

# Portal información REACH-CLP



## INFORMATION OF THE *INSTITUTO NACIONAL DE TOXICOLOGÍA Y CIENCIAS FORENSES (INTCF)* ABOUT THE NOTIFICATION OF CHEMICALS

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### INTRODUCTION

The National Institute of Toxicology and Forensic Sciences (INTCF, its acronym in Spanish) is a body attached to the Ministry of Justice that performs the functions of the Spanish Poison Centre. As such, it receives, via telephone, medical consultations on poisonings and exposures to chemical substances. The consultations are always attended by specialists in toxicology who provide toxicological information for the purposes of first aid and medical treatment to the person who makes the consultation, either health personnel or general public.



Article 45 of the CLP regulation establishes the obligation for importers and downstream users of mixtures classified by CLP for their hazards to human health or for their physical properties, to notify each appointed body of each member state where go to market them. Annex VIII to CLP harmonizes the information requirements to be included in notifications, as well as the mandatory use of the format developed by ECHA.

Art. 45.1 obliges Member states to designate the body in charge of receiving such notifications.

The INTCF is the appointed body in Spain responsible for receiving from importers and downstream users who place mixtures in the market, the pertinent information referred to in article 45.1 of the CLP Regulation (Law 8/2010, of March 31, DA third).

Likewise, it may be necessary to notify substances or mixtures to the INTCF for legal reasons other than Art. 45 of CLP or voluntarily, to include the emergency telephone number of the Toxicological Information Service (SIT) on labels or safety data sheets.

## NOTIFICATION OF MIXTURES TO NATIONAL POISON CENTRES (ART. 45 OF CLP REGULATION)

Article 45 of CLP obliges importers and downstream users of mixtures classified by CLP as hazardous to health or due to their physical effects, to notify to each poison centre of the Member states where they are going to commercialize said mixtures.

Annex VIII to CLP harmonizes the information that must be included in a notification made to any poison centre, as well as requires the use of the format developed by ECHA (hereinafter, harmonised notifications). Annex VIII to CLP is applicable as of January 1, 2021 or 2024 depending on the end use for which each mixture is intended: consumer, professional or industrial.

All appointed national poison centers must accept the harmonised notifications in accordance with Annex VIII in terms of information requirements and in the format established by ECHA starting from the application deadlines set out in Annex VIII.

However, it is at the discretion of each Member State:

- The criteria and terms of acceptance of notifications.
- The language of the notification: The information must be presented in the official language or languages of the Member State or States in which the mixture is marketed, unless the State or Member States concerned provide otherwise.
- The reasoned request for information or additional clarifications necessary to carry out the tasks for which it is responsible.
- The submission system of notifications. ECHA has developed a portal (ECHA Submission portal) that makes it easy to send notifications simultaneously to multiple poison centers. Each national poison center can choose whether to accept the submission of notifications through the ECHA Submission portal or through other channels.
- The collection of notification fees.

### REMEMBER:

- \* A **“HARMONISED NOTIFICATION”** CONSIST OF A NOTIFICATION DOSSIER MADE IN THE HARMONISED FORMAT DEVELOPED BY ECHA ([PCN FORMAT](#)) AND WHICH INCLUDES THE INFORMATION REQUIREMENTS HARMONISED BY ANNEX VIII TO CLP.
- \* THE **“HARMONISED FORMAT”** DEVELOPED BY ECHA (PCN FORMAT) IS XML-BASED AND AVAILABLE ON THE [ECHA WEBSITE](#). IT IS INTEGRATED IN IUCLID 6 AND IUCLID CLOUD, BUT IT IS ALSO AVAILABLE FOR COMPANIES TO PREPARE THEIR OWN TOOLS FOR THE PREPARATION OF THEIR DOSSIERS (SYSTEM-TO-SYSTEM SERVICE) IF THEY WISH.
- \* THE **“SYSTEM FOR SUBMIT HARMONISED NOTIFICATIONS”** TO POISON CENTERS IS AT THE DISCRETION OF EACH MEMBER STATE. ECHA HAS DEVELOPED A TOOL THAT ALLOWS, WHICH ALLOWS, IN ADDITION TO PREPARING THE HARMONIZED NOTIFICATION DOSSIER, THE SIMULTANEOUS SUBMISSION OF A HARMONISED NOTIFICATION TO MULTIPLE MEMBER STATES ([ECHA SUBMISSION PORTAL](#)).

PLEASE, CHECK THE FOLLOWING [DOCUMENT](#) TO CONFIRM WHICH MEMBER STATES ACCEPT THE SUBMISSION OF NOTIFICATIONS THROUGH ECHA SUBMISSION PORTAL.

TO USE THE ECHA SUBMISSION PORTAL YOU MUST CREATE AN [ECHA ACCOUNT](#) IF YOU DO NOT ALREADY HAVE ONE.

## NOTIFICATIONS OF MIXTURES TO THE NATIONAL INSTITUTE OF TOXICOLOGY AND FORENSIC SCIENCES (INTCF) ACCORDING TO ART. CLP 45 (ORDER JUS/288/2021)

The INTCF is the appointed body in Spain, responsible for receiving from importers and downstream users who place mixtures in the Spanish market the pertinent information referred to in article 45.1 of the CLP Regulation (Law 8/2010, of March 31, DA third).

Order JUS / 288/2021, of March 25, regulates the notification procedure of chemical substances and mixtures to the National Institute of Toxicology and Forensic Sciences and establishes:

Regarding the **APPLICATION DEADLINES** of the harmonised notifications established in Annex VIII according to the final use of the mixture:

- \* **Since January 1, 2021**, for **mixtures for use by consumers and professionals**, importers and downstream users who place chemical mixtures in Spanish market must prepare, prior to the placing on the market, a harmonised notification and submit it to the INTCF using the portal developed by ECHA (ECHA Submission portal).

- \* Importers and downstream users who place on the spanish market **mixtures for industrial use or mixtures with an end use not subject to notification**, may voluntarily continue to notify the INTCF in accordance with the provisions of Order JUS / 909/2017, of September 25, until on December 31, 2023.

Therefore, until December 31, 2023, the computer application, the manuals and installation instructions for said application will remain available on the INTCF website, as well as the necessary instructions for sending the toxicological files through the INTCF platform. All the information regarding the notification is available [here](#).

For more information on this notification procedure, use the [INTCF inquiry form](#).

- \* **As of January 1, 2024**, for **mixtures intended only for industrial use or mixtures with an end use not subject to notification**, importers and downstream users who place these chemical mixtures in Spanish market, must prepare a harmonised notification and submit it to the INTCF via ECHA Submission portal.

- \* **Until January 1, 2025**, in the case of **mixtures already succesfully notified to the INTCF** prior to the aforementioned deadlines, importers and downstream users will not have to update their notification to adapt it to the harmonised requirements established by Annex VIII and the harmonised format, unless it is necessary to update the notified information for any of the reasons described in section 4.1 of part B of Annex VIII to CLP.

In the event of such an update, the new harmonised notification will be submitted to the INTCF using the ECHA Submission portal.

- \* **As of January 1, 2025**, **all notifications** made to the INTCF must be harmonised and submitted through the submission portal developed by ECHA (ECHA Submission portal).

Regarding the **SPECIAL LIMITED NOTIFICATION PROCEDURE**, according to the provisions of Annex VIII of CLP, in the case of mixtures with an end use not subject to notification or mixtures that are marketed exclusively for industrial use, notifiers may choose for a limited notification, as an alternative to the general notification requirements.

- \* In limited notifications, the information to be submitted to the INTCF on the composition of the mixture may be limited to the information contained in the safety data sheet (SDS), **provided that** the complete information on the composition of the mixture is readily available through a telephone with service in Spanish, accessible 24 hours a day, 365 days a year, and an email address, to which the INTCF medical staff on duty has access.



Regarding the **NOTIFICATION SUBMISSION**:

- \* Harmonised notifications will be submitted to the INTCF electronically, through the [ECHA Submission portal](#).

Regarding the **REGISTRATION, PROOF OF NOTIFICATION OF PRODUCTS AND ACKNOWLEDGMENT OF RECEIPT**:

- \* Once the notification has been received, the INTCF will proceed to register the information in its database and will send, within a period not exceeding three months, a justification of receipt of the information received to the submitter.
- \* The INTCF may require the submitter, by means of a reasoned request, to provide, without undue delay, the information or additional clarifications it deems necessary to be able to give the health response with the due guarantees.

Regarding the notification of **THE CEASE OF THE PLACING ON THE SPANISH MARKET**:

- \* At the time of cessation of commercialisation of the mixture, importers or downstream users will be obliged to notify the INTCF directly by means of a document, electronically signed, which includes the name and the Unique Identifier of Formula (hereinafter, UFI ) of the mixture that is no longer on the Spanish market.

Regarding the **RESPONSIBILITY FOR THE CONTENT OF THE INFORMATION**:

- \* The submitter will be responsible for the veracity of the data provided to the INTCF, as well as compliance with the criteria established by it.

Any form of non-compliance that results in the inability to provide the appropriate health response will be attributable to the submitter who has not correctly communicated the data to which he is obliged in accordance with current legislation.

Regarding **CONFIDENTIALITY**:

The INTCF guarantees that the confidential nature of the information received will be preserved, and that it may only be used in the manner stated in article 45.2 of the CLP Regulation.

In addition, as reported in the document [\*"Overview of Member States decisions in relation to implementation of Annex VIII to the CLP Regulation \(Poison Centre Notification\)"\*](#) - version 8.1 (27.08.2021):

- \* The INTCF accepts notifications in the Spanish and English **LANGUAGES**.
- \* Harmonised notifications are not subject to **FEES**.

## OTHER NOTIFICATIONS TO THE NATIONAL INSTITUTE OF TOXICOLOGY AND FORENSIC SCIENCES (INTCF)

- \* SINCE IT MAY BE NECESSARY TO NOTIFY THE INTCF SUBSTANCES OR MIXTURES FOR LEGAL REASONS OTHER THAN CLP ART. 45 OR VOLUNTARILY, IN ACCORDANCE WITH ORDER JUS / 288/2021, ANY INTERESTED PARTY WHO, EITHER VOLUNTARILY OR IN COMPLIANCE WITH APPLICABLE LEGISLATION, INCLUDES THE EMERGENCY TELEPHONE NUMBER OF THE INTCF TOXICOLOGICAL INFORMATION SERVICE (SIT) ON THE LABELS OR IN POINT 1.4 OF THE SAFETY DATA SHEETS, MUST PREVIOUSLY NOTIFY THE INTCF OF THE SUBSTANCE OR MIXTURE IN QUESTION.
- \* THESE NOTIFICATIONS WILL BE IN ACCORDANCE WITH ANNEX VIII OF CLP, PREPARED IN THE FORMAT HARMONISED BY ECHA (PCN FORMAT) AND SUBMITTED ELECTRONICALLY THROUGH THE ECHA SUBMISSION PORTAL.

FOR MORE INFORMATION ON NOTIFICATIONS FOR REASONS OTHER THAN THOSE ESTABLISHED BY ART. 45 OF CLP, PLEASE CONSULT THE INTCF THROUGH THE FOLLOWING [FORM](#).

## More information

- Article 45 and Annex VIII to [CLP regulation](#) [PDF] [EN]
- Website of ECHA on [Poison centres](#)
- [ECHA accounts and EU Login](#)
- [Overview of Member States decisions on implementing Annex VIII to the CLP](#) [PDF] [EN]
- [Orden JUS/288/2021, de 25 de marzo, por la que se regula el procedimiento de notificación de sustancias y mezclas químicas al Instituto Nacional de Toxicología y Ciencias Forenses](#) [PDF] [ES]
- [INTCF](#) website on notifications