Classification, labelling and packaging of substances and mixtures

2022/0432(COD) - 23/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 533 votes to 11, with 65 abstentions, a legislative resolution on 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 European Parliament's position adopted at first reading under the ordinary legislative procedure amends the proposal as follows:

Substances containing more than one constituent extracted from plants

Scientific data on certain substances containing more than one constituent extracted from plants have indicated that specific constituents considered in an isolated way can have hazard properties that might not be expressed in the substance as a whole. Therefore, in order to allow time for a scientific evaluation of the suitability for substances containing more than one constituent extracted from plants to follow the rules on classification of substances containing more than one constituent, a derogation from certain rules should be introduced for those substances.

However, when no relevant information is available on the substance itself, manufacturers, importers or downstream users might apply these classification rules to their substances extracted from plants, in order to maintain the current level of protection and the existing good practice. The Commission should review the rules applicable to the identification and examination of the information on substances containing more than one constituent extracted from plants, within five years of the entry into force of this Regulation and submit, if appropriate, a legislative proposal.

Harmonised classification and labelling proposals

Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity based on scientific justification, allows for similar classification of all substances in the group. The grouping process should be scientifically robust, coherent and transparent for all stakeholders.

Where it is scientifically justified and possible, proposals for classification should **prioritise groups of substances** rather than individual substances. In the case of a proposal for harmonised classification and labelling of a group of substances, those substances should be grouped together on the basis of clear scientific reasoning taking into account how the available information supports the grouping of substances and allows the properties of the substances to be reliably predicted from other substances in the group.

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, respiratory or skin sensitisation, specific target organ toxicity, aspiration hazard, persistent, bioaccumulative and toxic, very persistent, very bioaccumulative, persistent, mobile and toxic, very persistent, very mobile properties, or endocrine disruption for human health or the environment.

Labelling

Labels should be **firmly affixed to one or more surfaces of the packaging** immediately containing the substance or mixture and should be readable horizontally when the package is set down normally. The label may be presented in the form of a **fold-out label**.

Where a **digital label** is used, a data carrier linking to that digital label should be firmly affixed or printed on the physical label or on the packaging next to the label in such a way that it can be processed automatically by digital devices that are widely used.

Where label elements are provided on a digital label only, the data carrier should be accompanied by the statement “More hazard information available online” or by a similar indication.

Where those label elements are provided on a digital label only, suppliers should, upon oral or written request or when the digital label is temporarily unavailable at the time of purchase of the substance or mixture, provide those label elements by alternative means. Suppliers should provide those elements independently of a purchase and free of charge.

Where a supplier affixes or prints a data carrier linking to a digital label, it should ensure that the information on the digital label should be accessible to all users in the Union and should remain accessible for a period of at least 10 years or for a longer period where required by other Union legislation.

Advertisement

Any advertisement for a substance classified as hazardous should indicate, as applicable, the hazard pictograms, signal word, hazard statements. Any advertisement for a substance for sale to the general public should in addition state: “**Always read and follow the information on the product label.**”.

Any advertisement for a substance or a mixture classified as hazardous should not contain statements that are not to appear on the label or packaging of that substance or mixture. When substances or mixtures are placed on the market through distance sales, the offer should clearly and visibly indicate the label elements.

Adaptation to technical progress

The Commission may adopt delegated acts to amend Annex I in order to include labelling elements that may only appear on a digital label. It will regularly evaluate the development of alternative approaches for the classification of substances and mixtures, in particular methods not involving animal testing, and adopt delegated acts to update Annex I of the Regulation to reflect this technical progress, if necessary.

The Commission, acting on behalf of the Union and the Member States, should, in the manner appropriate to their role in the relevant UN fora, cooperate with a view to promoting the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBTs), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile substances as well as the adaptation of criteria for alternative approaches, in particular non-animal test methods, and the assessment of the need for new criteria for immunotoxic and neurotoxic substances.’