

3 December 2020

**JOINT STATEMENT ON
ANNEX VIII OF CLP - NOTIFICATION TO POISON CENTRES: IMPLEMENTATION DATE FOR ADDITIVES
AND PREMIXTURES**

Commission Regulation (EU) 2017/542 of 22 March 2017 amended Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (hereinafter, the CLP Regulation) by introducing a new Annex (*i.e.* Annex VIII) on harmonised information relating to emergency health response - the [Poison Centre Notification \(PCN\) Regulation](#). In practice, such notification is required for any mixture falling under the scope of the CLP Regulation and classified as hazardous for human health. As regards feed, this concerns preparations of feed additives and premixtures of feed additives.

The first question relates to the **date of entry into application of the harmonized PCN obligation**. Two deadlines are set for the commencement of the new PCN of relevance for **feed not intended to be fed directly to animals**: January 1st 2021 for products for consumer and professional uses, and January 1st 2024 for products for industrial use. For premixtures of feed additives and feed additive preparations meant for use in feed mills, the later deadline applies. However, the legislation does not specify whether the on-farm use of a mixture should be regarded as professional or industrial use. Hence, what deadline applies to premixtures or preparations destined to farms, whether for use in compound feed, added to silage and/or in water? To answer this question, it is worth referring to the **recent amendment of Annex VIII** introducing a provision leading to understand that the PCN deadline for any premixture of feed additives (as well as for feed additive preparations) placed on the EU market is the **1st January 2024**.

In fact, on 13 November 2020, a revised version of Annex VIII was published in the Official Journal of the EU (OJ) as Commission implementing [Reg. \(EU\) 2020/1677](#) amending the CLP Regulation. In article 2.4 (4), the text introduces the concept of “**mixture with an end use not subject to notification**”. It is defined as “*a mixture, incorporated in another mixture where the latter is intended to be used by consumers or professional users, but which is not subject to the information requirements in Article 45*”. The new Annex VIII establishes that the notification deadline for “*mixtures with an end use not subject to notification*” is the 1st January 2024 (*c.f.* article 1.3 of the new annex).

In conclusion, given that:

- article 45 of the CLP legislation only relates to hazardous mixtures, and that mixtures used on farm that are in the finished state and intended for *final users* (ref. ANNEX TO THE JOINT STATEMENT) qualify as “mixture with an end use not subject to notification”;
- the amendment to Annex VIII clarifies that mixture with an end use not subject to notification may also benefit from the same deadline as the industrial products.

FEFANA and FEFAC underline that the deadline which applies to feed additive preparations and premixtures of feed additives which require PCN is the 1st January 2024¹.

¹ This interpretation takes also into account the 34th [CARACAL](#) (Competent Authorities for REACH and CLP) meeting [outcomes of 15 MAY 2020](#) (released on 26/10/2020) and the information previously released by the European Chemical Agency (ECHA) on their website.

ANNEX TO THE JOINT STATEMENT

ECHA Q&A

▼ **Do feedingstuffs have to be classified, labelled and packaged in accordance with the CLP Regulation, and their substances notified to the Classification and Labelling Inventory?**

According to Article 1(5)(e) of CLP, the CLP Regulation does not apply to feedingstuffs within the scope of Regulation (EC) No 178/2002 (Food Safety Regulation), which are in the finished state, intended for the final user, including when they are used:

- as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;
- in animal nutrition within the scope of Directive 82/471/EEC.

It is important to note that the conditions 'in the finished state' and 'intended for the final user' must both be fulfilled at the same time, otherwise CLP applies.

The terms 'finished state' and 'intended for final user' are not defined in CLP. The CLP definition of 'use' includes 'consumption', which would mean that a consumer qualifies as a user. Drawing a parallel between the term 'final user' in CLP and the definition 'final consumer of foodstuff'* in Regulation (EC) No 178/2002, feedingstuff can only be considered to be 'intended for the final user', if it is ready for direct oral feeding to animals.

In accordance with Article 2(a) and Article 2(e) of Regulation (EC) No 1831/2003 (Regulation on additives for use in animal nutrition), neither feed additives nor premixtures can be used directly to feed animals. They do not fulfil the condition of 'intended for the final user', since they require the additional activity of mixing/processing before being used by the ultimate consumer (animals). Therefore, CLP applies to all additives and premixtures, including those authorised, labelled and packaged in accordance with Regulation 1831/2003.

Feeding stuffs 'intended to be used by the final users' (animals), i.e. to be fed directly to animals, such as feed material or compound feedingstuffs are exempted from the scope of CLP, provided they are in the finished state. This includes both complete and complementary feedingstuffs - where the latter (although not sufficient for a daily ration) could be directly fed to animals and would thus also be exempted from CLP.

*Intended for the final user should be read as intended for the 'ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity'.

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This answer has been agreed with national helpdesks.

Source: European Chemicals Agency (ECHA) [webpage](#), consulted on November 2020