

**COMMISSION REGULATION (EU) 2022/1396****of 11 August 2022****amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the presence of ethylene oxide in food additives****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives <sup>(1)</sup>, and in particular Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings <sup>(2)</sup>, and in particular Article 7(5) thereof,

Whereas:

- (1) Commission Regulation (EU) No 231/2012 <sup>(3)</sup> lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) The specifications for food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application from a Member State or an interested party.
- (3) Ethylene oxide is an important chemical substance having multiple uses, including the use as a sterilising agent and as a raw material in the manufacture of various products. Ethylene oxide, however, is a substance of concern classified as carcinogenic, mutagenic and toxic for reproduction in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(4)</sup>. It is neither approved as a biocidal product under Regulation (EU) No 528/2012 of the European Parliament and of the Council <sup>(5)</sup> nor as an active substance for use in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>(6)</sup>.
- (4) Regulation (EU) No 231/2012 provides that ethylene oxide may not be used for sterilising purposes in food additives. However, there is no quantified limit for the presence of ethylene oxide regarding all food additives. In accordance with that Regulation a limit of not more than 0,2 mg/kg of ethylene oxide is set out only for those food additives, in the production of which ethylene oxide is used. That limit was first established by Commission Directive 2003/95/EC <sup>(7)</sup>, based on the opinion of the Scientific Committee on Food of 6 May 2002 <sup>(8)</sup>, which concluded that whilst estimated intakes from the few food additives manufactured using ethylene oxide are very low, intakes from food sources should be as low as possible since ethylene oxide is both genotoxic and carcinogenic.

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(2)</sup> OJ L 354, 31.12.2008, p. 1.

<sup>(3)</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

<sup>(4)</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

<sup>(5)</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

<sup>(6)</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>(7)</sup> Commission Directive 2003/95/EC of 27 October 2003 amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 283, 31.10.2003, p. 71).

<sup>(8)</sup> Opinion of the Scientific Committee on Food on impurities of ethylene oxide in food additives, 17 April 2002.

- (5) Recently, there have been several RASFF notifications concerning findings of ethylene oxide in a number of foodstuffs, and in particular in a number of food additives used for the manufacture of a variety of foodstuffs. On the basis of those notifications and information regarding official controls performed by Member States, Commission Implementing Regulation (EU) 2021/2246 <sup>(9)</sup> established measures as regards goods of non-animal origin entering the Union from certain third countries in order to protect human health in relation to the possible risk of contamination with ethylene oxide. However, as regards food additives, the enforcement of Union law may raise difficulties, because of it is difficult to establish whether the presence of ethylene oxide results from its use in the sterilisation of the food additives in breach of Regulation (EU) No 231/2012 or from any other reason.
- (6) In order to avoid those difficulties and to ensure a high level of protection of human health, it is therefore appropriate to lay down that the presence of ethylene oxide, irrespective of its origin, is not authorised for all food additives. For this purpose, a maximum limit for residues of ethylene oxide specific for food additives should be set out at the limit of quantification in those products, that is, at the validated lowest residue concentration, which can be currently quantified and reported by routine monitoring with validated control methods. In order to ensure consistency with Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(10)</sup>, in particular, with the limits it sets out for the raw materials used for the production of food additives, the residues of ethylene oxide should be defined in the same terms as in that Regulation.
- (7) Bearing in mind that the amendment of the specifications is not liable to have any negative effect on human health, a safety evaluation by the European Food Safety Authority in accordance with Article 3(2) of Regulation (EC) No 1331/2008 is not necessary.
- (8) The Annex to Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Regulation (EU) No 231/2012 is amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 August 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(9)</sup> Commission Implementing Regulation (EU) 2021/2246 of 15 December 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council (OJ L 453, 17.12.2021, p. 5).

<sup>(10)</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

## ANNEX

The Annex to Regulation (EU) No 231/2012 is amended as follows:

- (1) the introductory text 'Note: Ethylene oxide may not be used for sterilising purposes in food additives' is replaced by the following:

'Ethylene oxide may not be used for sterilising purposes in food additives.

No residue above 0,1 mg/kg, irrespective of its origin, of ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide (\*)) shall be present in food additives listed in Annexes II and III to Regulation (EC) No 1333/2008, including mixtures of food additives.

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(\*) i.e. ethylene oxide + 0,55\* 2-chloroethanol.;

- (2) in the entries for E 431 polyoxyethylene (40) stearate, E 432 polyoxyethylene sorbitan monolaurate (polysorbate 20), E 433 polyoxyethylene sorbitan monooleate (polysorbate 80), E 434 polyoxyethylene sorbitan monopalmitate (polysorbate 40), E 435 polyoxyethylene sorbitan monostearate (polysorbate 60), E 436 polyoxyethylene sorbitan tristearate (polysorbate 65), E 1209 polyvinyl alcohol-polyethylene glycol-*graft*-copolymer and E 1521 polyethylene glycol, under the specification 'Purity', the row 'Ethylene oxide' is deleted.
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