eQgest®

Regulatory Integrated IT Solution

Quick guide to European harmonized notification to Poison Centers

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CIMKEY

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INTRODUCTION

In **March 2017**, **Regulation (EU) 2017/542** represented a significant advance in harmonizing European notifications to poison centers. Previously, hazardous products had different notification systems across each Member State, leading to complex procedures and inconsistencies. This regulation adds **Annex VIII** to **CLP (Regulation (EC) No 1272/2008)**, establishing a unified structure for the notification of hazardous products. It standardizes essential information, such as product composition, facilitating the exchange of data between poison control centers. Consequently, this initiative has facilitated a more efficient and prompt response in emergency situations, ensuring heightened protection for citizens against exposure to hazardous substances.

Additionally, the regulation emphasized the importance of cooperation between member states and the European Commission in order to periodically update the list of substances, ensuring the inclusion of new dangerous products. This measure was crucial in keeping the regulation up to date with scientific developments and the introduction of new substances on the market. The focus on fostering collaboration and harmonization of notifications has contributed significantly to the protection of public health in the European Union, strengthening the capacity of poison control centers to deal with emergencies related to dangerous substances and mixtures.

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FROM ARTICLE 45 TO ANNEX VIII OF THE CLP

2008

Article 45 of the CLP

Article 45 of the CLP Regulation stipulates the obligation of importers and downstream users marketing mixtures **classified as hazardous either due to their effects on human health or physical effects** to notify responsible authorities (designated by each member country) with information regarding their hazardous products. This notification aims to ensure prompt medical aid during emergency scenarios. Additionally, Point 4 of the article emphasizes the necessity to harmonize both the information and format of these notifications.

2017

Regulation (EU) 2017/542 (1st version of Annex VIII)

The criteria for presenting information regarding the health response during emergencies were established. The concept of **UFI (Unique Formula Identifier)** was created to enable quicker and more precise identification of the exact composition of a substance or mixture during emergency situations.

2019

Delegated Regulation (EU) 2020/11 (2nd version of Annex VIII)

Amendments and modifications have been introduced to Regulation (EU) 2017/542, mainly focused on updating the list of hazardous substances and the inclusion of new information for notification. This regulation **postponed the compliance date from 01.01.2020 to 01.01.2021** for products intended for consumer and professional use.

2020

Delegated Regulation (EU) 2020/1677 (3rd version of Annex VIII)

To enhance the information provided, this regulation has incorporated definitions for different **types of use (consumer, professional and industrial)**. It has introduced additional considerations, including the concept of generic components, groups of interchangeable components, standard formulas, fuels, and specific treatments for customized paints.

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THE EUROPEAN HARMONIZED NOTIFICATION TO POISON CENTERS

Importers and downstream users marketing **mixtures with risks to human health and/or physical risks** are responsible for providing the required information in the Member States where the mixture is being sold. This obligation invariably lies with the EU-based legal entity; hence, a supplier not situated within the EU cannot substitute the designated responsible entity established within the Union. Mixtures are categorized based on their intended use, delineating between those for consumers, professional use, and industrial purposes.

The regulation that harmonizes the information and presentation format to be sent to the European Poison Centers includes the following main elements:

A harmonized format for presenting information to designated bodies: This is a common EU format that has replaced national requirements for information presentation.

Information to be provided regarding the chemical composition of hazardous mixtures: identity and concentration ranges of components, pH, packaging type, categories and hazard classes of mixtures, etc.

A Unique Formula Identifier (UFI): The UFI is a unique alphanumeric code associated with a particular hazardous mixture. It must appear on the label or packaging of the mixture, enabling precise and fast identification of the specific chemical formulation of the product. EQgest already includes this UFI generator in its specific module for compliance with this regulation. The UFI is associated with a composition and not with a commercial product; the same composition can have multiple UFI's associated with it if it is a different product, carries different trademarks, or for any other relevant reason.

Mixtures in mixtures: Companies whose formulations contain mixtures in a mixture (MIMs) can use the UFI of these MIMs to communicate the composition. In this way, suppliers avoid disclosing the full composition.

3.1 EXCEPTIONS

Certain mixtures already regulated by specific legislations are exempt from notification under Annex VIII of the CLP Regulation:

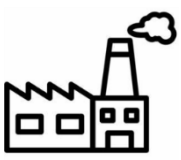
- Unclassified mixtures or mixtures with only environmental risks.
- Mixtures used in scientific research and development.
- Radioactive mixtures.
- Mixtures under customs control.
- Medicinal and veterinary products, cosmetics, medical devices and food products.
- Mixtures classified only as gases under pressure and explosives.

3.2 TYPES OF USE

In the current version of Annex VIII of the CLP Regulation (Delegated Regulation (EU) 2020/1677), mixtures are categorized based on their intended use: consumer use, professional use, and industrial use. The definitions for each category are outlined in the Regulation as follows:

Mixtures for use by consumers: A mixture intended for use by consumers, either on its own or incorporated into another mixture intended for use by consumers.

Mixture for professional use: A mixture intended for use by professional users, but not in industrial installations, on its own or incorporated into another mixture, intended for use by professional users, but not in industrial installations.



Mixture for industrial use: A mixture intended for use exclusively in industrial installations.

3.2.1 MIXTURES COMMERCIALIZED FOR INDUSTRIAL USE

There is an alternative for mixtures that are placed on the market for industrial use only. In this case, the information to be presented on the composition of a mixture for industrial use can be limited to the information contained in the safety data sheet. If the sender opts for this mode of presentation, they must ensure that the designated body has prompt access to supplementary information about the product.

Specifically, the regulation stipulates that:

> *"[...] a name, telephone number and an e-mail address shall be provided at which rapid access to detailed additional product information relevant for emergency health response purposes" [...] "The telephone number shall be accessible 24 hours per day, 7 days per week".*

3.2.2 CAN A SINGLE APPLICATION BE SUBMITTED FOR MORE THAN ONE MIXTURE?

There is an option to submit a single submission for more than one mixture, as long as they are similar to each other, called a **group submission**. All mixtures reported in the same group submission must have the same information in the following fields:

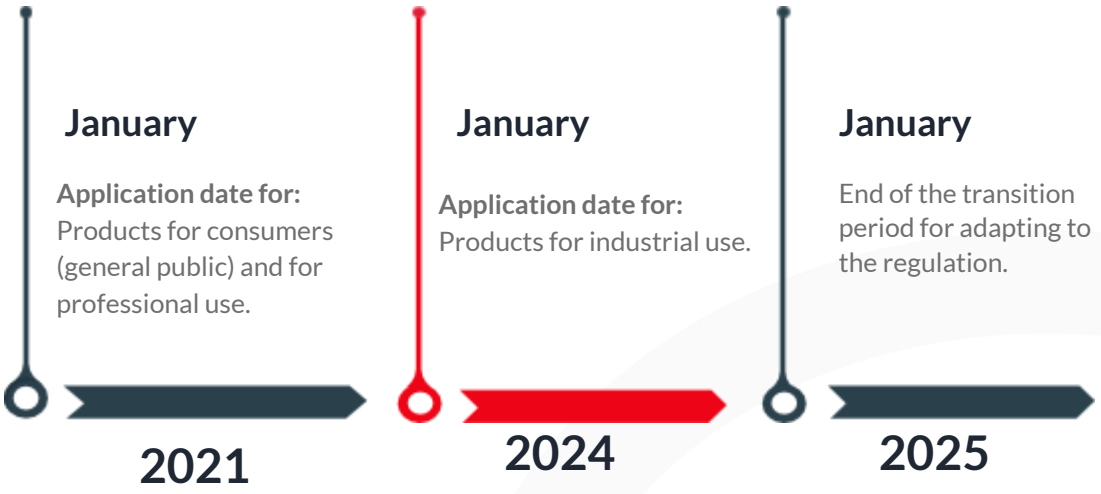
- Classification of physical and health hazards.
- Product category (EuPCS).
- Composition of the mixture. Perfumes and fragrances can vary as long as they do not exceed 5%.
- A single UFI can be assigned to a group of mixtures as long as they all have the same composition.
- If there are changes to the composition that affect only the perfumes or the addition of new perfumes, a list of the mixtures and the perfumes they contain must be provided, along with their classification. It will not be necessary to assign a new UFI.

There may be differences in the other fields. However, the required information for each of the mixtures included in the group must be provided in all of them.

3.2.3 WHAT HAPPENS TO MIXTURES THAT DON'T MEET THE MANDATORY REQUIREMENTS?

Mixtures that do not meet the mandatory requirements of Annex VIII can be notified on a voluntary basis. This procedure has advantages for both designated bodies and notifiers. It is possible for a designated body to receive a call regarding a mixture that is not classified with regard to physical or health hazards. If the mixture has been notified voluntarily, the response will be quicker and more effective. In addition, voluntary notification of a mixture used in another mixture will allow the designated body to know the full composition. Information on the composition of a mixture in the supply chain can be transmitted via UFI if it is notified, thus maintaining confidentiality.

3.3 DATES TO CONSIDER



The life cycle of the mixture up to its disposal as waste must be taken into account when determining the use of the product.

3.4 PRESENTATION CONTENT

Annex VIII of the CLP Regulation states that they must be notified:

- **Product registration:** Notification of new mixtures;
- **Modifications:** When one of the following changes is made to a mixture subject to individual or group presentation:
  - Product identifier of the mixture (including the UFI);
  - Classification of the mixture (physical or health hazards);
  - Toxicological information (section 11 of the SDS);
  - Composition of the mixture (beyond to the concentration range provided in the original submission).

Submitters must provide a **"presentation update"** before the modified mixture is placed on the market. The rest of the changes will not need updating, although it is recommended that this is done when the changes are relevant.

3.4.1 GENERAL SUBMISSION REQUIREMENTS

Prior to placing mixtures on the market, notifiers must provide information on mixtures classified as dangerous due to their health or physical effects in the Member State(s) where the mixture is placed on the market.

The submission must contain the information outlined in **Part B of Annex VIII to the CLP Regulation** (identification of the product and of the notifier, hazards identification, and other additional information). The presentation must be submitted electronically in an XML format provided by ECHA **(PCN format)**.

The submission shall be rendered in the official language(s) of the Member State(s) in which the mixture is being placed on the market, unless otherwise specified by those Member States.

The intended use of the mixture must be described according to the **harmonized product categorization system (EuPCS),** facilitated by ECHA.

The submission must be updated without undue delay whenever there are significant changes.

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THE UFI (UNIQUE FORMULA IDENTIFIER)

UFI:R300-E003-W009-G281

Since 2021, the UFI code has appeared on the labels of products notified under the harmonized notification system.

From 2025 onwards, all products that represent a **physical and/or health hazard, which were** previously notified to the Poisons Centers and have remained unchanged since then, must be **re-notified** through a notification complying with the harmonized format and must therefore include the UFI on the label.

The UFI code serves to identify mixtures classified as posing a physical and/or health risk to users in the European Economic Area (EEA). Therefore, importers and downstream users who place such products on the market must provide specific information on these products, including the UFI, to poison control centers.

4.1 WHAT IS UFI?

The UFI is a 16-character alphanumeric code that must be included on the label (and, in some specific cases, on the SDS) of all hazardous mixtures that pose health and/or physical hazards and that have previously been notified.

In addition to the UFI, the company that places the products on the market is also obliged to provide poison control centers with other information about the mixture: composition, trade name, color, type of packaging, product category, hazard classification and toxicological information.

All products labeled and notified with the same UFI coding must have the same mixture composition. If this is not the case, the coding will be different.

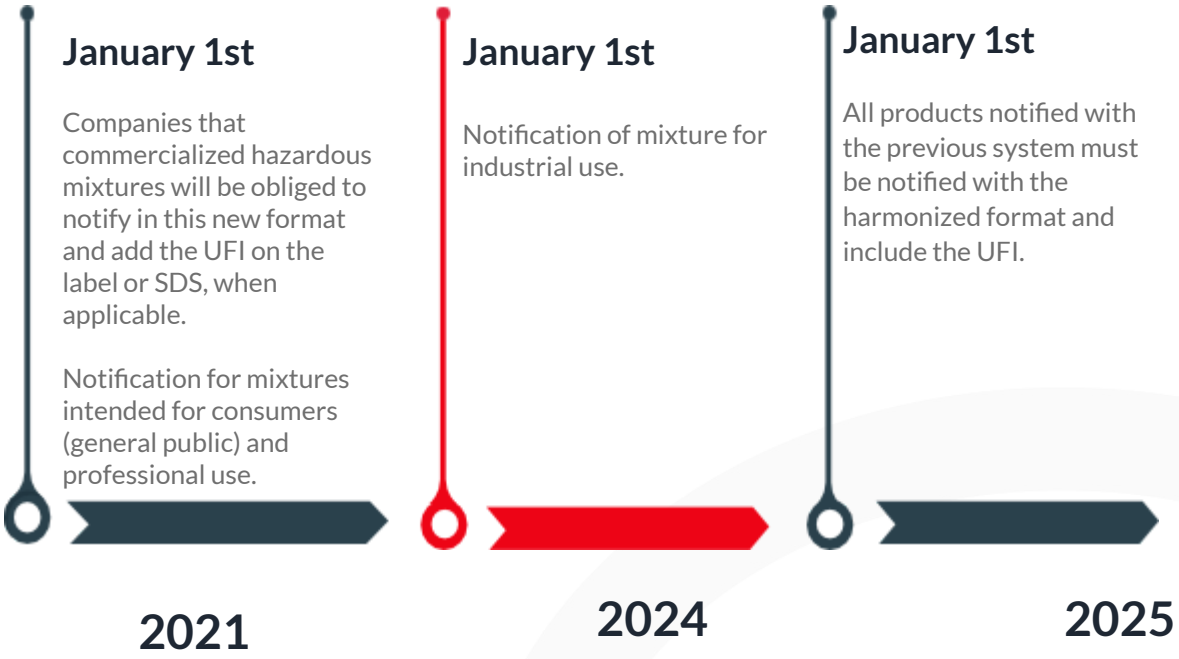
UFI's aim is that, in the case of an emergency, thanks to the information provided on the product label, one can directly contact the poison center and swiftly and accurately identify the product that caused the incident, thus enabling prompt action.

4.2 WHEN IS IT NECESSARY TO CREATE A NEW UFI CODE?

It is important to remember that new UFI codes must be generated if the composition of the mixtures changes according to the criteria described in Part 4 of Annex VIII of the CLP Regulation. However, if several products are composed of the same mixture, the UFI code can remain the same, even if a new packaging or a new trade name is created.

Regarding changes or removal of a specific substance from the mixture, a new UFI must be generated, notified to poison control centers, and products re-labeled.

Dates to be considered:



4.3 HOW TO CREATE A UFI CODE?

The UFI is constructed using an algorithm based on the company's tax identification number (VAT - according to each country's format) and a numerical code that identifies the formula and which must fall between 0 and 268 435 255.

If the formula codes used in the company do not follow this pattern (for example, because they are alphanumeric), it must to be assigned an equivalent numerical value. eQgest already has an integrated automatic assignment system for this case.

On the ECHA portal there is a utility for creating the UFI; eQgest includes this functionality, therefore users are recommended to generate it automatically within the application itself.

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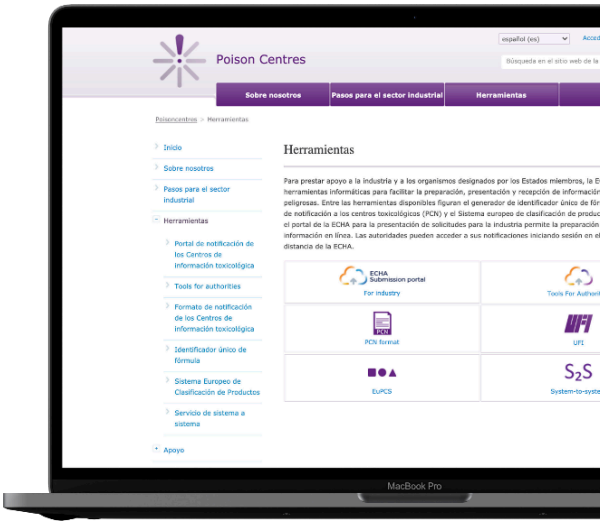
NOTIFICATION PROCEDURE

Next, we show you the information and tools offered by ECHA.

INFORMATION ON THE ECHA PORTAL

Accessing the following link: https://poisoncentres.echa.europa.eu/tools opens the following screen.



In this portal, you can choose between:

- **ECHA Submission Portal:** Online tool for preparing notification dossiers for hazardous mixtures. Any user can create their own dossiers.
- **PCN format (Poison Centres Notification Format):** ECHA provides information to guide users on the notification format (templates, validation rules, examples, among other information).
- **EuPCS (European Product Categorisation System):** Description of the relevant uses of mixtures. It is a dynamic system that reflects the needs of the industry: users can make requests to add a use to the list. It is currently only available in English.
- **UFI Generator:** Tool for generating UFI codes in a harmonized format. These codes are generated from the company's VAT number and a number assigned to the product.
- **System-to-system service (S2S):** This feature allows companies to create notification dossiers via other systems, according to the PCN format, and communicate them directly to the notification portal. eQgest uses this tool to communicate directly with the ECHA portal to make notifications automatically.

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EQGEST COMPLIES WITH THE LEGISLATION IN AN AUTOMATED WAY

At **eQgest** we offer you a module compatible with the PCN format to create dossiers in a simple and intuitive way.

The software uses product information from the program's main module to quickly create your dossier, avoiding the need to re-enter data. It also incorporates a tool for generating UFI codes, which includes the assignment of numerical values for their calculation. Another advantage is that it allows direct data connection with other systems to generate dossiers.

Want to know more? **Contact us** and we will answer all your questions and give you more information on how our module can help you comply with legislation quickly and easily.


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