



2024/2512

25.9.2024

**COMMISSION DELEGATED REGULATION (EU) 2024/2512**

**of 17 April 2024**

**amending Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as regards behenic acid from mustard seeds to be used in the manufacturing of certain emulsifiers**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004<sup>(1)</sup>, and in particular Article 21(2) thereof,

Whereas:

- (1) Annex II to Regulation (EU) No 1169/2011 establishes a list of substances or products causing allergies or intolerances in susceptible individuals and therefore, the information on their presence in food is always to be provided to the consumer in accordance with that Regulation.
- (2) In order to protect consumer against new food allergens and avoid unnecessary obligations on the provision of food information, the update of Annex II may consist in adding substances to the list or removing substances from that list where it has been scientifically established that they are not likely to cause adverse reactions in susceptible individuals.
- (3) To this end, potentially interested parties may communicate the Commission evidence establishing that products derived from substances listed in Annex II are not likely, under certain circumstances, to trigger adverse reactions in individuals.
- (4) As part of the re-examination under Article 21(2) of Regulation (EU) No 1169/2011 and in accordance with Article 29(1), point (a), of Regulation (EC) No 178/2002, the Commission requested the European Food Safety Authority ('the Authority') to give its opinion on the likelihood of adverse reactions triggered in susceptible individuals by the intake of behenic acid produced from mustard seed and used, under specific conditions, in the manufacturing of emulsifiers E 470a sodium, potassium and calcium salts of fatty acids, E 471 mono- and diglycerides of fatty acids and E 477 propane-1,2-diol esters of fatty acids.
- (5) On 25 October 2016, on the basis of the data presented, the Authority adopted a scientific opinion<sup>(2)</sup> concluding that oral consumption of food containing emulsifiers manufactured using behenic acid from mustard seeds (E 470a, E 471 and E 477) are unlikely to trigger an allergic reaction in susceptible individuals (mustard-allergic individuals) under the proposed conditions of use (i.e., behenic acid with a minimum of 85 % of purity and obtained after two distillation steps).

<sup>(1)</sup> OJ L 304, 22.11.2011, p. 18, ELI: <http://data.europa.eu/eli/reg/2011/1169/oj>.

<sup>(2)</sup> Scientific Opinion related to a notification from DuPont Nutrition Biosciences Aps on behenic acid from mustard seeds to be used in the manufacturing of certain emulsifiers pursuant to Article 21(2) of Regulation (EU) No 1169/2011 – for permanent exemption from labelling. *EFSA Journal* 2016;14(11):4631, 14 pp. doi:10.2903/j.efsa.2016.4631.

- (6) Following concerns raised by one Member State relating to the daily exposure to the substances in question and to the protein dose triggering allergic reactions in mustard-allergic individuals, the Commission requested the Authority to review its 2016 scientific opinion and, if necessary, to update it.
- (7) On 25 September 2023, the Authority published its second scientific opinion <sup>(3)</sup> which concluded that, based on the information and data available, it is extremely unlikely ( $\leq 1$  % probability) that the oral consumption of emulsifiers manufactured using behenic acid from mustard seeds (E470a, E471 and E477) will trigger an allergic reaction in mustard-allergic individuals under the proposed conditions of use.
- (8) On the basis of those conclusions, it is appropriate to exclude the emulsifiers manufactured using behenic acid from mustard seeds (E 470a, E 471 and E 477) from Annex II to Regulation (EU) No 1169/2011.
- (9) Annex II of Regulation (EU) No 1169/2011 should therefore be amended accordingly.
- (10) In order to enable food business operators to a smooth transition to the new rules, appropriate transitional measures should be provided in accordance with Article 47 of Regulation (EU) No 1169/2011,

HAS ADOPTED THIS REGULATION:

*Article 1*

Point 10 of Annex II of Regulation (EU) No 1169/2011 is replaced by the following:

‘10. Mustard and products thereof, except:

behenic acid with a minimum of 85 % of purity and obtained after two distillation steps used in the manufacturing of the emulsifiers E 470a, E 471 and E 477;’.

*Article 2*

Foods legally placed on the market or labelled before 1 April 2025 which do not comply with this Regulation may be marketed until the stocks of those foods are exhausted.

*Article 3*

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

It shall apply from 1 April 2025.

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

Done at Brussels, 17 April 2024.

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

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<sup>(3)</sup> Re-evaluation of behenic acid from mustard seeds to be used in the manufacturing of certain emulsifiers pursuant to Article 21(2) of Regulation (EU) No 1169/2011 – for permanent exemption from labelling. *EFSA Journal*, 21(9), 1–27. <https://doi.org/10.2903/j.efsa.2023.8240>.