

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 and e-mail, medical consultations on poisonings and exposures to chemical substances. 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 they are going to place them on the market. 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 on 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 of for legal reasons other than Art. 45 of CLP or voluntarily, in order 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 place said mixtures on the market.

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 placed on the market, unless the Member State or 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 HARMONIZED INFORMATION REQUIREMENTS 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 SO.
- * THE **“SYSTEM FOR SUBMIT HARMONISED NOTIFICATIONS”** TO POISON CENTERS IS AT THE DISCRETION OF EACH MEMBER STATE. ECHA HAS DEVELOPED A TOOL 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 CLP, ART. 45

(ORDER JUS/877/2023 which modifies ORDER JUS/288/2021)

The INTCF is the appointed body in Spain, responsible for receiving from importers and downstream users who place mixtures on 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, modified by Order JUS/877/2023, 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 end use of the mixture:

- * **Since January 1, 2021**, for **mixtures for end use by consumers and professionals**, importers and downstream users who place chemical mixtures on the Spanish market must prepare, prior to 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 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 on the INTCF website:

[Notification to the INTCF. Information to companies — National Institute of Toxicology and Forensic Sciences \(Ministerio de Justicia\)](#)

For more information on this notification procedure, contact with the [Toxicological Information Service \(SIT\) \(Ministerio de Justicia\)](#)

- * **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 on the 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 successfully 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 of CLP.

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

- * **As of January 1, 2025**, **notifications** made to the INTCF via national procedure will not be valid anymore. Therefore, companies should make sure of submitting a new notification via harmonised procedure, **before January 1, 2025**, in order to continue placing on the market mixtures, once the transition period ends.

Regarding the **SPECIAL LIMITED NOTIFICATION PROCEDURE**, according to the provisions of Annex VIII of CLP, in the case of **mixtures that are placed on the market exclusively for industrial use**, notifiers may choose 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 ACKNOWLEDGEMENT OF RECEIPT**:

- * Once the notification has been submitted, companies will be able to consult the **submission report** on the ECHA Submission Portal, which lets them confirm if the information **has been received by Spain**, and with that, fulfilling the obligation of communication to the INTCF.
- * 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 appropriate guarantees.

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

- * The cease of placing on the Spanish market of the mixture and eventually the reintroduction, must be notified through the procedure established by ECHA. For more information, please consult the document "**[PCN: A practical guide](#)**".
- * For those notifications made via national system, companies should notify the cease of the placing on the Spanish market to 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 placed on the 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.
- * For those notifications made via harmonised procedure and which have wrong or incorrect information, companies must submit an update or invalidation of the record, as appropriate. For more information, please consult the document "**[PCN: A practical guide](#)**".
- * **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 \(Poison Centre Notification\)](#)**":

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

NOTIFICATIONS TO THE NATIONAL INSTITUTE OF TOXICOLOGY AND FORENSIC SCIENCES (INTCF) FOR DIFFERENT REASONS TO THOSE OF CLP, ART. 45

- * 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 PREPARED IN THE **HARMONISED FORMAT**.
- * IN THOSE CASES, THERE WILL BE NECESSARY TO INCLUDE THE **UFI** IN THE NOTIFICATION AS A MIXTURE IDENTIFIER, BUT INCLUDING IT ON THE LABEL AND/OR THE SDS WILL **NOT** BE COMPULSORY.
- * FOR MORE INFORMATION ON THE OBLIGATIONS OF INCLUDING OR NOT THE EMERGENCY NUMBER ON THE LABEL OR SDS FOR ANOTHER REASONS THAN THOSE ESTABLISHED BY ART. 45 OF CLP, PLEASE CONSULT THE APPLICABLE LEGISLATION AND/OR THE COMPETENT AUTHORITY FOR EACH LEGISLATION.

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]
- [Orden JUS/877/2023, de 21 de julio, por la que se modifica la 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