

How to on-board to ECHA's PCN database

Instructions for appointed bodies

October 2020

ABC

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1. Introduction

1.1. Background

Under the Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation), Article 45 and Annex VIII, companies placing hazardous mixtures on the European market have an obligation to provide information about these mixtures to the relevant national appointed bodies.

Appointed bodies will receive notifications in the harmonised Poison Centres (PCN) format and can use ECHA's PCN database to handle them.

Appointed bodies in each Member State make this information available to poison centres to support response in the event of an emergency.

This document specifies how to request access to ECHA's PCN database for appointed bodies and poison centres.

ECHA also makes available a system to system component for data delivery to national IT systems. Such component is called eDelivery network. Appointed bodies can request to join ECHA's eDelivery network following the instructions in [REF1] How to join ECHA's eDelivery network.

1.2. Purpose

This document details the steps that appointed bodies need to take in order to get access to the **PCN database**.

Also, the document specifies how appointed bodies can request **access for poison centres**¹ in their member state.

1.3. References

Title	Description
[REF1] How to join ECHA's eDelivery network	This document describes the steps appointed bodies need to take in order to join ECHA's eDelivery network

¹ Poison centres that are not appointed bodies.

Title	Description
<p>[REF2] Management Board Decision 59/2019 with Annexes</p>	<p>The MB Decision 59/2019 approved the specific security requirements in the context of PCN database. Its annexes include the</p> <ol style="list-style-type: none"> 1) Standard security requirements for access to ECHA's Information Systems by Appointed Bodies ("AB") and the Poison Centres ("PC") identified by the Appointed Bodies
<p>[REF3] Service Level Agreement (SLA) between ECHA and bodies appointed under Article 45 of CLP regulation</p>	<p>The aim of this SLA is to establish a general cooperation framework defining the terms of the services that ECHA provides.</p>
<p>[REF4] Standard security requirements for access to ECHA's Information Systems by Appointed Bodies ("AB") and the Poison Centres ("PC") identified by the Appointed Bodies</p>	<p>The document contains the security requirements appointed bodies and the poison centres identified by the Appointed Bodies shall fulfil in order to be granted access to ECHA's PCN database.</p>
<p>[REF5] Implementation guidelines</p>	<p>The implementation guidelines help the appointed bodies and poison centres to implement the security requirements [REF4].</p>
<p>[REF6] Audit guidelines</p>	<p>The audit guidelines detail the requirements to complete a security audit.</p>
<p>[REF7] Login Manual to ECHA's IT tools for Authority users</p>	<p>Document describing how users can access to ECHA's IT tools.</p>
<p>[REF8] Identity and Access Management (IAM) Portal User Manual</p>	<p>Document describing how User administrators can request and assign business roles to the users of their organisation. E.g., assigning the business role 'Appointed Body Interact Portal' will allow the user to access the PCN database</p>

1.4. Glossary

Term	Definition
Appointed body	Organisation that has been appointed for the purposes of Annex VIII of the CLP regulation Article 45
ECHA's PCN IT tools	Group of applications provided by ECHA for industry, appointed bodies and poison centres in the context of Annex VIII of the CLP regulation Article 45
Poison Centre Notifications searchable database	'Search, browse and download' interface to the database of PCN dossiers submitted for each member state
Downloading site	'Browse and download' interface to the repository of PCN dossiers submitted for each member state, also called <i>remote folder</i>
PCN database	The term refers to the combination of the Poison Centre Notifications searchable database and the downloading site
eDelivery	Electronic means for secure dispatching of notification to appointed bodies' IT systems
Interact Portal	Is a 'one stop shop' portal for authorities which enables access to the PCN database, amongst other data and applications.
Legal representative	Person who is legally authorised to represent an appointed body and as such, appears in the consolidated Commission list of appointed bodies. The contact details of this person have been formally communicated to the European Commission
Poison centre	Organisation using PCN notifications for formulating preventative and curative measures, in particular in the event of emergency health response
Security Officer	The Security Officers are the primary security contact point for ECHA. They are formally nominated by the appointed body.

Term	Definition
User Administrator	The User Administrator manages the access to the ECHA's PCN database ² for the users of their own organisation e.g. appointed body; potentially, for the users of the poison centres the appointed body has requested access for.

² Excluding eDelivery because it is not meant for final users but for system to system data exchange

1.5. Roles and responsibilities

1.5.1. Appointed body

Role: Organisation that will use ECHA's PCN database for the purposes of Annex VIII of the CLP regulation Article 45. In the event that this organisation is also fulfilling the role of a poison centre, it will not be considered a poison centre for the purposes of this document.

Responsibilities:

- Decide to utilise the PCN database; decide to utilise the eDelivery network³
- Identify the organisations that need access, i.e. the AB themselves and any poison centres in their MS that needs access to the PCN database
- Ensure compliance with the 'Standard security requirements'⁴ for the organisation(s) that need access
- Nominate at least one User Administrator for the organisation(s) that need access
- Nominate a Security Officer (SO)
- Sign the Service Level Agreement
- Ensure testing of the connection to ECHA's PCN database and the access to notifications for the organisation(s) that need access
- Timely submit an audit report to ECHA within three months after the first login to the PCN database by the organisation(s) that need access⁵
- Timely inform ECHA of any change affecting the above, e.g. change of Security Officer

1.5.2. Poison centre

Role: Organisation using PCN notifications for formulating preventative and curative measures, in particular in the event of emergency health response. It can access ECHA's PCN database under the responsibility of an appointed body.

Responsibilities:

- Comply with the 'Standard security requirements'
- Provide the appointed body with the necessary information as requested by ECHA⁶, e.g. if applicable, identify a User Administrator
- Test the connection to ECHA's PCN database and the access to notifications
- Timely inform their AB of any change affecting the above

1.5.3. ECHA

Role: Organisation that provides the PCN IT tools, and notably the PCN database, in the

³ The two decisions can be taken at different times

⁴ See Section **Error! Reference source not found.** for further clarifications regarding previous compliance to ECHA's security requirements.

⁵ The appointed body can send a separate audit report regarding the compliance to the security requirements by the identified national poison centres that need access. Poison centres might be identified at different times, adding or changing to the list requires applying the listed responsibilities at the changed scope, e.g. submitting an audit report for the new organisation

⁶ See Section 4 for further information regarding the documentation that may be required from the poison centres

context of Annex VIII of the CLP regulation Article 45.

Responsibilities:

- Grant access based on fulfilment of the security model provisions
- On-board appointed bodies
- Support appointed bodies and poison centres in testing their connection to ECHA's PCN database
- Support Security Officers in achieving and maintaining compliance with the 'Standard security requirements'
- Receive and analyse the security audit findings
- Act on failure to comply with the audit obligations.

2. Pre-onboarding

ECHA recommends that **before commencing the on-boarding process** the appointed body analyses the following:

1. Who will coordinate the on-boarding and interact with ECHA?
2. Which organisation(s) in the purview of the appointed body need access? Have they access to PCNP V1 already?
3. Are all organisations aligned on what needs to be done to be granted access?
4. Who is the legal representative according to the definition in this document? Has he/she been briefed on what needs to happen and what he/she will have to sign?
5. Who is/will be the security officer? Has he/she been briefed on his/her role and responsibilities?
6. Has the information in this document reached the relevant people involved in the process?
7. When will the organisation(s) be ready to start? Has this been agreed with ECHA as part of the on-boarding planning?

Having answered the seven questions puts the appointed body and ECHA in a position of efficiency that will benefit all parties and is the best warranty for a smooth and successful on-boarding.

3. On-boarding process

ECHA has made available two possibilities to access PCN notifications for authorities:

- PCN database. The PCN database combines
 - ECHA Poison Centre Notifications searchable database, accessible through the ECHA Interact Portal
 - Downloading site, accessible through the Secure Remote Access.
- eDelivery network

The PCN database and eDelivery are provided under the Service Level Agreement (SLA) between ECHA and bodies appointed under Article 45 of CLP regulation [REF3]. The SLA integrates all the documentation we consider necessary for providing the above services in one single package. It therefore replaces the current Declaration of Commitment with regard to ECHA services provided under Article 45 of the CLP regulation, including as

well the Standard Security Requirements and the Terms & Conditions for eDelivery. The SLA defines as well the level of service for the Poison Centre Notification database and for ECHA submission portal.

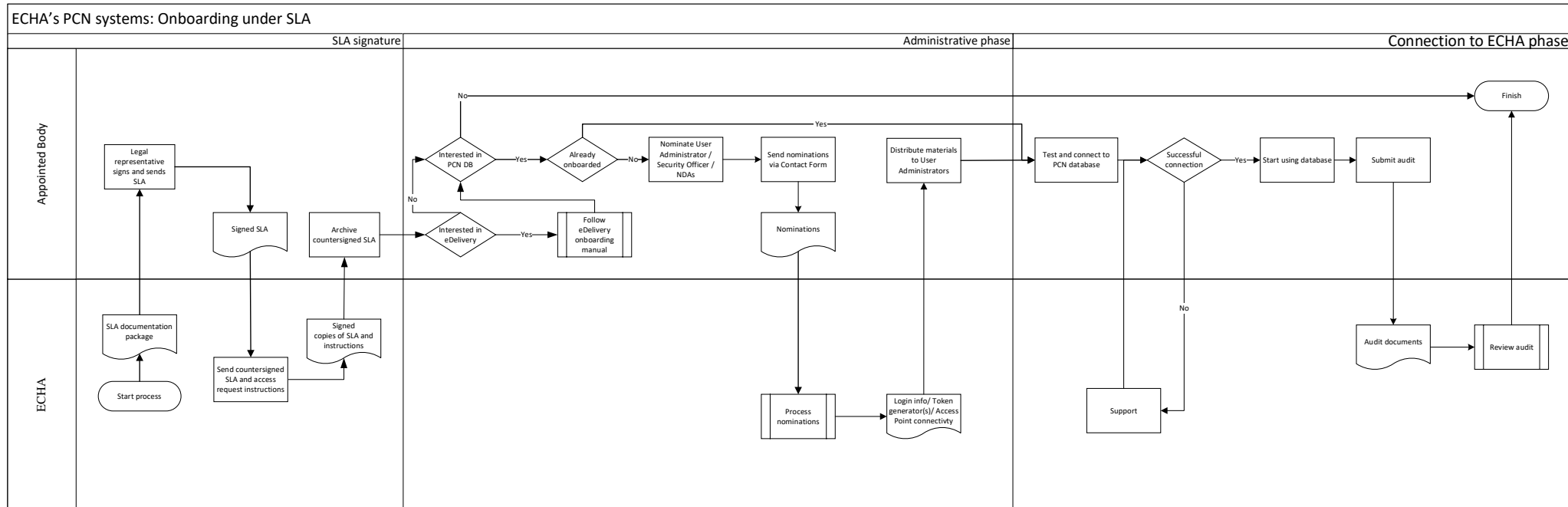
The SLA documentation is available at the [S-CIRCABC interest group for appointed bodies according to Art 45 and Annex VIII of CLP regulation](#).

The PCN database is available to both appointed bodies and poison centres. However, only appointed bodies can request access on behalf of poison centres as described in Section 3.1.2.

The eDelivery network is available to appointed bodies only. Appointed bodies that obtain access to the PCN database can also get access to the eDelivery network if they request it, and once they follow the process specified in eDelivery manual [REF1]. The appointed bodies that are only interested in requesting access for eDelivery shall only follow the first phase of this document and then continue with the dedicated manual [REF1].

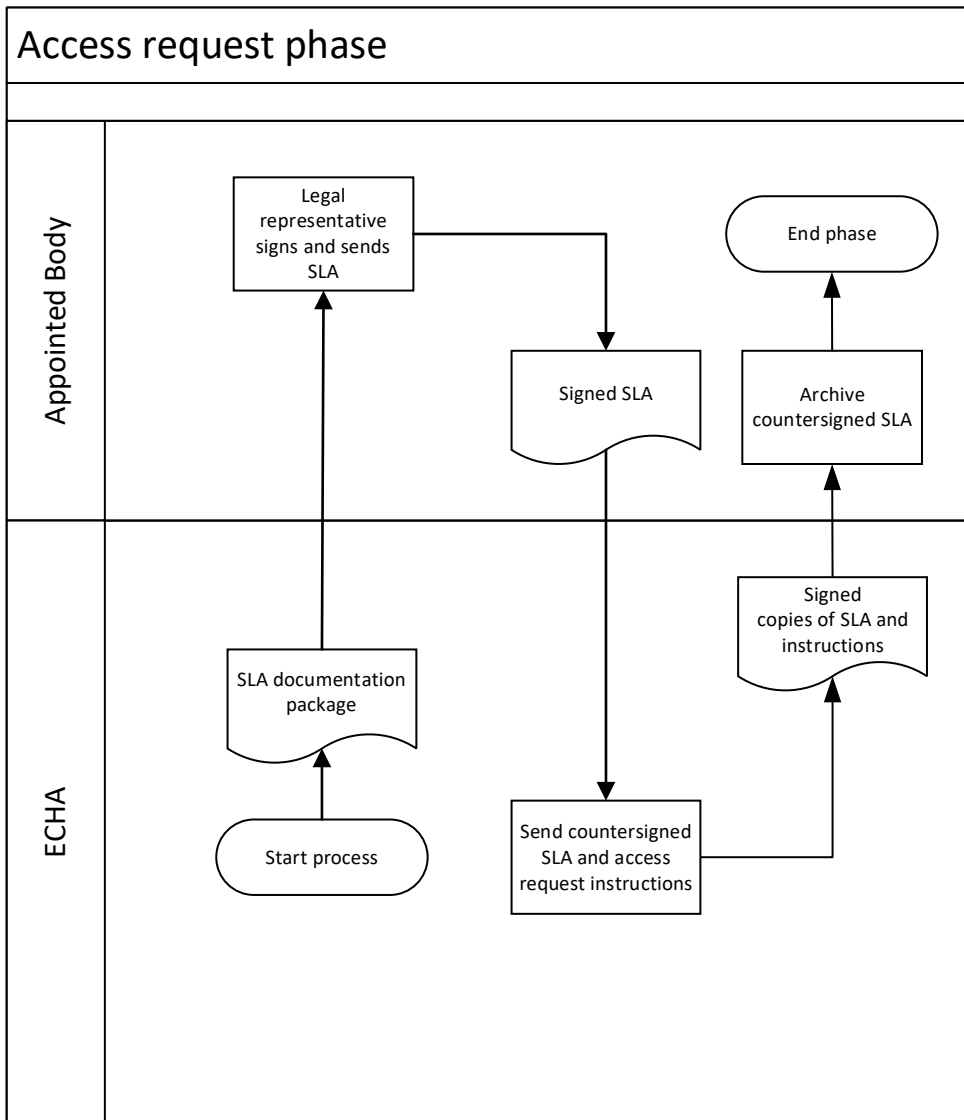
The on-boarding process consists of 3 phases (1) SLA signature phase, 2) administrative phase, 3) connection to ECHA phase) that are explained in the following sections.

Figure 1 Diagram of the on-boarding process with the different phases



3.1. SLA signature request phase

Figure 2 Diagram of SLA signature phase



Purpose: Start the on-boarding process of the appointed body to access ECHA’s PCN database

Actors:

- Appointed body
- ECHA

Process:

1. ECHA sends SLA documentation package
2. Appointed body signs and sends the SLA and relevant annexes

3. ECHA countersigns and sends the SLA back to the appointed body

3.1.1. ECHA sends SLA documentation package

ECHA sends the SLA documentation package to all the appointed bodies. If your organisation has not received it yet, you should request it using the [Contact Form for Authorities](#).

The SLA documentation package includes the template form for nominating security officers and user administrators, and the template for the declaration of confidentiality and non-disclosure.

Figure 3 Authorities Contact Form with fields filled in to contact ECHA with matters relevant to Poison Centres notifications.



Contact form for Authorities

I can't login

I need support with

Please select : *

- Poison Centres

Please give me access to the to the Interest Group 'Appointed bodies according to Art 45 and Annex VIII of CLP regulation' in S-CIRCABC.

My organisation is: <Organisation name>

My EU Login username is: <EU Login username>

- 1) 'I need support with'
- 2) Please select '- Poison Centres'
- 3) In the open comments field please state your request and complete your organisation

name and your EU Login⁷ username:

Please give me access to the to the Interest Group 'Appointed bodies according to Art 45 and Annex VIII of CLP regulation' in S-CIRCABC.

My organisation is: <Organisation name>

My EU Login username is: <EU Login username>

- 4) Fill in the contact details as shown in Figure 4. If your organisation does not appear in the list, please select 'Other'

Figure 4 Fields in the contact form to complete the contact details

The screenshot shows a web form titled "Contact details" with the following fields and values:

- Title: * Ms.
- First name: * AB contact person first name
- Last name: * AB contact person last name
- Email: * contact.person@email.example
- Email verification: * contact.person@email.example
- Telephone number: * +3411111111
- Country: * Spain
- Organisation Information: * Other

3.1.2. Appointed body signs and sends the SLA and relevant annexes

Once your organisation is ready to proceed with the signature of the SLA, we kindly ask you to fill in the following information:

- 1) In the SLA main text: please fill in page 1 the name of your appointed body, name of legal representative and title of legal representative. In page 3 the name of the Member State. And signature and date in page 11.
- 2) In Annex I: please fill in the name of contact point, together with telephone number and email address.

⁷ EU Login is the entry gate to sign in to different European Commission services and/or other systems, such as S-CIRCABC, where the SLA and annexes are stored. You can create an account [here](#) and online help can be found [here](#).

- 3) Annex VI: please fill in this Annex only if you need to request access to the PCN database for the poison centres in your Member State. See Section 4 for more information about requesting access for poison centres.
- 4) Annex VII: please fill in this Annex with the name of your appointed body and select access to the PCN database and/or eDelivery service. The ECHA Submission portal is already pre-selected as this is the basis for the SLA.

Please email a signed digital version to Poison Centres mailbox:
poisoncentres@echa.europa.eu

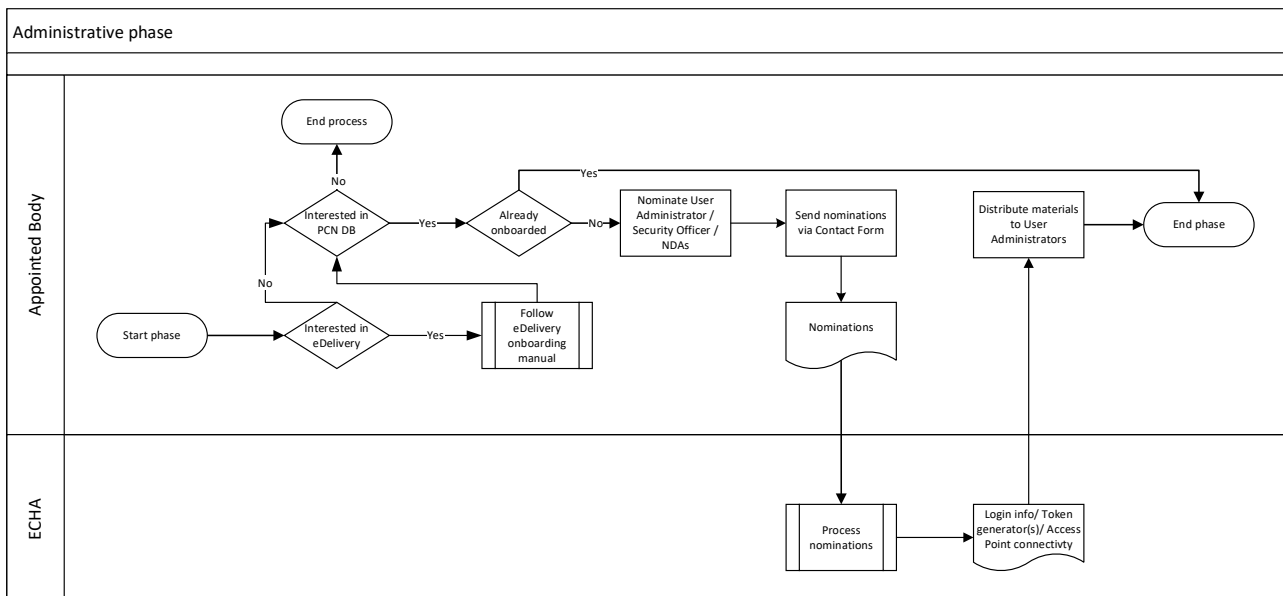
There is no need to send the physical copy to ECHA unless requested by ECHA separately.

3.1.3. ECHA countersigns and sends the SLA back to the appointed body

Upon reception of the documents and verification of the signature, ECHA's executive director will countersign the SLA. We will send you one copy for your archival to the address listed in [ECHA's webpages](#) for your organisation unless ECHA is informed of a different address.

3.2. Administrative and security phase

Figure 5 Diagram of Administrative and security phase



Purpose: Appointed body is granted access to ECHA's PCN database

Actors:

- Appointed body
- ECHA
- Poison centre(s)

Process:

Appointed body needs to fulfil certain security and administrative steps before it can be granted access to ECHA's PCN database. The appointed body needs to send the results of a

security audit at least 3 months after the first connection, see 'Connection to ECHA phase for more details.

If the appointed body is interested in joining ECHA's eDelivery network, the manual [REF1] for how to join should be followed from this stage.

If the appointed body was already onboarded to the PCN database, it can move to the next phase to test their connectivity to ECHA systems.

For new organisations to ECHA's PCN IT systems they need to fulfil the steps in this phase:

- 1) Appointed body nominates user administrator(s)
- 2) Appointed body nominates security officer
- 3) Appointed body sends the documentation to ECHA via the Contact Form for Authorities
- 4) ECHA processes the nominations and sends the required material to log in to ECHA's IT systems
- 5) Appointed body distributes the material to the users

3.2.1. Nominate User Administrator

The appointed body needs to nominate a User Administrator. If the appointed body has already nominated a User Administrator for another regulation, it is recommended that they nominate the same person for the Article 45 of the CLP Regulation (Annex VIII).

To nominate a User Administrator, the **appointed body's legal representative** (as defined in the glossary) needs to sign the nomination forms which specify:

- The institutional information of the appointed body⁸ (name and address). E.g.:

"Appointed body for Spain

National Institute of Toxicology and Forensics

Minister of Justice

Calle José Echegaray 4

Madrid, Spain"

- The contact information of each User Administrator
- The starting date of the nominations for the User Administrator
- If there is an end date of the nominations for the User Administrator, the end date field needs to be filled in.

Additionally, each nominated User Administrator needs to fill in and sign the Declaration of

⁸ If filling in the form for the User Administrator of a poison centre, then the form needs to be completed with the institutional information of the poison centre.

Confidentiality and Non-Disclosure for MSCA User Administrators.

3.2.2. Nominate Security Officer

The nomination of a Security Officer is mandatory for complying with the security requirements. Thus, appointed bodies accessing the PCN database must nominate one. If the appointed body has already nominated a Security Officer for another EU Regulation, ECHA recommends nominating this same person for the CLP Regulation (Article 45, Annex VIII).

To nominate a Security Officer, the **appointed body's legal** needs to sign a nomination form, specifying:

- The institutional information of the appointed body (name and address) as above
- The contact information of the Security Officer

3.2.3. Send nominations package

The appointed body can submit the nomination forms to ECHA. In summary, the nominations package should consist of:

- One signed nomination form with the contact information of the User Administrator and the Security Officer for the appointed body
- Filled in and signed copies by each User Administrator of the 'Declaration of Confidentiality and Non-Disclosure for MSCA User Administrators'

Additionally, in case of requesting access for a poison centre to the PCN database:

- One signed nomination form with the contact information of the User Administrator for each poison centre (if applicable)

The scanned documents will have to be sent to ECHA in a zip file by using the [Contact Form for Authorities](#) as shown in Figure 6. Fill in the contact details as shown in Figure 4

Figure 6 Contact form filled in to send documentation package back to ECHA

ECHA
EUROPEAN CHEMICALS AGENCY

Contact form for Authorities

I can't login
 I need support with

Please select : *

Other

Please find attached the on-boarding documentation package for the Spanish appointed body

Attachments

Upload Attachment :

Add attachment

Maximum file size is 10 MB.

3.2.4. Process the nominations and setting up secure remote access

ECHA will process the nominations of Security Officers and User Administrators and will issue relevant access rights to S-CIRCABC interest groups and Identity and Access Management Portal (for User Administrator only).

While setting up the remote access, ECHA will request from the nominated Security Officer the IP⁹ addresses of the appointed body and of the poison centres.

3.2.5. Send login information and token generator for User Administrator(s)

The appointed body will receive the login information and the physical RSA token generator(s) for the User Administrators they have nominated.

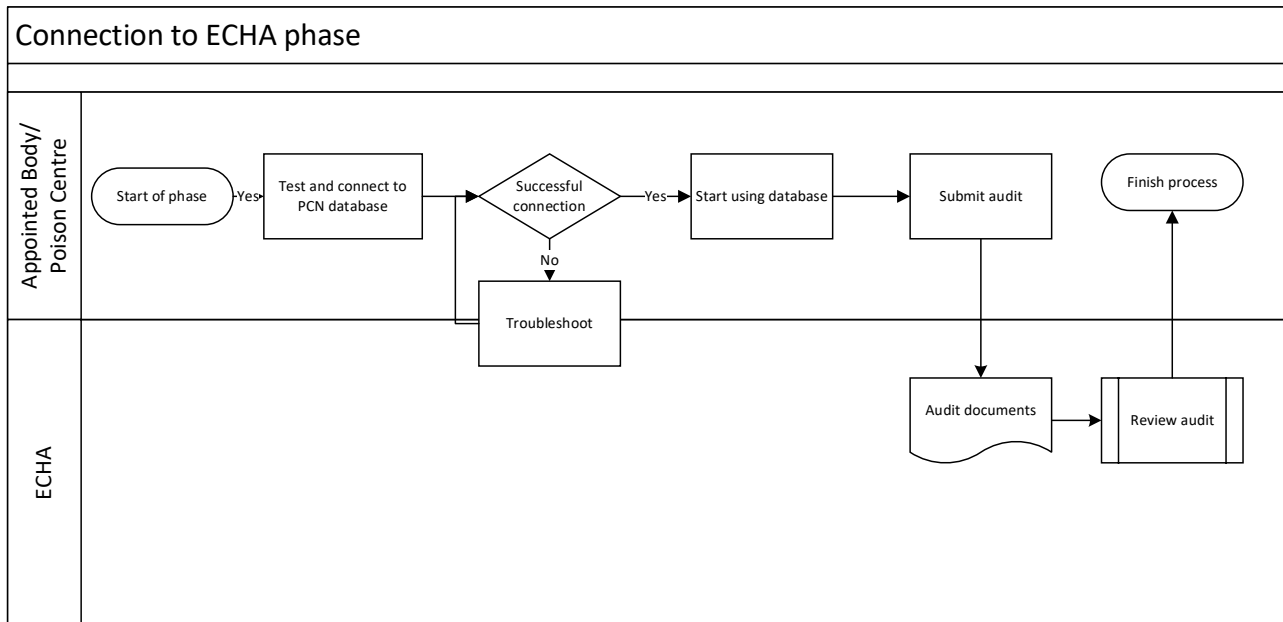
⁹ These addresses are the externally facing IP addresses used by the organisations to connect to the Internet. ECHA's PCN database can only be accessed from devices behind that address.

3.2.6. Distribute materials to User Administrator(s)

Upon reception of the login information and of the RSA token generator(s), the appointed body should securely distribute them to the User Administrators it has nominated.

3.3. Test and connection with ECHA phase

Figure 7 Diagram of Test and connection with ECHA phase



Purpose: Check that access to ECHA’s PCN database have been properly configured, and submit the security audit

Actors:

- Appointed body/poison centre
- ECHA

Process:

1. Appointed body tests and connect to ECHA’s PCN database
2. ECHA and appointed body troubleshoot connectivity issues
3. Appointed body starts using the PCN database
4. Appointed body submits security audit to ECHA

3.3.1. Test and connect to PCN database

Once the appointed body has fulfilled the security and administrative phase, it can connect to the PCN database. For that the user administrator should first assign a user in the organisation the right role 'Appointed Body Interact Portal' following the steps described in [REF8] Identity and Access Management (IAM) Portal User Manual. Users of PCN database should follow [REF7] Login Manual to ECHA's IT tools for Authority users.

3.3.2. Troubleshoot

If there are issues connecting to the PCN database, the organisation's contact person or User Administrator shall report their issue using the [Contact Form for Authorities](#) and create a message explaining the issue found. ECHA's ICT Helpdesk will provide the necessary support to resolve the request.

4. Requesting access for poison centres

The appointed body needs to formalise the access request by filing out the Annex VI to the Service Level Agreement for the poison centres of their member state.

On preparing for the request, the appointed body has to consider these aspects:

- Is the poison centre informed of the security model and of the on-boarding aspects relevant to them?
- Who will be the user administrator, the same as for the appointed body or someone else?

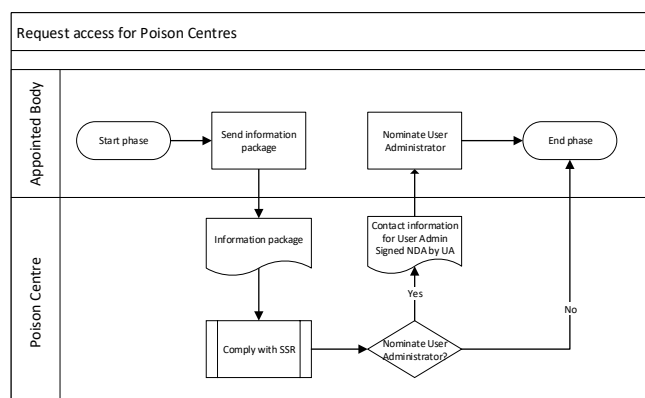
The User Administrators of the appointed bodies can create new users for the poison centres they are responsible for. ECHA recommends this option.

However, the appointed body can nominate a different user administrator for managing a single poison centre, ideally someone working closer to the poison centre users. If a new user administrator is appointed, ECHA expects a new nomination form specifying the institutional information of the poison centre (name, address) and the contact details of its new User Administrator.

- The audit report will have to be produced to cover the identified poison centre, will it be an expanded audit report or a separate one?

Figure 8 Suggested process for collecting the necessary information from poison centres before

they can access ECHA's PCN database



5. Security requirements and security audit

The 'Standard security requirements for access to ECHA's Information Systems by appointed bodies and the poison centres identified by the appointed bodies', specified in the Annex IV to the Management Board decision **59/2019**, apply to both appointed bodies and poison centres.

These security requirements replace the ones put in place during the transition period when only the downloading site was available for appointed bodies. Before they sign the Declaration of Commitment, those appointed bodies only complying with the transitional security requirements need to make sure they comply with the new security requirements.

The security requirements are complemented with two documents that highlight important details for the correct compliance with the security requirements:

- **Implementation guidelines:** the implementation guidelines help the appointed bodies and poison centres to implement the security requirements as required by ECHA. The document opens the possibility for appointed bodies to propose to ECHA alternative and adequate security arrangements that are better suited to the working context of the appointed bodies and poison centres.

The document includes an Annex comparing ECHA's security requirements with those of ISO27001.

- **Audit guidelines:** organisations accessing to ECHA's information systems for the first time need to provide ECHA with a security audit report within 3 months of the first access. The document describes the process and documentation required by ECHA to complete this first audit and the following ones.

Questions regarding the SSR or requests for support should be addressed to ECHA using the [Contact Form for Authorities](#) as shown in Figure 9.

Figure 9 Contact form with the correct topic ('Other') selected to request support regarding

security requirements



Contact form for Authorities

I can't login

I need support with

Please select : *

Other ▼

Question/Request (max 2000 characters) *

Please enter your question

6. Support mechanisms

Support can be requested via the [Contact Form for Authorities](#).

ECHA's business hours are 09:00–18:00 (EET) from Monday to Fridays.

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