



15 February 2024

(24-1332)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: European Commission Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: European Commission, EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Food
5. Title, number of pages and language(s) of the notified document: Draft Commission Delegated Regulation (EU) No .../... 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; (6 page(s), in English)
6. Description of content: This draft Commission Regulation aims at excluding behenic acid derived from mustard seed used for the production of certain emulsifiers from the obligation to be labelled as an allergen.
7. Objective and rationale, including the nature of urgent problems where applicable: Annex II to Regulation (EU) No 1169/2011 includes EU list of food allergens. In order 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. Such updating may consist in adding a substance to the list or removing them. In this context, following the data submitted by the applicant (Dupont) to the Commission, the European Food Safety Authority (EFSA) was requested to issue an opinion considering 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 have been 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, EFSA 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. In the light of new emerging evidence and a comment from a Member State, EFSA was requested to review its initial opinion and, if necessary, update it. On 25 September 2023, EFSA published its second opinion, in which it 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.

The objective of this delegated act is to exempt behenic acid derived from mustard seed used for the production of the above-mentioned emulsifiers from the obligation to be labelled as an allergen, and therefore amend point 10 of Annex II of the Regulation which refers to mustard.

8. Relevant documents:

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.

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R1169-20180101>

9. Proposed date of adoption: 1st Quarter 2024

Proposed date of entry into force: The proposed measure shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

10. Final date for comments: 30 days from notification

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

European Commission,
EU-TBT Enquiry Point,
Fax: + (32) 2 299 80 43,
E-mail: grow-eu-tbt@ec.europa.eu

The text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/>
https://members.wto.org/crnattachments/2024/TBT/EEC/24_01496_00_e.pdf