

ECHA-18-B-08-EN

How to prepare and submit information to poison centres

Key information for companies submitting information on hazardous mixtures and for the Member State appointed bodies receiving the information.



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The Poison Centres notification (**PCN**) **portal** is the online tool for industry to both prepare and submit information on hazardous mixtures that can be used by poison centres to help make an emergency health response.

The information to be submitted through the PCN portal is based on the harmonised PCN format which defines the information requirements established in Annex VIII to the CLP Regulation.



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WHY HARMONISE THE FORMAT?

Up until 1 January 2020, information submitted for the purposes of making an emergency health response may vary from Member State to Member State. The introduction of the new PCN format harmonises and reduces inconsistencies in the information made available to medical personnel in different Member States.

The PCN format is also compatible with IUCLID 6 which means that PCN data can take full advantage of the capabilities offered by the IUCLID platform (<https://iuclid6.echa.europa.eu/>). This includes full compatibility with the ECHA Cloud Services for data hosting, where industry can store their PCN data. More information on the PCN format and support material is available on ECHA's website (<https://poisoncentres.echa.europa.eu/>).

WHAT DOES THE PCN PORTAL DO?

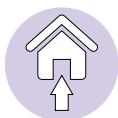
All information submitted by companies through the PCN portal will be securely forwarded to the corresponding appointed bodies identified in the notification.

Companies will also receive a reference number from the portal so they have an audit trail allowing them to track their notifications and be informed when their notifications have been received. In addition, an embedded validation assistant will support companies to submit quality data during the preparation phase.

Multilingualism support will be gradually implemented and will be one of the portal's key features. Ultimately, companies will be able to submit a single submission file in their preferred language to multiple appointed bodies in the required national languages, for example, through translatable selections made from structured dropdown lists.

WHAT ARE THE DIFFERENT WAYS TO PREPARE AND SUBMIT PCN INFORMATION?

There are a number of options for a company to prepare and submit information depending on e.g. the company's internal systems or the preferred submission route by Member States.



Online through the portal:

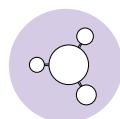
The portal includes a dossier preparation tool which guides the user to prepare their PCN dossiers online with step-by-step instructions. The dossiers are submitted directly in the portal or downloaded and saved locally for later submission – either through the portal or through the local submission system of the Member States. The dossiers will be stored centrally in the portal and accessible by the submitting company.



System-to-system integration:

For more advanced users, a system-to-system (S2S) integration service will be provided. With this

service, companies will be able to directly prepare their PCN notifications in IUCLID format (.i6z) within their own systems and automatically transfer them to the PCN portal. The data will be validated when it is submitted and any inconsistencies in the dossier will be highlighted through the portal.



Offline preparation:

As the PCN notification format is IUCLID compatible, notifications can also be prepared offline using IUCLID 6. A PCN user interface will be made available within the tool for those companies preferring to enter their data manually. The resulting IUCLID dossier can either be submitted through the PCN portal or through the Member States' local system. IUCLID 6 also provides the possibility to validate the data before submitting.

At any given time, companies will have access to the submitted information and their submission status through a submission report available in the PCN portal.



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IS THE USE OF THE PCN PORTAL COMPULSORY?

The use of the PCN portal by companies (or Member States) is not compulsory, as long as the harmonised format is used to prepare the information. However, it is up to each Member State to decide how companies will have to submit the information.

It may be decided by the Member State that companies can only submit through the PCN portal, or only through the national submission systems. Other Member States may give industry the choice between submitting through the PCN portal or national systems.

The use of the PCN portal is free of charge. Member States may decide to charge fees through their national legislation, as is currently the case in some countries.

HOW SECURE IS THE SUBMITTED INFORMATION?

The PCN portal will maintain the same high level of security that is required for other industry IT systems in ECHA (e.g. REACH-IT) and access to PCN data will only be allowed to authenticated users. Once the information is forwarded to the Member State's appointed body, the responsibility to ensure equivalent security measures is transferred accordingly.

WHEN WILL THE PCN PORTAL BE AVAILABLE?

The first release of the PCN portal is set for early 2019 to allow both industry and Member States time to get familiar with the new tool. There are also plans for a second release following further development with additional features, such as a searchable database, before the first applicable

deadline of January 2020 concerning mixtures for consumer use.

WHAT IS A SEARCHABLE DATABASE?

A searchable database could enable the appointed bodies to access and search submitted notification data directly from the PCN portal. Having direct access, Member States can still choose to build or maintain their own national system and operate independently from the PCN portal. However, in the absence of direct access, Member States will have to build their own national systems to connect with the PCN portal to receive the dispatched notifications.

Q&As and support:

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

List of nationally appointed bodies:

https://poisoncentres.echa.europa.eu/documents/22284544/22284829/contact_list_2018_appointed_bodies_en.pdf/aeb033d1-def4-5f4e-58e2-69fca529351e

PCN format:

<https://poisoncentres.echa.europa.eu/fi/poison-centres-notification-format>

IUCLID website:

<https://iuclid6.echa.europa.eu/>

Draft Guidance:

<https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-clp>