Questions and answers on the notification of hazardous products for emergency health response in Germany for submitters according to Art. 45 of the CLP Regulation

Questions and answers of the BfR of 23 December 2020

The Federal Institute for Risk Assessment (BfR) receives product notifications from industry and thus supports the emergency medical advice in Germany's poison centres.
Persons and companies placing hazardous mixtures on the market have to notify relevant information to the BfR. The legal basis for this obligation is Article 45 of the Regulation on classification, labelling and packaging of substances and mixtures (EC) No. 1272/2008 (CLP), which is implemented in national law via the Chemicals Act (Section 16e ChemG).

The German Federal Institute for Risk Assessment (BfR) has compiled frequently asked questions on the notification of hazardous products in order to provide answers quickly and in consistent quality. Some of the questions refer to the (conventional) national notification procedure for Germany (XProductNotification), others to the new European harmonised Poison Centre Notification (PCN) procedure. In order to clarify the allocation, sections are marked with **XProd** or **PCN** in the margin. The information compiled here cannot reflect all partial aspects of the individual question. Supplementary information can be found in the linked sources.

How can I notify my product and why is a submission of a file in PDF format not sufficient?

The product submission has to be n a structured, electronically readable format so that the product data can be automatically imported into the BfR database. For this reason, product notifications in the form of a letter, an e-mail or a pdf file will not be accepted by BfR. Valid formats result from the permissible notification procedures PCN and XProductNotification:

PCN

Product notifications to the BfR in the **European PCN format** are preferably made via the Submission Portal of the European Chemicals Agency (ECHA). [1] Following this notification procedure, you first generate at least one Unique Formula Identifier (UFI) for each mixture (i.e. for each product formula),[2] which you link to the formula via the notification and print on the label or packaging. After completing the notification via the ECHA portal, you will receive a link to a notification-specific *Submission Status Page*: Information on the status and success of your notification is available there under *Submission Events*. The product notifications are made available to BfR. BfR currently downloads product notifications from the ECHA portal once per working day. Once the notification has been received by BfR, you have formally fulfilled your obligation (Submission Event: *Dossier received by DE*).

XProd

Product notifications according to the conventional national notification procedure in Germany to the BfR in the **XProductNotification Format** can be submitted for

- private (end) consumers or commercial use until 31.12.2020
- Industrial use until 31.12.2023

[1] https://poisoncentres.echa.europa.eu/echa-submission-portal
[2] https://poisoncentres.echa.europa.eu/ufi-generator

be made. After the deadline, all products have to be notified in the European harmonised PCN format according to Article 45 of the CLP regulation**.** If the notification to BfR is successful, you will receive a confirmation letter within two to four weeks after receipt.

For product notifications submitted to BfR in the XProductNotification format by the respective deadline, new notification in PCN format is only mandatory from 1 January 2025 (CLP regulation, Annex VIII, Part A, Section 1.4). [3] However, this transitional arrangement only applies if no notifiable changes to the product occur in the meantime. Changes after the deadline must always be made in PCN format.

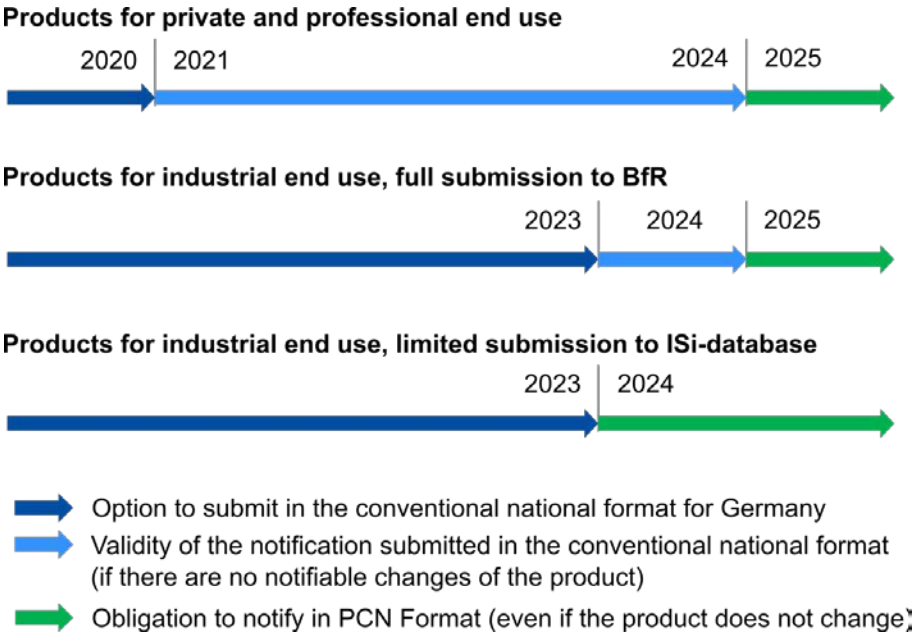

Figure 1: Deadlines and validity periods of notifications in the XProductNotification format (ISi database is used for limited submissions during a national transitional period according to Chemicals ACT §28 (12))

If there are any queries regarding your notification, BfR will contact you.

How does a product notification in the XProductNotification format actually take place?

You will find the tools required for the conventional submission procedure on the BfR website under *Notification of products* in the right-hand column. [4] With the first form[5] you apply for a BfR company code. The second file is in zip format[6] and contains, among other tools, the file *XProduktmeldung_BfR.xls* (32-bit version) and *XProduktmeldung_BfR_64_Bit.xlsm* (64-bit version). With the help of one of these files, you enter your product data and generate an XML file. You save the XML file locally and subsequently submit via the BfR portal[7]. A user

[3] https://eur-lex.europa.eu/eli/reg/2008/1272/2020-05-01
[4] https://www.bfr.bund.de/en/notification_of_products-10144.html
[5] https://www.bfr.bund.de/cm/349/data-for-the-company-documentation-in-the-poison-information-data-bank.pdf
[6] https://www.bfr.bund.de/cm/349/XProductNotification.zip
[7] https://apps.bfr.bund.de/bfrportal/

account is required to use the BfR portal: You shall create an account before your first submission. (This user account is independent of the BfR company code and guarantees secure submission of your product data.)

PCN XProd **What number shall I provide as an emergency contact within the Safety Data Sheet (SDS)?**

The legal basis for the indication of an emergency contact in the SDS is section 1.4 of Annex II of the REACH Regulation (EC) No 1907/2006. The Federal Institute for Occupational Safety and Health (BAuA) is - among many other tasks - responsible for answering questions on REACH and has set up the national REACH/BIOZID/CLP helpdesk for this purpose. [8] Under *Information on the Poison Emergency Number,* you will find detailed information on section 1.4 of the Safety Data Sheet for Germany. [9] Indicating a BfR phone number is not correct, because the BfR does not provide any emergency health response service.

PCN XProd **How do I create a unique product identifier (UFI) and how do I communicate the UFI to the BfR?**

You may generate a UFI with the UFI generator[10]. The UFI is a central component of the ECHA's new *Poison Centre Notification format* (*PCN*) but is not a mandatory component of the national German format *XProductNotification.* The UFI facilitates the quick assignment of a formula to a product record in case of poisoning. For the European harmonised notification procedure, enter the UFI in the dedicated form field.

A *XProductNotification* does not require a UFI. However, you could enter the UFI in the field titled *Other product identification* contained in the *Notification Part 4* sheet of the Excel form using the following format: "UFI: xxxx-xxxx-xxxx-xxxx" (without quotation marks). The BfR recommends optional UFI entry, as this would facilitate a quick and reliable formula assignment during the emergency health response service.

The BfR points out that in case of a submission of a voluntary UFI as part of a conventional *XProductNotification*, the obligation to notify the product in accordance to the PCN procedure remains after the expiry of the transitional period on 1 January 2025 (latest).

PCN **Where can I find information on the acceptance of the European harmonised PCN product notification procedure of the individual member states?**

Every EU member state is accepting PCN notifications since 1 January 2021.

Details

- on the acceptance of alternative submission channels
- on accepted languages for the submission
- on submission charges
- the earliest date for placing notified products on the market

[8] https://www.reach-clp-biozid-helpdesk.de/EN/Services/Contact/Contact_node.html
[9] https://www.reach-clp-biozid-helpdesk.de/DE/REACH/Sicherheitsdatenblatt/Sicherheitsdatenblatt-EN/Emergency-Telephone-number.html
[10] https://poisoncentres.echa.europa.eu/ufi-generator

can be found on the ECHA's Poison Centres website .[11]

PCN **Who are the Appointed Bodies of other member states according to article 45 of CLP Regulation (EC) No 1272/2008?**

The ECHA website provides information on the Appointed Bodies (AB) of the member states.[12]

PCN **Can I combine perfumes into one entry in the formulation?**

In order to simplify the notification of products that differ only in the composition of their perfumes, these products are allowed to submit as *group submission* under following conditions (CLP Regulation, Annex VIII, Part A, Section 4):

- All (product) mixtures in the group contain the same qualitative composition with the exception of perfumes.
- For each component, the reported concentration or concentration range is the same in all mixtures.
- All mixtures in the group have the same classification with respect to health and physical hazards (differences in classification with respect to environmental hazards are allowed).
- The total concentration of perfumes does not exceed 5 %.

Mixtures which are identical in qualitative composition but differ as regards the concentration of the constituents in the mixture cannot be grouped together in a *group submission*.

Group submission is an option provided to facilitate compliance with the obligations. Notifying parties may decide to submit a product notification for each mixture without grouping it with other mixtures.

Source: *Guidance on harmonised information relating to emergency health response - Annex VIII of the CLP regulation* (version 3.0, May 2020, sections 4 and 5.4).[13]

PCN **How do I specify a product formula if my supplier does not provide me the complete formulation information?**

If a supplier does not provide the complete formula information, it is possible to indicate the supplied mixture as a component of the formula (a so-called *mixture in* mixture, *MIM*). All information available about the MIM shall be reported. This results in the following (descending) order of priority of information that shall be included in a MIM notification:

(1) If the MIM was submitted to the BfR in a previous PCN notification:

- Trade name or designation of the MIM (Art. 18 para. 3a CLP regulation)[14]
- UFI
- Concentration

[11] https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf
[12] https://poisoncentres.echa.europa.eu/appointed-bodies
[13] https://echa.europa.eu/de/guidance-documents/guidance-on-clp
[14] https://eur-lex.europa.eu/eli/reg/2008/1272/2020-05-01

- Classification of health hazards and physical hazards

(2) If a UFI for the MIM is available, but the BfR has not received the information on the MIM in a previous PCN notification:

- Trade name or designation (Art. 18 para. 3a CLP regulation)
- UFI
- Name, e-mail address and telephone number of the MIM supplier
- Concentration
- Classification of health hazards and physical hazards
- Compositional information as contained in the safety data sheet of the MIM
- all other known components of the MIM

(3) If there is **no** UFI for the MIM:

- Trade name or designation (Art. 18 para. 3a CLP regulation)
- Name, e-mail address and telephone number of the MIM supplier
- Concentration
- Classification of health hazards and physical hazards
- Compositional information as contained in the safety data sheet of the MIM
- all other known components of the MIM

PCN **How shall I treat mixtures contained in an article?**

Section *3.1.1.4 Import/manufacture of a mixture/article combination* of the *Guidance on Harmonised Information for Emergency Health Care - Annex VIII of the CLP regulation* describes how such combined articles should be notified.[15]

PCN **How shall I notify multi-component mixtures (e.g. WC stone, dishwashing tab)?**

Section *4.2.8.1 'Multicomponent products'* of the '*Guidance on Harmonised Information for Emergency Health Care - Annex VIII of the CLP regulation'* describes how such products shall be notified.[16] In brief: Each mixture classified as hazardous for health or physical hazards under CLP regulation must be communicated in a separate notification with a separate UFI. Information on the mixture formed by chemical reaction during the use of the product may also be of interest for emergency health response and should be provided in the toxicology section of the safety data sheet, if applicable.

The BfR website provide more information on the subject of "Product Notifications":

Product notifications
https://www.bfr.bund.de/en/notification_of_products-10144.html

[15] https://echa.europa.eu/de/guidance-documents/guidance-on-clp
[16] https://echa.europa.eu/de/guidance-documents/guidance-on-clp

About the BfR
The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the German federal government and German federal states ("Laender") on questions of food, chemical and product safety. BfR conducts its own research on topics that are closely linked to its assessment tasks.

This text version is a translation of the original German text which is the only legally binding version.