Classification, labelling and packaging of substances and mixtures

2022/0432(COD) - 04/10/2023 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 519 votes to 99, with 8 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

The matter was referred back to the committee responsible for interinstitutional negotiations.

Subject

The purpose of the regulation is to ensure a high level of protection for human health and the environment, including the promotion of alternative methods for assessing the hazards of substances and mixtures.

Hazardous substances and mixtures and specification of hazard classes

Members specified that gender differences with regard to the susceptibility to chemicals will be taken into consideration, where relevant.

For the evaluation of substances containing more than one constituent in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’, ‘reproductive toxicity’, ‘**endocrine disruption** for human health’ and ‘endocrine disruption for the environment’ hazard classes, the manufacturer, importer or downstream user should use the relevant available information for each of the known individual constituents, impurities and additives in the substance.

Identification and examination of available information on mixtures

An amendment specifies that where the available test data on the mixture itself demonstrate a lack of biodegradation, persistency, mobility and bioaccumulation properties that have not been identified from the relevant available information on the individual substance, such data should also be taken into account for the purpose of evaluating the mixture.

Product identifiers

The product identifier of a mixture should include the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, endocrine disruption for human health, endocrine disruption for the environment, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard, persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent, very mobile (vPvM) properties.

General rules for the application of labels

Labels should be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and will be readable horizontally when the package is set down normally the label

may also be presented in a form of a **fold out label**. Where the label elements are provided by means of a fold-out label, the front page should contain at least certain information provided in all official languages of the Member State where the product is put on the market along with a reference to the additional information provided on the inside page or pages.

Procedure for harmonising the classification and labelling of substances

The Commission may ask the Agency or the European Food Safety Authority to prepare a proposal for harmonised classification and labelling of a **substance or a group of substances**. The Agency and the Authority may, on their own initiative, provide scientific advice to the Commission and Member States on substances or a group of substances where a harmonised classification could be necessary to protect human and animal health and the environment.

Whenever considered scientifically justified and possible by a competent authority or the Commission, proposals for harmonised classification and labelling should **prioritise groups of substances rather than individual substances**. In the event of a proposal for harmonised classification and labelling of a group of substances, those substances should be grouped together based on clear scientific criteria, including structural similarity and similar evidence-based hazard profiles.

Right to request action by the competent authorities and the Commission

Any natural or legal person, individually or in association, would be entitled to present substantiated evidence to the competent authorities or the Commission on the hazardous properties of a substance or mixture, or of several substances in several mixtures, indicating that these properties may not have been sufficiently taken into account in the classification or labelling process. Where the evaluation indicates that the substance does not meet the criteria for classification in any of the hazard classes referred to in the Regulation, the competent authority or the Commission will initiate a harmonised classification and labelling process.

Access to justice

Natural or legal persons who have submitted a substantiated report of concern should have access to an administrative or judicial procedure to review the procedural and substantive legality of decisions, acts or omissions of the relevant competent authority under the Regulation.

Advertising

Any advertisement for a mixture classified as hazardous should indicate the hazard pictogram, the signal word, the hazard class and the hazard statements. Any advertisement for sale of mixtures to the general public should, in addition, indicate "**always read and follow the information on the product label**".

The use of environmental claims should be **prohibited** for substances and mixtures which are classified as hazardous due to their germ cell mutagenic, carcinogenic, toxic to reproduction, endocrine disruption for human health or the environment, persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), or very persistent, very mobile (vPvM) properties.

Adaptation to technical progress

The Commission should promote and evaluate the development of alternative test methods for classification of substances and mixtures, including new approach methods and in particular **non-animal test methods**, at least every three years, and adopt delegated acts to update Annex I to this Regulation.