



Statement on the consequences of REACH and CLP Regulations on bakery ingredients

FEDIMA members are producing food mixes and bread ingredients for the Bakery, Confectionery and Patisserie Industries.

REACH regulation¹ explicitly excludes from the scope of **registration** substances **used in food**, taking into account in particular the existing food regulations and safety assessments.

This regulation also excludes food products provided as mixtures, when they are in the **finished state**, intended for the **final user**, from the provisions concerning Safety Data Sheets (SDS). On the contrary, food mixtures in the finished state, not intended directly to final user are subject to the establishment of a Safety Data Sheet.

When a SDS is required by REACH regulation, it shall be established according to annex II of REACH (as modified by (EC) regulation n°453/2010).

The regulation on classification, labelling and packaging of substances and mixtures² ("CLP regulation") is the translation of the GHS (Global Harmonised Systems of Classification and Labelling of Chemicals) within the European Union. The main purposes of this regulation is to harmonise the classification and labelling of substances and mixtures for protecting human health, including workers, and environment.

On 1st June 2015 the CLP regulation will replace the current rules on classification, labelling and packaging of substances (DSD³) and preparations (DPD⁴).

Before that date, mixtures could be classified and labelled according to DPD, or they can be classified and labelled in advance according to CLP regulation.

Substances and mixtures in the form of foodstuffs (including additive, flavouring...) "**which are in the finished state, intended for the final user**" are exempted from the scope of CLP regulation (art. 1.5)⁵.

¹ Regulation (EC) n°1907/2006, concerning the registration, evaluation, authorization and restriction of Chemicals (REACH)

² Regulation (EC) n°1272/2008, on classification, labelling and packaging of substances and mixtures

³ Directive (EEC) n°67/548, relating to the classification, packaging and labeling of dangerous substances

⁴ Directive (EC) n°1999/45, relating to the classification, packaging and labeling of dangerous preparations

⁵ Reference to ECHA's FAQ ID 182:

"According to Article 1(5)(e) of CLP, the CLP Regulation does not apply to food and feeding stuffs, as defined in Regulation (EC) No 178/2002 (Food Safety Regulation), and which are in the finished state intended for the final user. The CLP Regulation does not define the term "final user", but Regulation (EC) No 178/2002 defines "final consumer" as "the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity". The same concept can be applied in the context of CLP. This also applies to the use of a substance or a mixture

- as a food additive in foodstuffs within the scope of Directive 89/107/EEC,

In the absence of legal definitions, Fedima's understanding is the following:

- "finished state" means ready to be used by the final user;
- "final user" means the ultimate consumer of a foodstuff.

Food mixes and bread ingredients, which will be incorporated into a composite new product by industrial or craft bakers, should be considered to fall in the scope of CLP regulation. Consequently, some food mixes and bread ingredients may be classified as hazardous and labelled accordingly when they meet the criteria for classification and when sold business-to-business (cf. decision tree in Annex I).

Food mixes and bread ingredients sold to final consumers are exempted from CLP provisions (and consequently are not labelled as hazardous) and are not provided with a SDS according to REACH.

- ↳ Example of labelling for bread improvers containing enzymes⁶ in concentration $\geq 1\%$ in accordance with CLP regulation:



Danger

May cause allergy or asthma symptoms or breathing difficulties if inhaled

Contains.... (name of each enzyme $\geq 1\%$).
May produce an allergic reaction.

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- as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC,
- as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003 or
- in animal nutrition within the scope of Directive 82/471/EEC.

Since Article 1(5)(e) of CLP only refers to food or feeding stuffs in the final state intended for the final user substances or mixtures used in food or feeding stuffs at any stage of production are not exempt from CLP and therefore must be classified, packaged, labelled and notified. For instance, the CLP Regulation applies to the manufacturer/supplier of a food additive (e.g. preservatives) who supplies the substance to another company that uses it in the production of food. In such a case, the chemical substance in the form in which it is supplied should not be regarded as a product being in the finished state intended for the final user, and the exemption stated in Art. 1(5)(e) CLP is not applicable (see also FAQ 3.7)."

⁶ According to AMFEP Statement Enzyme Classification (Amfep/12/02), "the active enzyme protein shall be used as basis for classification and labelling of enzyme products".

According to AMFEP Factsheet on Enzymes and CLP regulation (AMFEP/12/01), "where enzymes of similar catalytic activity (i.e. belonging to the same IUB EC, CAS and EINECS numbers, or belonging to the same enzyme type as listed in Annex I to Dir.67/548/EEC) are used in a formulation, the levels of these enzymes is considered to be additive, unless there is evidence from immunochemical/immunological testing that they induce specific responses and can consequently be considered as separate entities".

Annex I – Decision tree about REACH, SDS and CLP

