search for processes;
- View a process;
- Terminate a process;
- Resume a process.

## 6.5 System

### 6.5.1 Perform notification workflow processes

The core process of the system takes care of receiving notifications submitted by the Industry through the portal. The core process includes the following technical checks: virus scan and validation upon a predefined schema for technical compliance. In addition, the portal performs business checks to ensure that the provided

notification complies with a series of business rules related to the notification's completeness. Those business rules could include e.g. verifying that a trade name has been provided in the notification or that the provided UFI is valid. A validation error could result in a failure of the business check (in this case the submission is not processed and the user is informed accordingly), or in a warning (in this case the submission is processed and considered valid however the portal generates a report to inform both Industry and Appointed Bodies accordingly).

The following processes are foreseen:

- Process and store a submitted notification;
- Perform business rule checks on submitted notification file.

### 6.5.2 Provide integration with ECHA substance inventories

The system integrates with existing ECHA Substance inventories and provides a level of automation and assistance when the Industry user provides or updates the mixtures components. The user searches and retrieves the substance identity using the EC/CAS/Chemical Name and Index No. for existing harmonised classifications (CLP Annex VI).

### 6.5.3 Provide multilingual User Interface

The portal's User Interface is available in all EU official languages and allows all users to select the language of preference through the account preferences.

### 6.5.4 Provide audit functionality

The portal provides a comprehensive audit functionality where selected key business events and actions are logged (e.g. upload and submit notification, update notification, legal entity change), together with the actors initiating the event or the action. Operations are always tracked. Depending on their role, users can view if another user has initiated a specific action, for example checking the last time a specific action had been performed and by whom.

## 6.6 Provide dedicated services for Member States

The scope outlined in the previous paragraphs of this chapter covers the main functionalities envisaged for the central notification portal. The portal's objective is to support the notification process by providing a secure, integrated platform where Industry actors submit notifications, while MS actors search, access and retrieve them.

In earlier discussions, a number of EU Member States expressed their interest on fully relying on ECHA-hosted IT services to replace the need for local IT systems for their Appointed Bodies and/or local Poison Centres. This

requires ECHA to offer **dedicated** IT services to interested MSs (following bilateral agreement), extending the scope of the centralised portal outlined above.

These services are offered in an isolated MS-specific environment that hosts the MS's share of data which is continuously replicated from the portal's central repository. This isolated MS-specific environment can provide higher availability compared to the portal, if needed.

On top of the existing portal's features, additional features are developed in order to support functions typically implemented by local MS IT systems. Stakeholder feedback during the study was insufficient to conclude an agreed, prioritised list of functionalities to implement, but the following ideas were captured as indicative functions that could be addressed in this extended scope, provided that there is sufficient demand:

- Support for advanced comprehensive search capabilities;
- Support for recording emergency health incident data;
- Additional reporting capabilities or data analytic services;
- Support for notification quality checks at national level (e.g. national-level workflow orchestration).

At a higher level, the dedicated services for MS foresee the following features:

- Provide an isolated MS-specific environment;
- Enable 24/7 availability for MS-specific environments;
- Provide additional features to support AB/PCs use cases (to be defined later).

## 7 NON-FUNCTIONAL REQUIREMENTS

**Note:** This section refers to the non-functional requirements of the portal. In case ECHA provides additional services to some Member States (see §6.6 [Provide dedicated services for Member States](#)), then adjusted non-functional requirements could apply (e.g. higher availability). The requirements below would set the baseline for the definition of such a service.

### 1. [Availability](#)

Following discussions at the workshop in June 2017 and with the IT User Group, an availability rate analogous to other ECHA systems (~99%) supporting similar processes is considered sufficient, like R4BP for BPR as far as accepting submissions is concerned (generally available 24/7 unless under maintenance). The main reasons behind this can be summarised as follows:

- There is a very high cost behind very high availability (for more than 99%);
- Complex software technology is required in order to ensure no downtime;
- The portal usage envisioned does not demand for higher than 99% availability:
  - System-to-system integrations do not require above 99% availability;
  - Real-time searches by Poison Centres officers on external (to the PC) sources is not the norm. They rely on multiple means: local (first) and remote IT, but also non-IT resources.
- A highly available system accessed via unreliable networks (internet) is not really highly available.

Additionally, the following should be noted:

- Availability changes during the lifetime of a system (as subtle software defects are ironed out, availability increases until a new major part of functionality is released);
- Availability changes also depending on the regulatory deadlines, for instance;
- Availability requirements can be different per sub-component of the portal.

Achieving an availability of higher than 99% would require significant infrastructure and increase software licensing costs.

### 2. [Security](#)

Most of the information included in a notification file is considered confidential. Therefore, special care is needed around secure transfer of notification files and/or notification content in general. This includes the communication channels via which the portal receives information (the online notification preparation tool or a web service called by an Industry operated system), as well as the communication channels via which the portal dispatches information (the user interface allowing downloads through human interaction or a web service called by an Appointed Body operated system).

In terms of data access via the portal, Industry users will have access to their submitted data which will only be available to the intended Appointed Body and Poison Centres users. Furthermore, the possibility for MSs to access notifications submitted in other MSs and the cooperation between Appointed Bodies, for example having access to the results of the quality checks performed by a different MS, has also been discussed but for the time being, this has been left out of the initial scope. As such, the architecture should be designed with



the prospect of possibly sharing notification data between different Appointed Bodies in case a relevant agreement between MSs is reached, even if this feature is not part of the initial scope.

Regarding authorisation, although ECHA Accounts can provide the portal system with each user's roles, it remains up to the portal to define what each role can or cannot do. The system uses a permission based access system internally and roles are mapped to specific permissions via the role administration functionality.

The current security practices that ECHA is using in other submission systems have been considered as a baseline, expanded with standard practices to address new elements. It must be noted though, that the security processes mentioned below should not be considered final, and they may be tuned further following stakeholder consultation for the definition of an agreed security model. The reasons why such tuning may be needed are described below:

- Data included in the Poison Centre notifications are more sensitive compared to REACH registration dossiers and BPR applications or notifications;
- Up until now there is no:
  - external system integration with ECHA's systems;
  - ability for Industry actors to directly download/access previously submitted information.
- Data needs to be propagated to MS systems.

As a baseline, the following security processes are foreseen per actor:

- ▶ [Industry users](#): One factor authentication (username/password) via ECHA accounts;
- ▶ [Member State users](#): Two factor authentication (username/password) via ECHA accounts, access to the portal via VPN with the use of an RSA token as well;
- ▶ [ECHA users](#): Two factor authentication (username/password) via ECHA accounts, access to the portal via VPN when working remotely;
- ▶ [Industry systems](#): 2-way SSL model where both ECHA and Industry servers use digital certificates;
- ▶ [Member State systems](#): 2-way SSL, although IPsec tunnels and IP restrictions remain as an option;
- ▶ [Other internal ECHA systems](#): Token-based model via ECHA accounts.

**NOTE:** An extension to the baseline above could imply extra implementation effort.

### 3. [Reliability](#)

In order for the portal to maintain its availability, it is expected that it will be composed of reliable components. In other words in case of external – to the system – failures (power failures, network failures, operating system failures, etc.) the system maintains its functionality, or gracefully reduces functionality, or eventually shuts down. In meeting such requirements various factors play a role, indicatively:

- Operational support (data-centre service level agreements and application management service level agreements) ;

- Level of automation supported for deployments;
- Overall system monitoring/alerting;
- System design around clustering;
- Provision of redundancy wherever possible and cost-effectively.

#### 4. Recoverability

Regarding recoverability or the system's capability to handle wrong or insufficient input data, the system should be able to handle invalid data by recovering gracefully and terminating the relevant invalid data processing with an error or a warning. Recoverability is greatly enhanced by adding a monitoring console to the back-end system that allows a human operator to restart or permanently end blocked instances of running processes. Such a console is envisaged and will be provided for the ECHA administrators and service desk officers for the operational support.

#### 5. Resilience

In terms of resilience the system should be fault-tolerant and be capable of handling both internal and external errors. In other words, the system is expected to behave consistently in the event of a problem that may arise so that any kind of instability is not introduced. More precisely, a notification submission will either be processed and its whole dataset will become available, or the transaction will be rolled-back and the notification will be rejected. At the same time such problems/errors should be consistently reported to operational services for follow up.

#### 6. Auditing, monitoring and management

The portal will need to provide comprehensive audit functionalities around selected key business events and user actions. The purpose of this functionality is to allow ECHA administrators or service desk officers to investigate business issues, resolve disputes, monitor submission events, and provide for accountability of user actions. For security reasons the audit logs will be maintained in a secured and protected system area and made accessible only to ECHA authorised users.

In addition, as mentioned above on the topic of recoverability, an administration console is envisioned as a web application that provides information and control on running notification process instances, to assist with any blocked operations. This administration console can be further augmented as needed during the course of development.

#### 7. Interoperability

The portal must provide interfaces with other external systems such as Industry-operated systems that will generate and provide notifications, and Appointed Body systems that will need to retrieve the notifications. There is, therefore, the need for two integrations:

- Web Services for Industry systems;
- Web Services for Appointed Body systems.

Interoperation between the portal and other ECHA internal systems will use the respective APIs provided by those target internal systems.

## 8. Constraints on the IT solution arising from the Legal and regulatory context

The final solution is in part constrained by Article 45 of the CLP Regulation (the portion that sends information to Appointed Bodies), and particularly the provisions in Annex VIII of this regulation. In short the following are mandated:

- The overall content required in a notification is clearly specified;
- The notification exchange file must be formatted in XML;
- Similar mixtures (following some constraints) may be submitted as one group.

## 9. Internationalisation and localisation

There are two aspects around internationalisation that are of concern to the portal.

The first one is the typical user interface internationalisation, which is presenting the user interface in multiple languages according to the end user's default locale, falling back to English if the requested locale is unavailable.

The second one is related to the notification content. It is expected that the content of a notification is targeted to a specific Appointed Body and, more importantly, it is delivered using the Appointed Body's language or languages if more than one is required or allowed (e.g. Belgium). This means that the exchange file must support multiple languages and that the portal user interface should be able to display such content regardless of the user's chosen locale.

## 10. Accessibility and Usability

Although, there are no specific requirements recorded around accessibility, serious effort will be made towards making the portal accessible to the majority of users as much as possible, taking into account specificities of the public (e.g. colour-blindness, non-availability of mouse, limited screen resolution, etc.). In terms of guidelines and considering that the portal's user interface will be web based, World Wide Web Consortium's (W3C) Web Accessibility Initiative [Web Content Accessibility Guidelines](#) will be used.

## 11. [Enterprise Architecture Strategy Compliance](#)

The portal needs to be designed around – and fit in – ECHA's Enterprise Architecture. The portal is not meant to exist as an independent application but rather integrate and collaborate with other existing ECHA systems and supporting tools to maximise the benefits.

User and Legal Entity management is expected to be handled via standard (for ECHA hosted systems) integration with ECHA accounts. Notification data will be indexed, processed and validated in the standard scientific data tools used at ECHA, namely IUCLID.

In the future, access may be needed beyond pure tracking, or records of notification for reporting and statistical analysis. The proposed solution does not consider this in detail at the moment but does not prevent further integration with a Data platform in the future.

## 12. [Load, Performance, Capacity and Scalability](#)

In a previous [study](#)<sup>2</sup> on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation), the EU Commission projected an annual amount of about 100 million notifications – in that context a notification is a submission (initial or update) about one mixture in one of the EU Member States – per year for consumer and professional uses, and about 650 million per year when industrial uses are added.

In terms of scalability and load, based on the regulation timeline we should plan on a system that will start with a yearly load of 100 million notifications (assuming an even distribution, this amount would translate to about 3 notifications per second), and after 5 years that load will **sextuple** at 650 million notifications (assuming an even distribution, this amount would mean about 19 notifications per second) per year. However, even distribution is not expected. Higher load should be expected in order to reliably handle peak periods e.g. around deadlines, thus, realistically, the expectations should be doubled to about 6 notifications per second the first 4 years and 40 notifications from the 5th year onwards.

In terms of performance there have not been any special requirements, so rather standard user interface performance guidelines apply. Namely most web page actions should complete within 3-4 seconds, with an exception on searches which could go up to 10 seconds. However reaching these performance requirements, particularly on searches with such a high volume of data being searched, could pose a significant issue. Again considering an underlying IUCLID database storage (see [§9 Internationalisation and localisation](#)), there are a number of possible solutions to specific problems, nonetheless it is advisable that a performance test is setup as soon as the main components are developed.

In terms of storage capacity required there are a number of issues that need to be taken into consideration:

---

<sup>2</sup> Study on the Harmonisation of the information to be submitted to Poison Centres [ISBN:978-92-79-35803-6]

- Since the portal both receives and sends out notifications, copies of incoming and outgoing notification files should be archived for auditing purposes;
- Notification content can exist as draft in the notification preparation tool and as final in the notification preparation tool;
- Notification content will definitely be present in the main portal processing back-end;
- Notification content contains both plain XML data and binary attachments;
- IUCLID is used as database storage in both the notification preparation tool and the portal processing back-end, so all binary files are checksum checked and if checksums match, the binary is not stored again but rather a link to the existing content is generated;
- On the other hand, the archival storage simply stores exactly what it receives.

In order to simplify our calculations, we assume an average size of a notification to be 30KB of XML data, and another 30KB of binary data to a total of 60KB per notification. Further details on the reasoning behind these assumptions can be found in [R\[3\]](#).

Taking into consideration a worst case scenario, we need to multiply as follows (assuming of course no changes to the format):

Year	Total number of Notifications stored	Average Notification Size	Average Stored Notification Size	Total Size Required
<b>Year 1</b>	100.000.000	60KB	300KB	30TB
<b>Year 5</b>	1.000.000.000	60KB	300KB	300TB
<b>Year 10</b>	4.250.000.000	60KB	300KB	=~ 1.275PB

The sheer size of the projected volume as identified so far, indicates capacity as a potential risk, and should thus be closely monitored as the project develops. Some steps towards mitigating this risk are already in progress and more specifically:

1. The EU Commission will conduct a workability study during 2018 and may potentially revise the regulation in an effort to reduce the volume of data and resulting loads;
2. Take advantage of the underlying IUCLID capabilities and analyse, during the project's elaboration phase, how to optimise the notification format and submission processes in order to reduce volumes.

## 8 MINIMUM VIABLE PRODUCT AND PRODUCT BACKLOG

Given the very tight development time of one year, it is recommended to go for a staggered approach starting with a first version of the portal (referred below as **Minimum Viable Product** or **MVP**) and followed by subsequent releases increasing the features and business value to all stakeholders. The above mentioned requirements have been analysed and this section shows which of them are identified as ‘must have’ for being included in the MVP, sufficient to allow:

- **Entering into operation**: enabling the core notification process and secure MS access to the notified data;
- **Gradual product evolution**: setting stable architectural foundations that will allow a gradual extension of the functional scope;
- **In-time delivery**: providing in the earliest possible, the essential tools to support notifications in the scope of the first regulatory deadline.

In more detail, the MVP shall aim to provide at least the following:

- ❖ A multi-lingual web UI for **Industry to upload and submit their notification files** (according to the final file format that will be published by ECHA);
- ❖ A multi-lingual web UI for **Member States authorities (Appointed Bodies or Poison Centres) to extract/download these notifications** in a secure manner;
- ❖ Basic user management functions (sign-up, authentication, authorisation) so that each action can be traced back to identified system users with the appropriate privileges);
- ❖ An automated submission process that ensures submitted files conform to the format specifications;
- ❖ A searchable central repository containing the full history of notified data where actors can retrieve their portion of the data.

The release to follow (below referred to as V2) shall aim to complement the initial scope with a number of key features whose high business values have been acknowledged during this study. Although ideally these would be available already as part of the MVP, delivery is currently positioned in V2 for the reasons outlined below.

Key functional area	Rationale for positioning in V2
<i>Allowing preparation of notification files fully online using a dedicated web UI that seamlessly integrates with the portal's submission process.</i>	This feature is essential to companies with smaller portfolios. However, the MVP gives priority to building a web-based user interface for uploading and submitting notification files that have been prepared offline by relying only on the format specification. This submission method is prioritised since during the study, Industry stakeholders expressed a notably stronger interest for adapting their own IT systems to generate notification files directly.

Key functional area	Rationale for positioning in V2
	<p>Additionally, as the proposed solution (see <a href="#">§9 Architecture of the Notification Portal</a> and <a href="#">§10 Description of the building blocks</a>) aims to align the notification format with the IUCLID XML format, the IUCLID software becomes an initial, immediate option to prepare notification files for those companies which would require a tool to support this, before the online option becomes available under release V2.</p>
<p><i>Exposing a web service integration layer that allows secure submission and retrieval of notified data from the Industry and MS IT systems respectively.</i></p>	<p>The need for this feature has been strongly expressed by both the Industry and Appointed Bodies. It is essential to ensure the stability of the system's core that will be developed under the MVP (notification process, repository, interaction pattern) before defining external facing interfaces.</p> <p>A pilot testing phase that would allow collaboration and feedback collection from a group of early-adopters would be useful for validating that the interface definitions are fit for purpose, before expanding their use.</p> <p>Finally, an extension of the security model is required. This interaction pattern would be a new element for ECHA IT. The study noted a lack of consensus on the security requirements. A development of a policy that will be acceptable by all stakeholders will require additional consultation rounds.</p>
<p><i>Performing automated checks on submitted files to ensure minimum content compliance against a commonly agreed set of business rules.</i></p>	<p>Implementation of those business checks is foreseen once the Industry and Authorities have become familiar with the technical implementation of the new format.</p> <p>It also requires broad consensus among stake holders and MSs on the set of rules to check for completeness. Some checks may already be in place as part of the MVP, but a wider scope is anticipated to be covered by V2.</p>

The remainder of the scope is positioned in the releases according to the matrix below. The proposed prioritisation will be confirmed during the project elaboration phase and after further elicitation of the requirements and stakeholder feedback.

Functional Area		Feature	System Versions		
			V1 (MVP)	V2	V3
Common functionalities					
01	<a href="#">Sign up / authenticate and manage users</a>	Sign up new Legal Entity	✓		
		Sign up new user	✓		
		Authenticate user	✓		
		Manage user roles	✓		
02	<a href="#">Manage message box</a>	Search messages	✓		
		View messages	✓		
		Archive messages	✓		
		Configure email notification preferences	✓		
		Send ad-hoc message			✓
03	<a href="#">Manage notifications on-line</a>	Search notifications	✓		
		View notifications	✓		
		Download notifications	✓		
		Print notifications	✓		
04	<a href="#">Display on-line help</a>	Browse online help topics	✓		
		Search for specific text in the online help library	✓		
		Display related help topics	✓		
		Display context-sensitive help	✓		
		Provide multi-lingual help content	✓		
Industry					
05	<a href="#">Fill-in and submit a notification on-line</a>	Fill-in, validate pre-submission and submit a notification online		✓	
		Save and recall an online notification draft			✓
		Export/Import a draft notification file		✓	
06	<a href="#">Upload and submit notification files that were prepared offline</a>	Upload and submit notification file(s) (single or bulk)	✓		
07	<a href="#">Update a notification</a>	Update a notification online		✓	



Functional Area		Feature	System Versions		
			V1 (MVP)	V2	V3
		Upload and submit updated notification file(s) (single or bulk)	✓		
08	<a href="#">Industry system integration</a>	Submit initial notification via web service		✓	
		Update a notification via web service		✓	
		Retrieve notifications into local systems via web services			✓
09	<a href="#">Validate a notification file</a>	Validate a notification file via a validation tool		✓	
10	<a href="#">Manage contacts</a>	Manage contact records		✓	
		Update already assigned contact		✓	
11	<a href="#">Change Submitter Legal Entity</a>	Communicate a Legal Entity change		✓	
Appointed Bodies and Poison Centres					
12	<a href="#">Review notification</a>	Record notification review status		✓	
		Request clarification		✓	
		Annotate notification fields			✓
13	<a href="#">MS system integration</a>	Retrieve notifications into local systems via web services		✓	
ECHA					
14	<a href="#">Provide operational support</a>	Search for processes	✓		
		View a process	✓		
		Withdraw a process	✓		
		Resume a process	✓		
System					
15	<a href="#">Perform notification workflow processes</a>	Process and store a submitted notification	✓		
		Perform business rule checks on submitted notification file		✓	✓
16	<a href="#">Provide integration with ECHA substance inventories</a>	Provide integration with ECHA Substance inventories		✓	
17	<a href="#">Provide multilingual User Interface</a>	Enable multilingualism	✓		
18	<a href="#">Provide audit functionality</a>	Log business events	✓		
ECHA services for Member States					

Functional Area		Feature	System Versions		
			V1 (MVP)	V2	V3
19	<a href="#">Provide dedicated services for Member States</a>	Provide an isolated MS-specific environment		✓	
		Enable 24/7 availability for MS-specific environments		✓	
		Provide additional features to support AB/PC use cases <i>* To be defined later</i>			✓ (*)

## 9 ARCHITECTURE OF THE NOTIFICATION PORTAL

The following sections provide an overview of the notification portal software and system architecture, presenting the driving guiding principles, along with the core elements that synthesise the overall solution.

### 9.1 Founding principles

There are a set of principles that guide the suggested architecture. These should be treated as important background influential aspects for some architectural decisions.

#### 9.1.1 ECHA Enterprise Architecture

ECHA's IT architecture landscape has evolved into a highly integrated environment by following architectural principles of standardisation and reuse, principles that promote coherency between solutions. In that respect, the EU PCN Portal architecture must provide an additional solution building block that will fit into and extend ECHA's IT landscape, leveraging existing capabilities already in place where meaningful (e.g. ECHA accounts for authentication needs).

#### 9.1.2 IUCLID format and software reuse

The XML format developed under the IUCLID project has served as the backbone for most interactions between the Industry, ECHA and European authorities in the context of the regulatory processes implemented by the Agency's current IT systems, including CLP ones. An initial analysis has proven that there is a substantial overlap between the notification information requirements and concepts already modelled in IUCLID documents. As such the architecture considers IUCLID as a core element of the final solution, both as a means to carry the notification content but also for processing and storing such content. Further details on the choice of the final format follow in section 10.1

The decision to use IUCLID in the final solution was assessed very carefully. All parts of the IUCLID ecosystem were **thoroughly** analysed as part of this study, starting from the format and progressing to various back-end components, front-end clients (current and future) and even potential data volume handling techniques that can be applied in agreement with emerging business needs. Various ways to reuse IUCLID were examined before reaching the suggested approach, all the elements are detailed in **R[4]**.

#### 9.1.3 Notifications must be stored

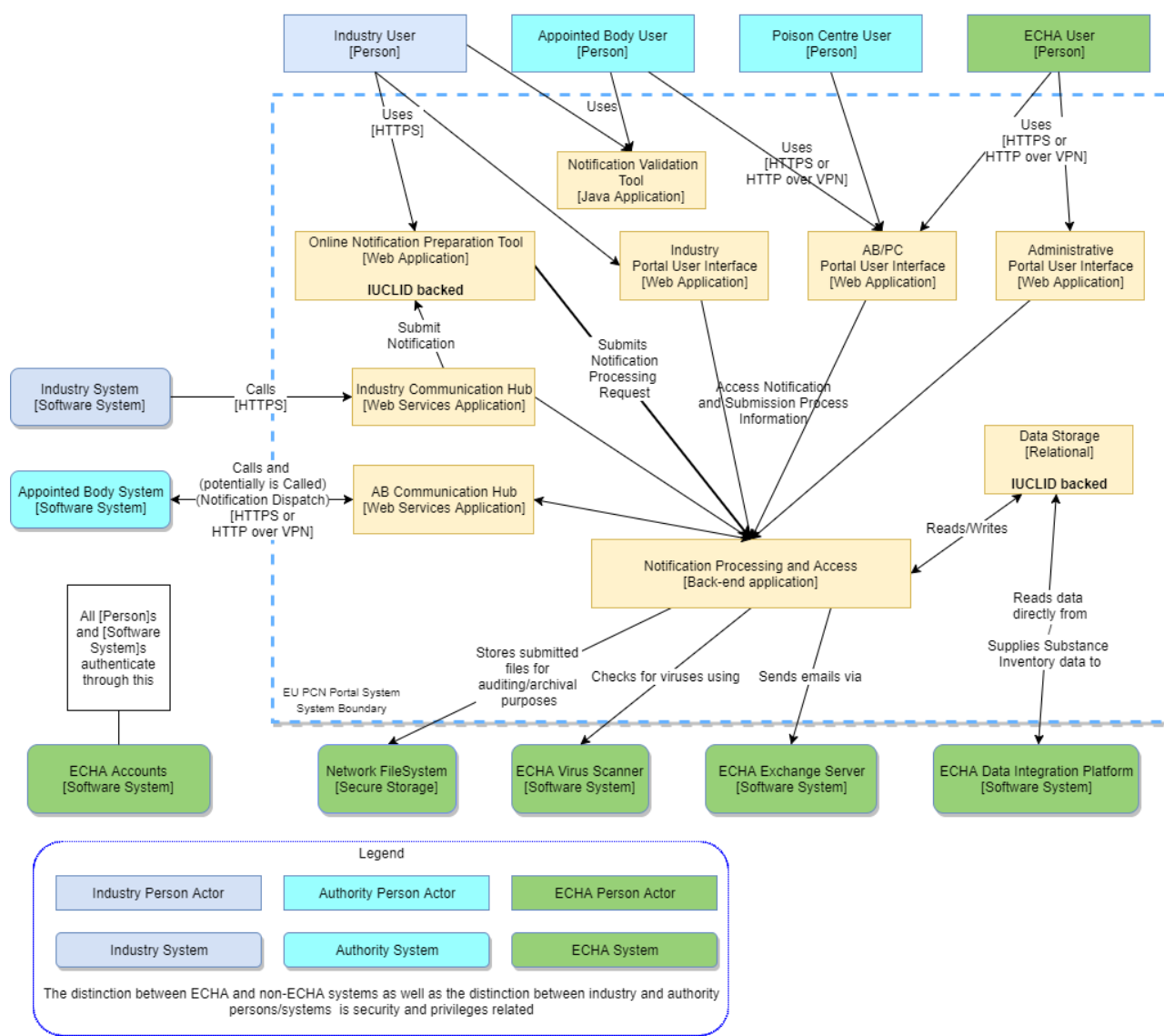
Storing the notifications is required to properly correlate data across different notification files, particularly across notification updates and, potentially, across Member States, and subsequently support reporting; in general we need to facilitate collaboration between Member States in cases of emergency health response incidents. Storing the notifications also allows Poison Centres' operatives to search for information online in case of temporary inaccessibility of their local systems, providing in this way a readily accessible fall-backup solution.

### 9.1.4 An incremental delivery approach must be possible

The architecture should allow for an incremental delivery, utilising where possible distinct collaborating modules that can add functionality to the final solution in a step-wise manner. The various modules or building blocks used should be easily extensible to accommodate the needed features, according to the suggested implementation plan.

## 9.2 Information and application architecture

The following diagram presents an overview of the major architectural components and how these are inter-related, as well as how they connect to other existing ECHA systems in order to reuse already implemented functionalities.



It is important to notice that the suggested architecture consists of a set of modules that can be worked upon, largely independently. For completeness, all envisioned modules are depicted even if they are not of equal importance (or in other words not part of the MVP).

In order to support the core business concern of processing Industry-submitted notifications, and making them available to targeted Appointed Bodies, the following core components will be needed:

- A preliminary version of the *Online Notification Preparation Tool* to provide the user interface for submitting notification files prepared offline;
- The *Notification Processing and Access back-end* to process the notification;
- The *Data Storage* to store the notification during and after processing;
- The various *Portal User Interfaces* to enable access to the processed notification.

The *Communication Hubs* providing web service access to the Portal and integration with external Industry or Appointed Body systems, as well as the *Notification Validation Tool*, are considered secondary.

Staying true to the principles of incremental delivery, fitting into ECHA Enterprise Architecture and maximizing reuse of existing elements, it should be mentioned that a large part of the *Notification Processing and Access back-end application* will be supported by existing ECHA systems and in particular:

- ECHA Virus Scanner to protect against virus-infected submitted notification files;
- ECHA Exchange Server to handle email communications;
- ECHA Accounts system to handle all authentication related concerns;
- IUCLID software (albeit a separately installed instance) to handle notification storage needs of the portal, but also for running its validation assistant engine to perform business rules check, and potentially the internal reporting engine to support printing requirements.

Further reuse scenarios, particularly around the underlying IUCLID usage, include the following:

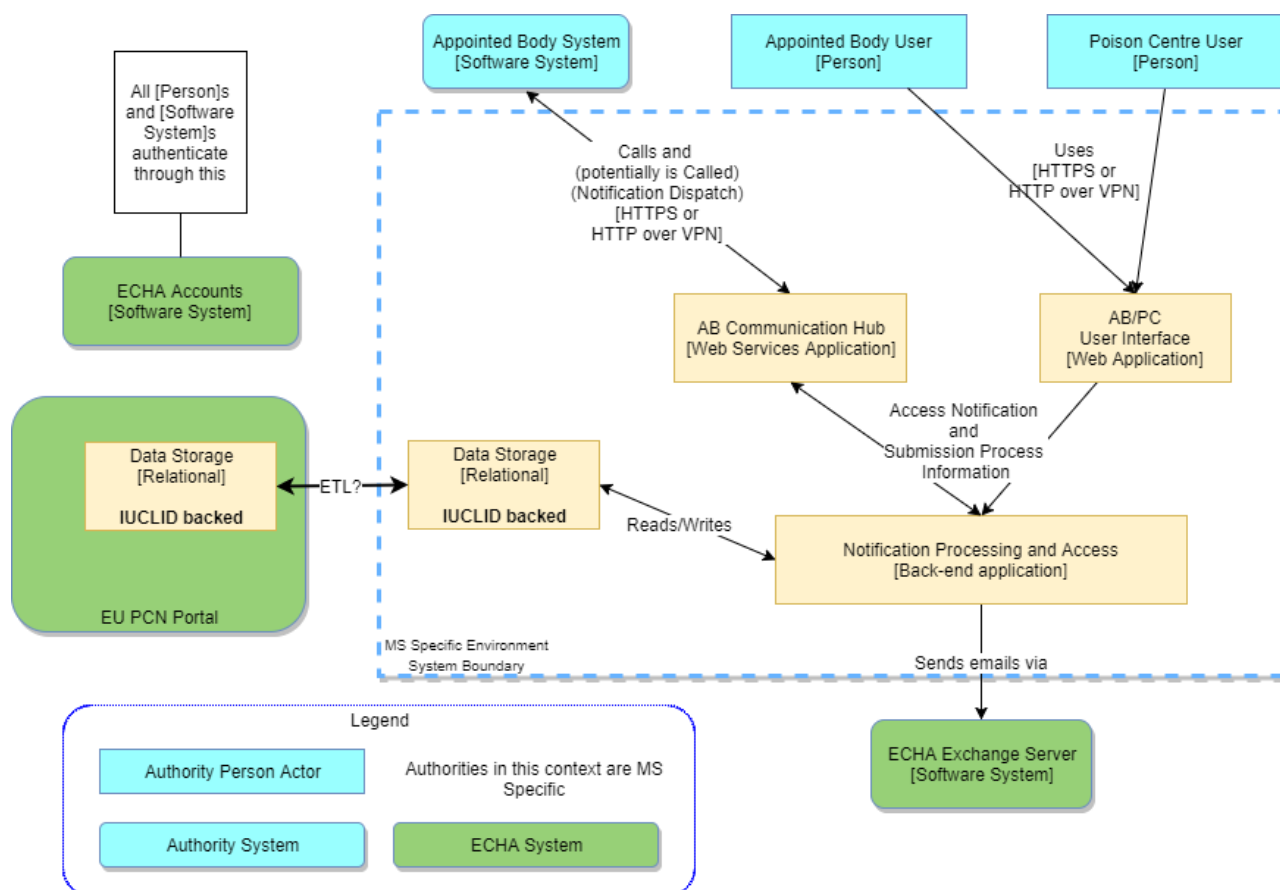
- Readily available IUCLID software can also be used by Industry as an offline preparation tool;
- IUCLID cloud-based instances could also be used by Industry as a private online preparation tool. Notice though that further development to support this option will be required.

Finally, it should be mentioned that the overall integration between the *Notification Processing and Access back-end*, the *Online Notification Preparation Tool*, the *Data Storage* and the various pre-existing deployed ECHA systems, closely resembles the integration model of *REACH-IT*, its *Online Dossiers module* and *IUCLID*. Recommendations for examining these and other existing components for further reuse, as well as a more detailed presentation of the proposed architectural elements follows in section §[10](#).

### 9.2.1 ECHA Services to MSs

Providing an isolated environment (with a potentially higher availability service level agreement) as a service to some Member States, as well as developing and deploying extra functionalities there, has been designed as a separate development activity or as add-on work to the portal. It is considered mostly independent work that may or may not happen depending on relevant demand.

As depicted below, this will be achieved by reusing and extending existing portal architectural components, and operated by replicating data from the portal's main data storage.



*Data storage, Appointed Body User Interface, Appointed Body Communication Hub and Notification Processing and Access Back-End* can be reused as-is by the portal and of course be further extended with any requested features. The MS specific environment's *Data Storage* will be kept in sync with the main portal's *Data Storage* potentially via an underlying database ETL (extract, transform, load) process or through an extension of the main portal's processing pipeline (exact approach to be finalised at a later stage).

It may be possible to reuse cloud-based IUCLID instances to support the isolated environment data storage component, however this should be separately assessed when specific needs and extra features are better understood.

### 9.3 System Architecture

The required infrastructure to cover the total EU PCN Portal solution can be split according to the major architectural elements described previously. The following table describes the needed hardware by analogy to other already deployed ECHA systems.

Of particular interest is the "Production" environment for the REACH-IT-IUCLID integration, utilising a 2-node JBoss clustered application server for REACH-IT and integrated with a 2-node Glassfish clustered application

server for IUCLID. The hardware configuration for those nodes, as well as the node handling the database for the IUCLID application, is considered a reference for the hardware capacity planning for the EU PCN Portal.

It must be mentioned that the following suggested capacity (number of nodes or hardware upgrades) can be gradually delivered according to the overall implementation roadmap.

Architectural Component	Application Server Nodes	DB Nodes	Application Server Node Hardware CPU and Memory	DB Server Node H/W CPU and Memory
Data Storage	2-4 nodes Glassfish (IUCLID)	1-node Oracle (IUCLID, processing engine temporary data)	Equivalent to IUCLID production	Equivalent – 2x to IUCLID production
Notification preparation tool	1 or 2 nodes Glassfish (IUCLID)	1-node Oracle (IUCLID)	Equivalent to IUCLID production	Equivalent to IUCLID production
Notification Processing and Access Back-end, Portal User Interfaces, Communication Hubs	2-4 nodes JBoss	-	Equivalent to REACH-IT	-

As already pointed out in the Non Functional Specifications section, the storage capacity required to hold the projected notifications volume is quite large. This is the primary reason why a separate IUCLID infrastructure will be needed to serve as the main portal data repository, and why the current one deployed in production for REACH-IT/R4BP cannot be reused. It is true that this storage capacity will be required incrementally at a rate of about 30 terabytes per year for the first 4 years increasing to about 180 terabytes per year from then on, reaching about 1.275 petabytes of data stored after 10 years. This capacity needs to be split between the archival filesystem and the two databases (one for the notification preparation tool and one for the portal) using a 2:2:1 ratio.

In terms of the technology selected to deliver the solution, the standard ECHA development guidelines and technologies already in use on other ECHA systems are proposed. Namely:

- User Interfaces will be delivered with client side technologies and in particular AngularJS (potentially Angular 2 or Angular 4, depending on maturity at the time of development);
- The Communication Hubs and Notification Processing and Access Back-end will be based on standard JEE 6 technologies to further facilitate reuse of existing components from other ECHA systems, as needed (e.g. reuse and integrate the processing engine of R4BP or REACH-IT).

### 9.3.1 ECHA Services to MSs

Delivering an isolated environment as a service to specific Member States creates separate capacity requirements. Exact requirements, storage and hardware capacities would be MS-specific, depending on the number of notifications applicable to that Member State.

As mentioned in section 9.2 this environment is a scaled-down replica of the portal (minus the Industry related functionalities) but potentially with higher availability requirements. This means that clustering technology should potentially be used at the database layer and specifically Oracle Real Application Clusters (RAC) or possibly Oracle RAC One. This would require a different licensing scheme and hardware infrastructure at the database layer.



## 10 DESCRIPTION OF THE BUILDING BLOCKS

The architectural modules depicted in the previous diagram will be further described in this section grouped as needed into larger architectural elements. It is worth mentioning here that there is a further important underlying architectural element which, although already mentioned cannot be depicted, namely the actual format used for notification content exchange.

### 10.1 Notification Format

As part of a previous EU Commission study on interlinked databases, format and basic application to facilitate exchange of information between Poison Centres (see **R[2]**), a draft PCN XML format has been created. On the other hand, ECHA has already established the IUCLID XML format at its core IT systems. The need to align the two formats became obvious from the beginning of this study.

A preliminary gap analysis (see **R[5]**) has verified the overlaps between the previous draft PCN XML and IUCLID XML formats, and provides an initial confirmation of the feasibility to extend the latter to cover the remainder of the information requirements in the scope of CLP Annex VIII.

It is strongly recommended that work around the final alignment should begin as soon as possible to allow for a timely publication of the final format as committed by ECHA, followed by a subsequent IUCLID software release that supports this format to assist in further development activities (for both the portal side as well as any interested Industry/Appointed Bodies producing custom systems to be integrated with the portal).

The set of expected benefits derived from using an extended IUCLID format, both around data standardisation and in terms of maintenance/operational costs, are summarised on the table below:

Data standardisation	<ul style="list-style-type: none"><li>• PC notification format becomes and remains aligned with CLP concepts already modelled in the IUCLID format. Harmonisation of formats for CLP processes is achieved;</li><li>• New or existing data sets become candidates for reuse and exchange in multiple contexts, owing to the increasing global applicability of the IUCLID format;</li><li>• Industry/Authorities and their local IT systems need to be competent with only one “language” when interacting with ECHA;</li><li>• Increase ECHA’s mission effectiveness in this key area.</li></ul>
PCN portal maintenance and operational costs	<ul style="list-style-type: none"><li>• Reuse of IUCLID ecosystem elements, as core backend architectural components for the PCN portal implementation, decreases long term maintenance costs, through harmonisation of tools and code modules, as well as standardises the format evolution process to support future business needs;</li><li>• The Agency efficiently manages the competences of its internal resources, by linking the governance of the PC notification format with already established processes;</li><li>• Maximise value of existing ECHA IT assets.</li></ul>

At the same time, additional synergies are made possible, particularly:

1. The choice of notification preparation tools for the Industry expands. All current IUCLID clients (locally

installed IUCLID, cloud-based IUCLID) can become valid options for preparing notification files. This option may be especially appealing for companies already maintaining IUCLID formatted data sets for other regulatory purposes. In this way, overlapping data on mixtures/products (e.g. Biocidal products) would not have to be re-recorded in another format/system.

2. A IUCLID environment could rapidly enable MS to store, view, and query notifications. As the format is complemented by a software platform to support it, it can be considered as an enabler for MSs who do not have or plan to have dedicated IT systems to receive and process the data. A cloud-based installation of that environment is also a possibility under this context too, though some additional development effort is expected to properly support this part of the regulation.

## 10.2 Online Notification Preparation Tool

For the *Online Notification Preparation Tool* it was clear from the start of this study that a direct analogy with the Online Dossiers exists. The *Online Notification Preparation Tool* was therefore modelled after it and in a great part reuses the architecture but also, and perhaps most importantly, acquired the lessons learned from Online Dossiers.

Based on existing work from Online Dossiers but also from the cloud-based IUCLID web client, the *Online Notification Preparation Tool* is envisioned as a custom user interface backed by a IUCLID server. This choice flows naturally after the decision to use an extended IUCLID format as the final notification format, as well as reusing the prior experience with the development of Online Dossiers and the undergoing development of the cloud-based IUCLID web client.

This component's functionalities can be incrementally delivered, which means that the underlying backend IUCLID instance's previously requested capacity can be supplied incrementally. A basic version of this tool is expected to support the functionality of uploading and submitting notification files. That version will include most of the needed architectural elements to support future increments. As an example, the IUCLID backend will be installed even if, strictly speaking, this specific functionality could be implemented without it.

The final set of functionalities supported by the tool should be further analysed and potentially carefully weighed against expected or monitored usage patterns. It is important to keep in mind that there are alternatives to preparing notification files, namely other existing IUCLID clients like the default desktop application client or, potentially, the cloud-based IUCLID web client (albeit this would have to be extended to support the PCN related parts).

As a side note, it should be pointed out that the *Online Notification Preparation Tool* is architected in such a way that it relies solely on a IUCLID back-end. This presents an opportunity to deploy instances of that tool on the cloud-based IUCLID infrastructure and, in this way, provide a privately hosted notification preparation tool as a service to interested Industry, and with the same familiar user interface that will be publically available.

It is recommended that a further study on potential synergies with the cloud-based IUCLID development team is performed, to further investigate current or future potential reuse opportunities, along with possible services offered by ECHA to the Industry regarding this part of the regulation.

## 10.3 Web Services Communication Hubs

Both the Industry and Appointed Bodies expressed the need for system-to-system integrations between the portal and their own existing or future IT infrastructure. Expectedly, the two groups' functional needs are different, therefore two separate applications have been envisioned. This separation allows the flexibility required in terms of delivery, maintenance updates and deployments, and can facilitate the overall planning for the project roadmap.

It is important to stress that the two applications have separate security related requirements, since one is targeted to a more "closed" circle of people (Appointed Bodies and Poison Centres), potentially accessing it via a VPN, while the other is more open (Industry) and accessible via the Internet.

Implementation wise, a number of the requested functionalities (a typical example being the download of notifications) can actually be implemented in a precise "pass-through" way, by calling through to the underlying IUCLID backing instance Public REST API (following the previous example, reuse of "Export Dossier" IUCLID web service is expected).

Finally, in terms of whether the web services exposed from the hubs would be following the SOAP protocol or the RESTful model, it is proposed to use the RESTful variety for its simpler and faster development model. However, if further security related analysis mandates a more standards oriented approach around specific functionalities, this choice could be re-examined.

### 10.3.1 ECHA Services to MSs

If extra functionalities need to be exposed, the required extensions would be deployed only on the Member State specific environment.

It should be noted that the existence of an MS-specific environment would potentially reduce the load on the portal's communication hub, so it should be considered that the existence of a number of such member-specific environments could reduce the total hardware requirements for the portal.

## 10.4 Portal User Interfaces

As already mentioned, the portal is targeting separate groups of actors with different needs. Therefore once again separate applications have been envisioned per actor (unified in look and feel, styling, etc.) that can be independently maintained, deployed and secured according to their relevant needs.

An incremental approach to delivering the needed functionalities per application will be taken according to the overall roadmap. All applications will be based on – potentially different sub-modules of – the *Notification Processing and Access Back-end*. Common functionalities such as the ability to download or print a notification or view its status in the overall process, will be encompassed in common back-end modules, uniformly accessed by all user interface modules that need them. It is also expected that common front-end assemblies of components will be created to deliver these functionalities, so a high overall reuse factor is achieved.

As a final note, particularly for the administration user interface and depending on the actual processing engine component that will be used in the *Notification Processing and Access Back-end* application, a relevant

process monitoring dashboard can be extracted, adapted and ultimately reused from either R4BP or REACH-IT projects.

### 10.4.1 ECHA Services to MSs

Similar to the communication hub situation, if extra functionalities need to be exposed, the required extensions would be deployed only on the MS-specific environment.

Particularly for the administrative operations, further investigation will be required on the feasibility of a unified single user interface across all environments, being either MS-specific or the main portal environment. The alternative of deploying an administration console per environment, although directly feasible, is less desirable from an operational standpoint.

## 10.5 Notification Processing and Access Back-end application and Data Storage

The portal back-end application and the related data storage component are the heart of the architectural solution. All user interface and communication hub exposed functionalities pass through them. Incremental delivery of these components is crucial to the successful delivery of the overall project.

### 10.5.1 Data storage

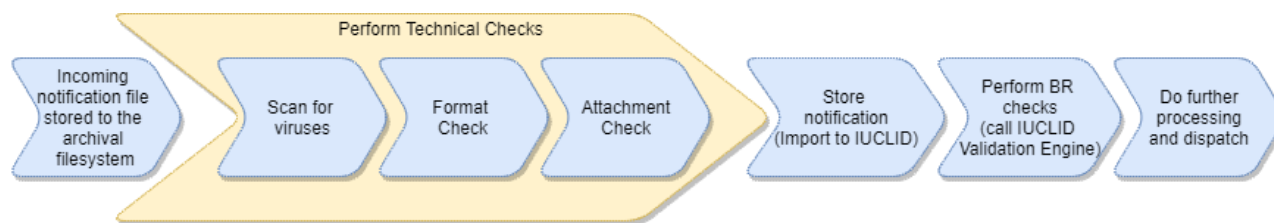
Since the final notification format is IUCLID-based, using a IUCLID-backed storage component is the default approach. It is expected that the end database server that will host the IUCLID schema will also host any process engine specific schema. Via reusing the custom entity/document concepts from the cloud-based IUCLID development process, it is expected that the above two schemas will be sufficient. Any portal specific database requirements could in this way be stored directly in IUCLID.

The required storage capacity can be deployed incrementally following the regulation timelines. In the same mind set, hardware requirements for the application servers (IUCLID Glassfish) can be deployed incrementally.

### 10.5.2 Notification Processing and Access Back-end application

The back-end part of the portal can be seen as largely consisting of three major sub-components, namely the processing system, a queuing mechanism to deliver load to this processing system, and the accessing system to allow status checks and viewing of the processed results.

The processing system is tasked with supporting all relevant business processes that will be covered by the portal. Further business analysis will be required during an elaboration phase to determine the needed details, however the core business process around processing and storing notifications is roughly represented in the following diagram:



This is more or less similar to what either REACH-IT or R4BP submission pipelines perform (apart from the last step). It is therefore expected that either system's core processing engine can be reused together with the code elements (basic process steps) that perform identical functionalities, as well as its relevant process dashboard administrative user interface.

However, at this point, it should be stressed that a potential for a higher level reuse of the already existing REACH-IT ecosystem level exists and must be further analysed. It may be feasible to directly reuse the already installed, configured and tested REACH-IT/Online Dossiers/IUCLID/cloud-based IUCLID (soon-to-be) combination of deployed systems to perform some of the portal functionalities replacing in this way some of the architectural blocks of the suggested solution. A separate targeted gap analysis can follow up on this concept.

In order to efficiently deliver the load of incoming notifications, a queuing subsystem will be used guarding the processing system. An assessment of possible technical choices for this subsystem has not been concluded at this stage but it is more than likely that either the application server's JMS subsystem will be utilised or an externally hosted Kafka stream, leveraging the experiences of the ECHA Cloud Services Platform.

Finally, to provide the different user interfaces with the ability to monitor (and for administrative purposes also control) the various running business process instances, as well as to enable all related functionalities around processed notifications (searching, viewing, downloading, printing, etc.), an access subsystem or layer will be created. It is important to understand here that implementation-wise, similar to some parts and functionalities to the communication hubs, some of the notification related functionalities can be delivered via calling through to the data storage's underlying IUCLID backing instance's Public REST API.

### 10.5.3 ECHA Services to MSs

Depending on the features and extensions requested, significant work could be required. Further processes, potentially requiring manual intervention, could be needed to support Appointed Bodies in their role while performing quality checks. Details and exact requirements remain to be determined during an elaboration phase. As for the communication hubs and the user interfaces, all extra development will be deployed only on MS-specific environments.

## 10.6 Notification Validation Tool

A fully separate way of validating notifications has been requested multiple times from the Industry's side. This validation tool could be delivered either as an offline desktop application, an online application (most likely as part of the *Online Notification Preparation Tool*), or simply as an extra web service via the *Industry Communication Hub*. The final choice has been deferred to a future elaboration phase.

In case this tool is delivered via one of the existing components (*Online Notification Preparation Tool* or *Industry Communication Hub*) the implementation will be delivered via reusing the underlying IUCLID instance and, in particular, the Validation Assistant Engine. A notification content related ruleset will be created and run on the submitted data.

In case an offline desktop application must be created, IUCLID components and libraries will be combined (Validation Assistant Engine, IUCLID input/output modules and IUCLID Domain modules) to form the core of the solution. On top of the required notification content related ruleset, a User Interface will also have to be created in this case.

## 11 RELATED SERVICES

If the implementation of a central notification portal goes forward, it will mean that ECHA will need to adapt or introduce new services that will support this new capability. This section presents the recommended additional services and activities required for the system's use and operation:

### 1. Training

Training the system's users could include the following activities:

- Organising a series of on-site workshops for the following users:
  - Internal ECHA users (e.g. service desk agents);
  - Member State / Appointed Body users;
  - Selected Industry / Industry association representatives or other consultants that could act as future trainers ('train the trainers').
- Organising a series of webinars (preferred option due to the volume of the Industry's segment) for Industry.

### 2. Communication/Publicity

Raising the general awareness of the stakeholders regarding the features and benefits of the new initiative. This could include updates to the Accredited Stakeholders via the Stakeholder Update, press releases and news items for smaller updates published on the website and sent to media, background articles in the newsletter (published once per quarter), snippets in the Weekly published every Wednesday, Social Media posts with links to the content above; Facebook for general public and LinkedIn for professional audiences, updates in the Enterprise Europe Network (EEN) online forums. Additional web content such as videos, webinars, infographics for special cases and printed material such as leaflets. Consultation of ASO communicators' network and possible joint communications projects. Annual ASO workshop agenda could potentially feature a topic on this as well.

### 3. Stakeholder Engagement

The existing channels (S-CIRCABC, project functional mailbox) should be retained (even after going live) to encourage discussions on open issues, express any other ideas in which the product could be further evolved or simply monitor the impact/progress of the project during its lifetime.

Stakeholders' input/comments will provide a basis for future improvement of the system. Such input could be retrieved via:

- Stakeholders' day workshops;
- Performing Stakeholders' questionnaires/surveys;
- Creating customer empathy maps on how the users are interacting with the system.

*To be further elaborated*

## 4. Service Desk

Service desk operation would include the following activities (see also [§14Service and support costs](#)):

- Setting up the service desk infrastructure (tools, processes or any other environment for the purpose of verifying/resolving production issues), or adapting the existing one to accommodate the new system;
- Staffing and training the service desk resources (per level);
- Configuring user accounts and access rights in the ticketing system;
- Maintaining/extending FAQs and the Knowledge Base;
- Adapting the Contact form system.

## 5. Documentation

Provide sufficient and comprehensible documentation such as:

- Online help text which assists the users when they are engaged with the systems, e.g. on each field provide a help description of what the user should provide;
- User manuals (for Industry and Member States);
- Operation/administration manuals (describing specific administration tasks, e.g. system configuration/fine-tuning, troubleshooting, back-up and recovery processes, etc.);
- Other material (e.g. API specification) to provide guidance on how to utilise/interact with the system via the web services integration layer.

## 6. EU Product Categorisation System (EU PCS)

The EU PCS is a hierarchical system of product categories based on intended use of the mixture. A single category is required to be selected by the Industry in the notification from a hierarchical tree. Although the aim of the system is to be robust and fit for purpose as possible, it is a dynamic system that will need to reflect changes considered necessary or desirable, such as:

- legislative changes;
- Industry needs;
- reporting requirements for Appointed Bodies/Poison Centres.

ECHA is responsible for the update and maintenance of the EU PCS.

## 7. Guidance

*This section needs further elaboration.*



## 12 SYSTEM IMPLEMENTATION COSTS

### 12.1 Estimation methodology

For producing the figures below, we relied on the following *bottom-to-up* estimation techniques and took into consideration some cost drivers, specifically:

- Define the Product Breakdown Structure (PBS) as outlined in §6 Functional Areas and Features;
- Provide development estimates<sup>3</sup> for each feature (in man-months). Since there is still a number of open issues/uncertainties around various portal functionalities, we resorted to comparative analysis e.g. actual development time of similar architectures already deployed (e.g. Online Dossiers vs Online Notification Preparation Tool) having also in mind the specific nature of the current project and other important factors impacting the development costs, such as:
  - Multi-market notification handling complexities;
  - Optimisations required to handle projected notification volumes.
- Having the total number of development days, the needs of other profiles were extrapolated based on certain (best practices) assumptions (e.g. 1 tester per 3 developers).

### 12.2 Cost Projection

The following table presents an estimation of the system implementation costs across **2018-2022**.

2018	2019	2020	2021	2022
1.178.320,00 €	1.182.750,00 €	826.920,00 €	501.120,00 €	501.120,00 €

---

<sup>3</sup> By development effort we assume only the implementation (coding, unit testing) effort done by the developer to implement a feature (without any reference to analysis or testing activities).



Figure 12-1: 2018-2022 Implementation Costs

### 12.2.1 ECHA Profiles

As a prerequisite for an efficient execution of the implementation tasks, ECHA should ensure the availability of the following profiles (expressed in FTEs on an annual basis).

Profile	Yr. 2018	Yr. 2019	Yr. 2020	Yr. 2021	Yr. 2022
<i>IT Project Manager</i>	1	1	1	0,5	0,5
<i>Product Manager/Product Owner</i>	2	2	1	1	1
<i>Enterprise Architect</i>	0,25	0,25	0,25	0,125	0,125
<i>Business Analyst</i>	1	1	1	0,5	0,5
<i>Service Manager</i>	0	0,5	0,5	0,25	0,25
<i>Roll-out Manager</i>	0,125	0,125	0,125	0,125	0,125
<i>Test Lead</i>	0,5	0,5	0,5	0,25	0,25
<b>Totals</b>	<b>4,875</b>	<b>5,375</b>	<b>4,375</b>	<b>2,75</b>	<b>2,75</b>

## 13 SERVICE AND SUPPORT COSTS

This section presents the activities/processes/tools, as well as, the necessary staff required by ECHA to fulfil the service desk requirements of the PCN Portal.

### 13.1 Service Desk Organisation

During preliminary discussions with ECHA, it was advised that the Portal service desk structure should be part of the existing submission cluster service desk in order to:

- ▶ Leverage existing processes, tools and resources;
- ▶ Achieve cost reduction due to sharing of resources and scaling;
- ▶ Capitalise on the acquired business knowledge from other submission systems;
- ▶ Review historical info, statistics for a possible extrapolation of key figures (e.g. number of contacts per channel/user, number of issues per priority/severity/complexity, average time resolve an issue, etc.).

### 13.2 Identifying the PCN Portal service desk staffing needs

In order to estimate the resources needed for running the service desk operations, the following questions have to be addressed:

1. Volume of notifications expected (**annual rate**);
2. Number of incidents expected (**daily**);
3. Average time required for an agent to respond/resolve a given issue.

Having these figures, it is straightforward to calculate the service desk man-power.

#### Step 1. Estimating the notifications volume

Due to lack of actual figures on incoming submission data, a prediction on the expected model can be made:

- ▶ Comparing with existing ECHA submission systems (e.g. REACH-IT, R4BP). Due to the specific nature of the Poison Centres domain and the legislation of information requirements, it was decided not to follow such a comparison approach as it would lead to biased results with little applicability. E.g. it was often stated amongst Member States that comparing to REACH, the volume of PCN notifications is significantly greater but the notification file size is much smaller;
- ▶ Number of notifications may be estimated based on the number of Industry<sup>4</sup> that trade hazardous mixtures across EU and their size (large, medium, small, etc.). Following a Gaussian distribution (e.g.

---

<sup>4</sup> Based on EUROSTAT figures.

30% of the large companies are expected to contact at least once the ECHA service desk) the number of requests per day can be concluded;

- ▶ Consider the relevant model developed by the previous DG GROW studies – see R[1]) stating approximately 100 million submissions (for consumer/professional uses by companies both trading in domestic or across the EU market area. This figure was further challenged (divided by 20 which is the average number of countries in which a company has market presence);
- ▶ The last two approaches resulted in very similar volume number.

## Step 2. Estimating the daily number of incidents and mean resolution times

Following a similar Gaussian distribution, the total number of notifications is further classified based on their severity (critical, medium, minor). E.g. 10% of issues will be in the critical range, 70% in the medium, etc. For each severity level, an average resolution time is assumed (e.g. 1 day for critical, 0,5 days for a medium, etc.).

## Step 3. Calculating the required service desk resources

Based on the previous steps, it was estimated that running the PCN service desk activities **would require 10 FTEs on an annual base** that can potentially be distributed as following:

Organisation	FTEs	Tasks / responsibilities
ECHA	3	Level 1 incident management (iTex)
ECHA	2	Business users assisting in Level 1/Level 2 incidents
Contractor	5	Level 2/Level 3 support

### NOTE:

- *iTEX provides support to Industry, MSCA and ECHA and also acts as dispatcher and coordinator of tickets resolution;*
- *ECHA should also consider increasing the service desk capacity (e.g. 50%) for short periods (3-4 months) close to the registration deadlines (1 Jan 2020 mixtures for consumer uses, 1 Jan 2021 for professional uses, 1 Jan 2024 for industrial uses, 1 Jan 2025 when the transition period ends and all importers and downstream users shall comply with the new regulation) to cater for the extended volumes of notifications expected to be submitted;*
- *National experts could assist ECHA on the resolution of L1 incidents leading to potential cost reductions for ECHA.*

A possible service desk organisation and incident flow is illustrated below; a setup of the process will be finalised during the early phase of a project.

Ticket Assignment matrix	ECHA	L1	L2	L3
ECHA Helpdesk (ITEX)		✓		
L1			✓	✓
L2	✓			✓
L3	✓			

### 13.3 Open Issues

#### Accuracy of estimations

The biggest concern when estimating the service desk resources is the accuracy of incoming data. DG GROW studies provide an analytical model but the total number (approximately 100 million of notifications annually) may prove to be over-pessimistic and far from reflecting the industrial reality. The actual number will also be influenced by the wider acceptance/adoption of the PCN portal by Industry (e.g. submitting via the portal will not be legally mandated and maybe some companies would prefer to maintain the existing direct communication channels with the national bodies). In addition, the European Commission will conduct a workability study in 2018 that may impact on the number and reduce the amount of expected notifications.

Likewise, the models described in this section are quite fundamental and do not consider how important factors in the industrial world may affect the volume of notifications and, thus, the number of service desk requests. For example, an Industry may submit thousands of notifications but they may relate to similar substances (with slightly different compositions), thus the expected contact frequency with ECHA's service desk would be only a small percentage of the actual submissions. These models need to be extended (e.g. using the 'incident-flow-model distribution') so they can predict/specify more accurately the resource needs or the percentage of issues that could be resolved at each level.

#### Scope of service

A first high-level classification of incidents could be as follows (similar to all ECHA submission systems). This classification will need to be refined during the setup of the service.

- a) IT-related issues regarding use of the tool, reporting problems/bugs, etc.;
- b) Business issues related to the interpretation of the legal text, guidance during submission preparation process, etc.

The processing of IT issues would be more or less similar to other submission clusters and would be handled by ECHA. Regulatory issues, would be shared between ECHA and the Member States according to an agreed process. One challenge that may be faced by ECHA will be the language of the communication (e.g. smaller companies, usually dealing with domestic markets, may prefer to use another language than English to submit their enquiries. The process will need to clarify whether users directly contact the national help desks or if this should be done via ECHA. It should also define what types of issues should be assigned to national help desks.

## 14 SUGGESTED IMPLEMENTATION PLAN

This section presents:

- ▶ A high-level project timeline stating the system release dates in relation to the legislation deadlines;
- ▶ An overview of key features per release;
- ▶ A high-level implementation plan for the 1<sup>st</sup> version (MVP).

### 14.1 Project Timeline

As per the following diagram depiction, 3 major releases are expected (all before the 1<sup>st</sup> legislation deadline for submitting notifications for consumer uses):

- ▶ **Version 1 (MVP)** planned to be released **Q4/2018**;
- ▶ **Version 2** planned to be released **Q4/2019** (an intermediate version may also be provided during the Q2/2019);
- ▶ **Version 3** planned to be released **Q4/2020**.

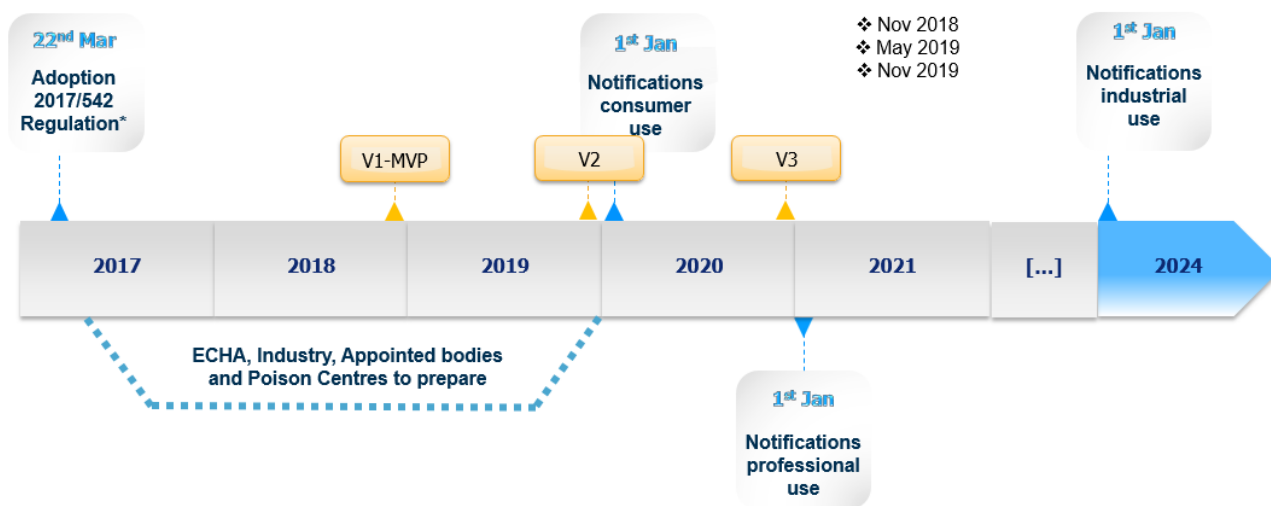


Figure 15-1: Project Timeline

## 14.2 MVP Implementation Plan

The following diagram presents a high-level timeline of the activities required to implement, verify, configure and deploy the 1<sup>st</sup> version of the PCN portal (MVP) in the production environment.

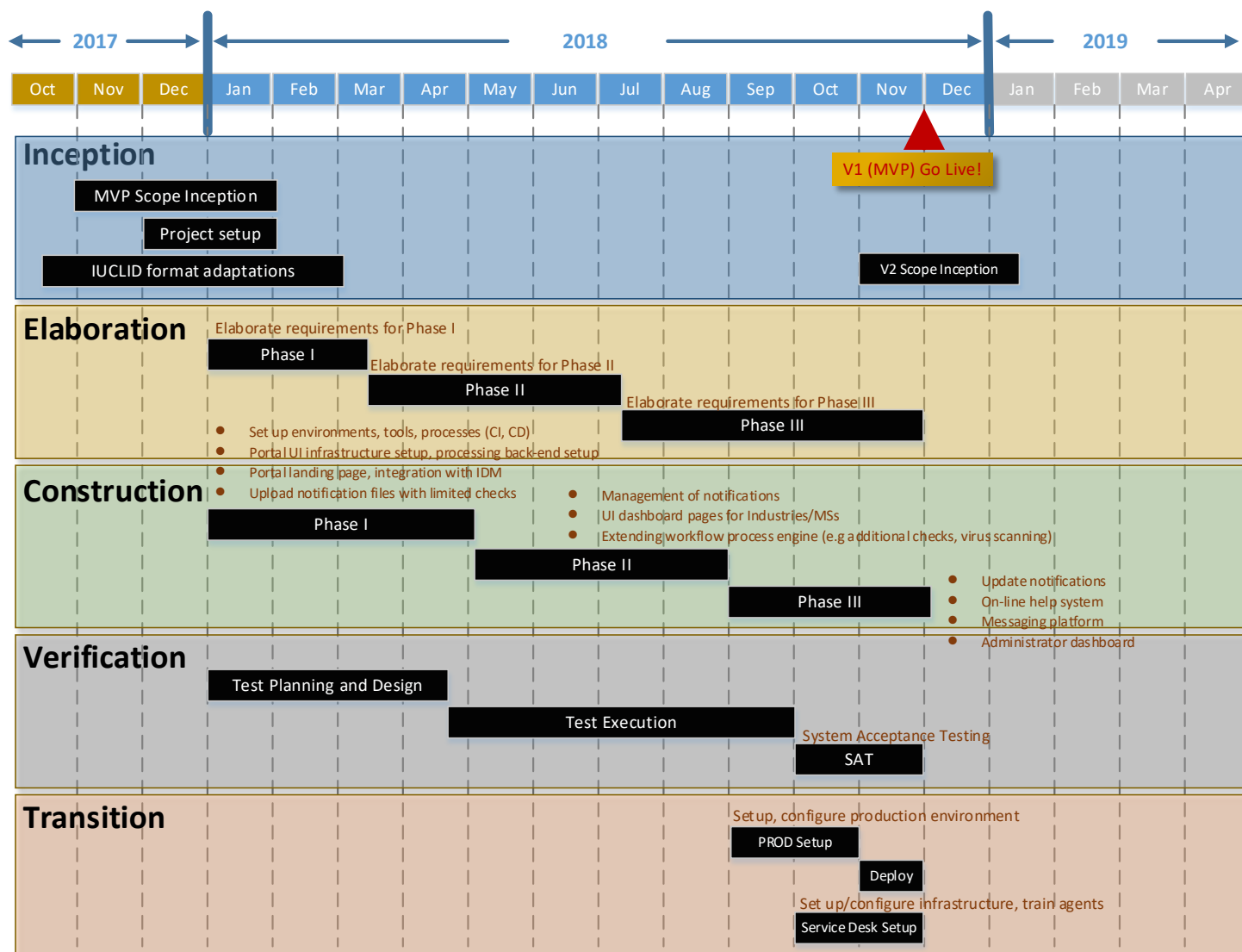


Figure 15-2: MVP Implementation timeline

## 15 ELEMENTS FOR THE EX-ANTE EVALUATION

The purpose of this section is to summarise the possible benefits of the portal in a quantitative and qualitative approach.

All projects or activities occasioning budget expenditure or changes to the Single Programming Document shall be the subject of an ex ante evaluation. The following gives the overall description and requirements that have been set. All evaluations must follow a clearly defined, robust methodology intended to produce objective findings. As a minimum, evaluations must assess effectiveness, economy, efficiency, relevance, coherence and EU added value. If it is not feasible to assess one of the criteria extensively, the reason of it should be inserted in the roadmap. The evaluation shall be proportionate to the mobilised resources and project's impact. More specifically, **the Ex-Ante evaluation** is a process that supports the preparation of proposals for new or renewed projects. Its purpose is to gather information and carry out analyses that help to ensure that the delivery of the project's objectives will be successful, that the instruments used are cost-effective and that a reliable ex-post evaluation will be subsequently possible.

The European Commission's communication on Evaluation (SEC(2000)1051), emphasises that **the practical modalities for conducting an ex-ante evaluation** should be decided in a pragmatic way, taking into account the real information needs in each situation:

"The form and method for conducting the necessary ex ante assessment needs to be decided case by case, taking into account the political context, time constraints and decision makers' need for information. The scope of an ex ante assessment will depend, among other things, on the amount and quality of information available from earlier evaluations, studies or other sources, on the amount of expenditure and resources involved and on the type of the decision making process".

### 15.1 Cost savings for Industry and Appointed bodies

During this feasibility study, possible cost savings have been identified both from the Industry and the Member States' point of view. From the Industry's perspective, instead of having to assimilate and adapt to 28 different systems that require a lot more resources, the Industry will be able to adapt to only one centralised notification portal. On the other hand, for Member States that do not have a notification portal, there will be no need to implement a new system; Member States that have one system already in place could decide to adapt it, instead of using the portal.

### 15.2 Quality of information and data integrity

Data quality was one of the topics that was discussed several times with the Appointed Bodies, Poison Centres and also the Industry. The majority of Member States have already noted that a great deal of time is lost due to incorrect or incomplete notifications. A lot of discussions with Appointed Bodies have already taken place in order to come up with a list of checks/validations which will ensure a high level of data quality contained in the notifications. Furthermore, since the portal will be constantly receiving feedback regarding the notification data received (e.g. comments to add/amend validation rules), the quality of information is expected to increase over time. Additionally, since the agreed level of security will be very high, it is expected to have more data in the notifications leading to a better quality of the information. It should be noted at this point that



many Appointed Bodies do not have the time to perform quality checks. Thanks to the considerable time gained from the automated technical checks and business rules implemented in the portal, the Appointed Bodies will have sufficient time to allocate to their own quality/scientific checks which will eventually improve the quality of information.

### 15.3 Notification submission and preparation process

During the feasibility study it was identified that both the preparation (identifying the proper details for substances/mixtures, contacts for each MS, etc.) and the submission (fill-in of all information) of a notification can be quite a time consuming process. More precisely, it was noted that it can take approximately one hour for the Industry to complete a submission process. Since the Industry will have the possibility of using a centralised notification system where:

- a multi-market approach/submission will be available;
- the fact that features such as ECHA's inventory and contacts management will be in place;
- group and bulk submission will be available;

it will bring a major gain in efficiency and time regarding the process of preparing and submitting the notification.

### 15.4 Security and accessibility

A clear request from Member States is the ability for fast access and search capabilities on the notified data. Additionally, the above request concerns also the difficulties faced when having to access information regarding mixture-in-mixture (MiM) cases which end up being very time consuming. In order to overcome this problem the portal will offer such functionality where the MiM information will be accessed instantly (in case the mixture is notified to the same MS). Another aspect of this issue is the fact that it is very difficult to maintain the level of quality offered throughout the years, so many systems turn out to be outdated. The PCN portal will be built based on these assumptions, so data accessibility and state-of-the-art technology are considered standard. Furthermore, Member States that do not have any system in place yet, and no resources for developing it, will benefit Poison Centres which will see an improvement to data availability.

The need for a high security level of the portal has been identified, especially from the Industry's point of view, playing a vital role in using the system. Security vulnerabilities occur every day so it is very important not only to create a notification system, but to maintain it on the day-to-day standards/threats as well. There is notably more effort required in order to maintain such security issues in 28 different systems rather than in one, especially when confidential data is at stake. In order for all Member States to have a different portal with such requirements met, a very strong technological knowledge/expertise and budget is required.

The following table describes the points explained above:

Criteria	Measurability
<i>Cost savings for Industry</i>	<ul style="list-style-type: none"><li>• No licence fees or hidden costs;</li><li>• Implementation costs reduced through integration and adaptation.</li></ul>

Criteria	Measurability
<i>Cost savings for Authorities</i>	<ul style="list-style-type: none"><li>• No licence fees or hidden costs;</li><li>• No maintenance costs;</li><li>• Implementation costs reduced through integration and adaptation.</li></ul>
<i>Quality of information and data integrity</i>	<ul style="list-style-type: none"><li>• Quality checks from MSs should increase;</li><li>• Iterations required for a complete notification should decrease.</li></ul>
<i>Notification submission and preparation process</i>	<ul style="list-style-type: none"><li>• Processing time is expected to drop;</li><li>• Efficiency gain.</li></ul>
<i>Security and accessibility</i>	<ul style="list-style-type: none"><li>• Check the number of possible security violations;</li><li>• Feedback on potential improvements;</li><li>• Streamlined and improved collaboration between actors.</li></ul>

## 16 CONCLUSIONS

This feasibility study recommends the implementation of a **central notification portal** which will, in short, simplify the process of submission of information for industry in addition to harmonising the information received by the Member States appointed bodies and their poison centres.

Given the very tight development time of one year, it is recommended to go for a staggered approach starting with a first version of the portal and followed by subsequent releases increasing the features and business value to all stakeholders. Therefore, all features that have been identified as 'core' would be developed and implemented before the first deadline of 2020. Other releases providing additional features are foreseen in the following years.

This phase-approach will allow gradual product evolution by setting a stable architectural foundations that will allow a gradual extension of the functional scope. It will also allow in-time delivery by providing in the earliest possible time, the essential tools to support notifications in the scope of the first regulatory deadline.

The recommended central notification portal will reuse elements of the current ECHA enterprise architecture, leveraging existing capabilities already in place where this is deemed necessary. It is worth noting that IUCLID will be considered as a core element of the final solution.

The study is meant to serve as support to the decision-making process by the relevant authorities on whether ECHA should develop this portal, and what is the best approach and related timelines.

### 16.1 Open Issues

The following is a list of open issues (identified but not sufficiently addressed during the feasibility study):

Issue	Areas to be clarified
<b>Business / Functional Requirements</b>	
<i>Elaborate on the business model and the core entities</i>	Core business entities (e.g. mixture, product, notification, submission, notification asset, etc.) should be clarified along with their relationships. For each entity a reliable identification scheme should be defined (current proposals including UFI/TFI/DVI should be further explored).
<i>Elaborate on the submission processes</i>	Identify main business events that would require submitting a new or updated notification (e.g. new product in market, change in recipe, change in contact information, product withdrawal, and company merge/acquisition) and how these are mapped to the processes supported by the portal.  Elaborate on the conditions under which a new notification needs to be created and when to be updated.

Issue	Areas to be clarified
	<p>Elaborate on the key business processes and their specific elements (e.g. request for additional information currently entails personal interaction between the submitter and the receiving authority).</p> <p>Define how multi-market notifications will be handled (e.g. one file to single or multiple Member States, how updates in this case will be managed).</p>
<i>Finalise the PCN format</i>	<p>Adapt the PCN according to the IUCLID platform specifications.</p> <p>Extend to support missing legal obligations (group submission, bulk submission, PCS classification).</p>
<i>Handling MiM (Mixture In Mixture)</i>	<p>This issue also was considered of utmost importance by the majority of the stakeholders but no final conclusion has been reached. The following topics need to be elaborated:</p> <ul style="list-style-type: none"> <li>• What validation rules should be in place for the MiM?</li> <li>• Cases of deeper MiM hierarchies (MiMiMiMiM) have been reported by various Member States. How these should be handled?</li> </ul>
<i>Validations</i>	<p>Scope of technical/business checks should be discussed. Existing rule sets applied by various Member States should be assessed for their applicability in the PCN Portal.</p>
<i>Integration with ECHA substance inventories</i>	<p>Define which existing inventories should be considered.</p> <p>Elaborate on the business scenarios where substance does not exist in any inventory.</p>
<i>User roles and access rights</i>	<p>Define the various user roles of the system and their corresponding access rights</p>
<i>Appointed Bodies subscription model</i>	<p>Elaborate on the requirements regarding the subscription model for receiving notifications from the Appointed Body (e.g. define subscription methods, configuration details etc.)</p>
<i>Contact / Legal Entity management</i>	<p>Elaborate on more advanced features (e.g. maintaining hierarchies of companies, on-behalf submissions, etc.).</p> <p>Elaborate on the Legal Entity Change process.</p>
<i>Fee calculation / Invoicing</i>	<p>The financial perspective of the submission process was raised but the details of how and to which extend it would be supported needs to be clarified. A specific survey (specific for the MSs that impose submission fees) should be conducted to evaluate the national fee calculation schemes and whether these can be applied by a central EU PCN portal.</p>
<b>ECHA Services to Member States</b>	
<i>Scope</i>	<p>The scope/nature of the additional functionalities to be provided is yet to be defined (e.g. additional services that are not covered by the basic portal, fee calculation, invoicing, extending the model to support PC operations, support for custom UI search views, etc.)</p>

Issue	Areas to be clarified
	Potential actors (the Members States include both Appointed Bodies and Poison Centres with quite different needs) and the way they wish to interact/use the system must be further elaborated.
<i>Data synchronization</i>	Synchronization/data replication mechanism between main portal and MS specific environment needs to be defined.
<i>Integration with other systems</i>	<p>Integration requirements with other systems (ECHA internal or existing national systems) should be specified.</p> <p>Support for Member States that wish to join (opt-in) or leave (opt-out) the platform should be evaluated, e.g.:</p> <ul style="list-style-type: none"> <li>• In case of opt-in, a migration/upload procedure of existing data (from the national DB) could be foreseen;</li> <li>• In the same sense, in case of opt-out, a procedure for mass export of their data could be also defined.</li> </ul>
<i>Non-functional requirements</i>	<p>The following non-functional aspects needs to be assessed:</p> <ul style="list-style-type: none"> <li>• What will be the availability of the Member State specific environment? Should it be higher than the main portal?</li> <li>• Load / Capacity (estimated storage needs per Member State)</li> </ul>
<b>Non-Functional Requirements</b>	
<i>Expected volume of notifications</i>	<p>The volume of incoming data needs to be more accurately refined since these figures will have a significant impact on the portal infrastructure. The following metrics should be considered:</p> <ul style="list-style-type: none"> <li>• Estimations on notifications expected annually;</li> <li>• Percentage of new submissions vs updated;</li> <li>• Average size of notification files;</li> <li>• Other metrics (e.g. frequency of updates).</li> </ul>
<i>Expected number of users</i>	<p>The following user related metrics should be estimated:</p> <ul style="list-style-type: none"> <li>• Number of registered users (also per role);</li> <li>• Number of concurrent users.</li> </ul>
<i>Security</i>	<p>Possible approaches for ensuring secure dispatching of notifications between the portal and Member States should be described and evaluated.</p> <p>A high level description of what Member States need to do to comply with ECHA security policies, should be provided.</p>
<b>Operational Support</b>	
<i>Service Desk operations</i>	<p>Elaborate on the service desk operations, e.g:</p> <ul style="list-style-type: none"> <li>• Expected number of incoming requests (Member State historical data may be requested via the IT User Group);</li> <li>• Types/classification of questions expected;</li> <li>• Assignment policies, e.g. what kind of questions can be addressed by ECHA and what by national help desks;</li> <li>• Role of national help desks should be more clearly defined (how they could be part of the resolution process).</li> </ul>

For the complete list of open issues see [R\[6\]](#).

## 16.2 Next Steps

### Inception: Elaborate on open issues, functional and non-functional requirements

Although the majority of the user/business/security needs have already been identified, further clarifications are deemed necessary in order to be able to conclude to the optimal solution. An inception phase should succeed the feasibility study in which:

- All critical open issues (as described in the previous section) will be further elaborated and addressed.
- Identify core business entities and how they are interconnected.
- Identify main business events and elaborate on how these will be handled by the system.
- Attempt a more precise estimation on the expected volume of notifications that will significantly impact both the system architecture and the related infrastructure and capacity costs.

### Finalise PCN Format

Following the inception phase (where the core system entities and their relationships have been identified), the PCN format will have to be adapted in order to:

- Support any missing features not addressed by the current draft PCN format (e.g. group submission, bulk submission, integration with PCS, etc.)
- Be compatible with the IUCLID platform.





The format itself (XSDs, explanation of fields, format validation rules) along with any supporting documentation will then be made available to all project stakeholders.

### Gap analysis with existing ECHA systems

An internal study should be conducted to investigate possible synergies with existing systems in the ECHA ecosystem (such as REACH-IT, R4BP, ECHA Cloud Services). As part of this, a thorough gap analysis with each of these systems will be required in order to assess:

- The scope and nature of re-usability (e.g. utilizing libraries/frameworks or adapting existing systems to fulfil the submission requirements).
- Perceived benefits related to expected adaptation costs.

## 17 APPENDIX 1: REFERENCES AND RELATED DOCUMENTS

ID	Reference or Related Document	Location
R[1]	European Commission (DG GROW) Studies	<a href="http://ec.europa.eu/growth/sectors/chemicals/poison-centres_en">http://ec.europa.eu/growth/sectors/chemicals/poison-centres_en</a>
R[2]	Study on interlinked databases (XML format) between poison centres	<a href="http://ec.europa.eu/DocsRoom/documents/16420">http://ec.europa.eu/DocsRoom/documents/16420</a>
R[3]	Proposed EU PCN Portal Architectural Solution	 Software Architecture Docum
R[4]	IUCLID6 Platform Assessment	 Candidate Architecture Study -
R[5]	Gap Analysis - PCN XML / IUCLID	 Gap Analysis - PCN XML / IUCLID
R[6]	Open Issues	 Open issues

## 18 APPENDIX 2: IT USER GROUP PARTICIPANTS

### 1. Member States Appointed Bodies

Organisation	
1.	Lithuania - Environmental Protection Agency
2.	Belgium - Federal Public Service - Health, Food Chain Safety and Environment
3.	Poland - Bureau for Chemical Substances
4.	Sweden - Poisons Information Centre
5.	Germany - The Federal Institute for Risk Assessment
6.	United Kingdom - National Poisons Information Service
7.	Denmark - Working Environment Authority
8.	Netherlands - National Poisons Information Centre
9.	Italy – National Centre of Chemicals, Cosmetics and Consumer Protection
10.	Romania – National Institute of Public Health

### 2. Poison Centres

Organisation	
1.	Belgium – Belgian Poison Centre
2.	France – Poison Centre (Nancy)
3.	Germany – Poison Centre (North Germany)
4.	Italy – Poison Centre (Lombardia)
5.	Spain – Spanish Poison Centre

### 3. Associations

Organisation	
1.	CEFIC - The European Chemical Industry Council
2.	FECC - European Association of Chemical Distributors
3.	VCI - German Chemical Industry Association + BDI - Federation of German Industry (represented by BASF)
4.	AISE - International Association for Soaps, Detergents and Maintenance Products (represented by The Procter & Gamble)
5.	CEPE aisbl - European Council of the Paint, Printing Ink and Artists' Colours Industry (represented by AkzoNobel Decorative Paints)



Organisation	
6.	ECPA – European Crop Protection (represented by Syngenta)
7.	EMO - European Mortar Industry Organisation

#### 4. Individual stakeholders

Organisation	
1.	NCEC - National Chemical Emergency Centre
2.	opesus AG
3.	Akzo Nobel

#### 5. Observers

Organisation	
1.	European Commission - DG for Internal Market, Industry, Entrepreneurship and SMEs
2.	Austria - Federal Ministry of Agriculture, Forestry, Environment and Water Management
3.	Finland - Safety and Chemicals Agency
4.	Sweden - Swedish Chemicals Agency
5.	Switzerland Federal Office of Public Health
6.	FEFANA asbl - EU Association of Specialty Feed Ingredients and their Mixtures
7.	EIGA - European Industrial Gases Association