HARMONISED SUBMISSION OF INFORMATION TO POISON CENTRES ACCORDING TO ANNEX VIII TO THE CLP REGULATION

An Implementation Aid

CONTENT

1. INTRODUCTORY REMARKS

The new Annex VIII to the CLP Regulation (EC) No 1272/2008 governs the submission of product-related information for poison centres. The member companies of Deutsche Bauchemie (the German association of construction chemicals manufacturers) need to implement the new submission requirement; this calls for considerable effort on their part. Deutsche Bauchemie strongly recommends its member companies to look into the new rules intensively and without delay and to prepare the necessary submissions. The timely implementation of the new obligations is an ambitious challenge, particularly if the first submission obligation applies already from 1 January 2020.

This paper by Deutsche Bauchemie wants to give a general overview and includes references to the prerequisite tools and user guidance documents – while it does not directly provide the in-depth details that the companies need to prepare for and comply with their new obligations. However, useful sources are listed with links.

2. SCOPE OF ANNEX VIII TO THE CLP REGULATION

- The new Annex VIII (Regulation (EU) 2017/542 of 22 March 2017) is based on Article 45 of the CLP Regulation and entered into force in April 2017. Annex VIII brings about European harmonisation in the submission of product-related information for poison centres.
- All mixtures which are classified as hazardous on the basis of their health or physical effects fall under the submission requirement. No submission is required for products (mixtures) which are not or exclusively classified as hazardous to the environment.
- Formulators (downstream users) and importers have to make submissions if they place mixtures that fall under the submission requirement on the market in the European Union.

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- The dates from which submissions are required are determined by the use of the respective products (mixtures):
  - 1 January 2020 for mixtures for private end consumers (DIY)
  - 1 January 2021 for mixtures for professional use (e.g. by construction industry and building trade)
  - 1 January 2024 for mixtures exclusively for industrial use
  - After these dates, submissions have to made before the products are placed on the market
- Submissions are addressed to the appointed bodies of those Member States where a mixture is placed on the market.
  A central notification portal will be set up at the European Chemicals Agency (ECHA) for submissions to all the relevant Member States. As matter stand at present, all Member States will accept the submissions via this central ECHA portal. Details and the question of whether also a central database will be established at ECHA are still under discussion.
- It is mandatory to use a given electronic XML standard format for submissions.
- The scope and further particulars of the new submission requirement are laid down in Annex VIII (see link below) and in the existing user guidance documents (see section 3 of this paper).

The legal text of Annex VIII to the CLP Regulation as published in the Official Journal of the European Union can be downloaded at this link:
OJ-EU: CLP, Annex VIII

3. GUIDANCE DOCUMENTS AND SUPPORTING INFORMATION FOR MANUFACTURERS OF MIXTURES REQUIRING THE SUBMISSION OF INFORMATION

Since lately, ECHA offers a new internet page with stepwise instructions on how the concerned companies can prepare and make submissions under Annex VIII:
ECHA: steps-for-industry

Additionally, ECHA has published some summary information (4 pages) on preparing and implementing the new obligations:
ECHA: UFI in brief

Furthermore, a list of frequently asked questions (FAQs) can be accessed on the ECHA website:
ECHA: FAQs - questions-and-answers

The official ECHA guidance on Annex VIII is currently available as a draft; it is just under 200 pages strong. The final version of this guidance document will probably come out by the end of 2018.

4. TOOLS FOR IMPLEMENTING ANNEX VIII TO THE CLP REGULATION

A number of tools are needed for implementing Annex VIII. ECHA is responsible for their development and making available.

In particular, these are the following tools:

- *Poison Centres Notification format (PCN format)*
  According to Annex VIII, submissions have to be made by means of an XML standard format called "PCN format".

- *Unique Formula Identifier (UFI)*
  Labelling with a Unique Formula Identifier (UFI) is prescribed in Annex VIII. An UFI enables the reliable identification of a product of a distinct composition (formulation).

- *European Product Categorisation System (EuPCS)*
  Annex VIII also regulates the categorisation in a product category. The basis for this is the European Product Categorisation System (EuPCS) developed by ECHA.

- *Poison Centres Notification portal (PCN portal)*
  In order to improve the workability of submissions in several EU Member States, the European Commission and the Member States have agreed to set up a central notification portal at ECHA.

The relevant documents and tools as well as information on their respective status can be accessed at:
ECHA-website poisoncentres tools

4.1 Poison Centres Notification format (PCN format)

The PCN format is a standard XML format that must be used for the electronic transmission of submissions. ECHA published version 1.0 of the PCN format on 30 April 2018; it is available as XML format. A PDF file with the data model, information about the content of the various fields and the relations between them is provided too.

PCN format:
ECHA: PCN format xsds v1_0 en

Data model of the PCN format:
ECHA: PCN format data model v1_0 en

Version 1.0 of the PCN format is currently being validated in pilot projects. The results of this validation are expected to bring some minor changes. These will be incorporated in the PCN format version 1.1 which is anticipated to come out at the end of 2018.

ECHA has published two guidance documents for using the PCN format:
The first part is entitled "Poison Centres Notification Format, Part A: Preparing a PCN dossier". This document is written in an easily understandable language and includes the basics and practical support for preparing a submission dossier in the required XML submission format:
ECHA: practical guide preparing a PCN dossier

"Poison Centres Notification Format, Part B: Developer's Guide to IUCLID Format" is the title of the second part of the ECHA guidance. It is rather addressed to experts, for use with the ECHA software IUCLID 6. The document gives information on implementing the XML submission format within existing software in the companies:
ECHA: Guide PCN format part b developers guide iuclid format v1_0_en

There are several examples to illustrate proper submissions:

Example of a single submission:
ECHA:example PCN format submission example v1_0_en
IUCLID 6 report on an exemplary single submission:
ECHA: example PCN format submission example v1_0 en IUCLID report

Example of a group submission:
ECHA: example PCN format group submission example v1_0 en
IUCLID 6 report on an exemplary group submission:
ECHA: example PCN format group submission example v1_0 en IUCLID report

4.2 Unique Formula Identifier (UFI)

The Unique Formula Identifier (UFI, for short), is the new labelling element that is used in connection with Annex VIII submissions. The UFI clearly links the notified product in its distinct composition and the submitted items of information. Thus, one UFI can never be used for products of different composition. An exception are group submissions which are possible under strictly defined criteria. Conversely, several UFIs can be generated for one product of the same composition. The UFI Generator is available to provide Unique Formula Identifiers: on the basis of the company VAT number and a product and formulation-specific number of the manufacturer which result in the generation of an UFI. It is worth noting that UFIs do not allow any conclusions regarding the company VAT number that was taken as input.

All particulars, tools and guidance documents regarding UFIs can be accessed here:
ECHA-website UFI

The UFI Generator enables manufacturers of mixtures requiring submission to generate individual or bulk UFIs. Link to the UFI Generator that can be used in all official languages of the EU:
ECHAs UFI Generator

For those companies that do not wish to work with the UFI Generator at ECHA, there is guidance on how to integrate the UFI Generator in the companies' own software. This guidance document is entitled "UFI Developers Manual":
ECHA: UFI Developers Guide

ECHA guidance on using UFIs and the UFI Generator was published in June 2018. The English version is entitled: "UFI Generator application – User Guide"
ECHA: UFI User Guide

Numerous questions have arisen in the ongoing discussion about the use of UFIs. Many of them were answered during a comprehensive ECHA webinar that lasted just under 50 minutes. Link to the webinar:
Video ECHA-Webinar UFI

4.3 European Product Categorisation System (EuPCS)

The items of information to be submitted include a product category which is to be assigned to the product. The product category of relevance to the mixture requiring submission needs to be chosen from the European Product Categorisation System (EuPCS). The current version of the EuPCS is called "European product categorisation system (EuPCS) v. 1.0 for mixtures within the scope of Article 45 of the CLP Regulation". It is available as PDF file and Excel spreadsheet.

EuPCS as PDF file:
ECHA: EuPCS v1 en PDF 

EuPCS as Excel spreadsheet:
ECHA: EuPCS v1 en XLS 

Furthermore, ECHA published a comprehensive guidance document for using the EuPCS. It is entitled: "The European product categorisation system: A practical guide."
ECHA: Guide EuPCS en 

4.4 Poison Centres Notification Portal (PCN portal)

Under Annex VIII to the CLP Regulation, the manufacturers of mixtures requiring submission need to make separate submissions in each Member State where they place the product on the market. At the request of industry and some Member States, it was decided – based on a workability study – to set up a central notification portal at ECHA that forwards the submissions to the relevant Member States. This approach wants to make it easier for industry to comply with the submission obligations.

It is still under discussion and not yet decided whether, additionally to the central notification portal at ECHA, a central ECHA database will be established and what functionalities that database should have.

According to current planning, a first version of the ECHA's PCN portal will be available in the first quarter 2019. A version with extended application options has been announced for the third quarter 2019.

5. WORKABILITY STUDY OF THE EUROPEAN COMMISSION

Some sectors indicated credibly to the European Commission that Annex VIII might not work in practice for their products. These concerns were raised, inter alia, by associations of construction product manufacturers. Responding to this, the Commission has mandated a "workability study". Amongst other issues, now the contractor is to examine whether an adequate workability for the construction products sector calls for an amendment of the legal text. In particular, this is about the use of "mixtures in mixtures" (MIMs), such as e.g. cement. The association Deutsche Bauchemie has a decisive role in the ongoing talks on this topic and in the development of potential solutions. It is deplorable that the study, which already had a tight schedule, started with a six-month delay so that an amendment of the legal text is no longer feasible in the given timeframe. Against this backdrop, it remains to be hoped that the study will lead to changes that make matters easier for construction products. However, the impacted companies cannot be recommended to wait for the study results before they become active. In the present situation, the only way forward is to prepare for an implementation based on the existing legal text and to take it as the likely basis at least for the first submission deadline (1 January 2020).

Beside the questions specific to construction products, the workability study addresses further open points that might partly affect the manufacturers of construction chemicals too. These include:

- *What is decisive for the use-specific deadline? (private consumer, professional, industrial)*
  Is the use of the direct customer or the use at the end of the whole supply chain relevant?

- *Do "private label customers" (re-labellers, re-branders) have obligations under Annex VIII?*
  Downstream users in the meaning of REACH and CLP have obligations under Annex VIII CLP. This does not include distributors. It is currently being discussed whether private label companies (re-labellers, re-branders) are distributors or downstream users. They would have obligations only in the latter case. Otherwise, the formulator who supplies the "private label customer" would be responsible for submissions according to Annex VIII.

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