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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	18 July 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2024) 2407 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 17.4.2024 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

Delegations will find attached document C(2024) 2407 final.

Encl.: C(2024) 2407 final



EUROPEAN
COMMISSION

Brussels, 17.4.2024
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COMMISSION DELEGATED REGULATION (EU) .../...

of 17.4.2024

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers¹ establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling.

Annex II to Regulation (EU) No 1169/2011 establishes a list of substances or products causing allergies or intolerances. Point 10 of that Annex lists mustard and products thereof. To ensure better information to consumers and to take account of the most recent scientific knowledge, Article 21(2) of the Regulation requires the Commission to systemically re-examine, and where necessary, update Annex II.

As a part of this re-examination, in 2016, the Commission asked the European Food Safety Authority (the Authority) to issue an opinion on the likelihood of adverse reactions triggered in susceptible individuals by the consumption of behenic acid produced from mustard seed used in the manufacturing of emulsifiers under specific conditions. The following substances were evaluated: 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. On 25 October 2016, the Authority adopted a scientific opinion concluding that the oral consumption of the above-mentioned emulsifiers is unlikely to trigger an allergenic reaction in mustard-allergic individuals under the proposed condition of use.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Expert Group on Regulation (EU) No 1169/2011 on the provision of food information to consumers was consulted during the preparation of this draft Delegated Regulation on the basis of a Working Document prepared by the Commission services in the meeting that took place on 24 November 2017.

Following the adoption of the Authority's ANS Panel Scientific Opinions (re-evaluation) on E471², on E470a and E470b³, and of the Authority's FAF Panel Scientific Opinion on E477⁴, in 2017 and 2018, the Expert Group was consulted for a second time in a meeting devoted to the preparation of this draft Delegated Regulation on 9 October 2019. In that meeting, one delegation expressed doubts on the daily combined dietary exposure to the emulsifiers in question estimated by the Authority, in its 2016 scientific opinion on behenic acid from mustard seeds⁵. In this regard, it was pointed out that different levels for the same emulsifiers were indicated in the latest opinions adopted by the Authority's ANS Panel in 2017 and 2018 published in the context of their re-evaluation.

The Commission sent a new mandate requesting the Authority to update its 2016 scientific opinion, taking into consideration the newly emerged elements. In its 2023 scientific opinion⁶,

¹ OJ L 304, 22.11.2011, p. 18.

² EFSA Journal 2017;15(11):5045.

³ EFSA Journal 2018;16(3):5180.

⁴ EFSA Journal 2018;16(12):5497.

⁵ EFSA Journal 2016; 14(11):4631.

⁶ EFSA Journal 2023;21(9):8240.

the Authority concluded that based on the information and data available it is extremely unlikely ($\leq 1\%$ probability) that oral consumption of emulsifiers to be manufactured using behenic acid from mustard seeds (i.e., E470a, E471 and E477) will trigger an allergic reaction in mustard-allergic individuals under the proposed conditions of use.

Therefore, this draft Delegated Regulation aims at amending point 10 of Annex II to Regulation (EU) No 1169/2011 as regards mustard, in accordance with the conclusions of the Authority's opinion on the matter.

Against this background, the Expert Group was consulted again in a meeting that took place on 8 December 2023, where the new scientific opinion on behenic acid and the revised draft Delegated Regulation were presented and discussed.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis for this Delegated Regulation is Article 21(2) of Regulation (EU) No 1169/2011, based on which Annex II to that Regulation may be amended by delegated acts.

COMMISSION DELEGATED REGULATION (EU) .../...

of 17.4.2024

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 on the provision of food information to consumers¹, 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 opinion² concluding that oral consumption of food containing emulsifiers

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

² 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.

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).

- (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 opinion³ 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.

³ 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>.

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

Done at Brussels, 17.4.2024

For the Commission
The President
Ursula VON DER LEYEN