



FEFANA interpretation of Article 1.5 of Regulation (EC) N° 1272/2008 on labelling rules for dangerous substances and preparations

Regulation (EC) N° 1272/2008 on classification, labelling and packaging of dangerous substances and mixtures (CLP Regulation) entered into force on January 2009¹. It aligns existing EU legislation to the United Nations Globally Harmonised System (GHS). The aim is that the same hazards will be described and labelled in the same way all around the world. This Regulation will replace Directive 67/548 and Directive 1999/45.

Article 1.5 of this Regulation provides for exemptions from the application of the labelling rules. According to it, this Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:

- (a) medicinal products as defined in Directive 2001/83/EC;
- (b) veterinary medicinal products as defined in Directive 2001/82/EC;
- (c) cosmetic products as defined in Directive 76/768/EEC;
- (d) medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;
- (e) food or feeding stuffs as defined in Regulation (EC) No 178/2002 including when they are used:
 - (i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC;
 - (ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;
 - (iii) as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003;
 - (iv) in animal nutrition within the scope of Directive 82/471/EEC.

Compared to the former directives, the new Regulation enlarges the exemption for labelling, although keeping the same view (worker protection is at stake).

Taking into consideration that the aim of the regulation is to protect worker safety, the important words in the text are the following: **products at their finished stage and intended for the final user.**

The definitions of the finished stage and the final user are not provided and can be interpreted as follows:

- 'finished stage' means ready to be used by the final user
- 'final user' means the final consumer in the feed/food chain, i.e. the farmer feeding its animals

As a conclusion, any products needing a further process before being used does not fall under the scope of the exemptions indicated in Article 1.5 of Regulation 1272/2008. Substances such as additives and preparations of substances such as additive formulation and premixtures intended to be used by premixers, feed millers and on farm millers (in order to be processed further) are not exempted from the labelling rules detailed in this Regulation.

As examples:

- A premixture sold to a farmer to be further mixed with feed materials to produce a compound feed shall be labelled.
- A complementary feedingstuffs sold to a farmer to be fed directly shall not be labelled, as well as complementary feeds used for top dressing or to be further diluted in water.

¹ OJUE L 353, 31.12.2008 p.1

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:01:EN:HTML>