WORLD TRADE ORGANIZATION

G/TBT/N/EU/1147

16 July 2025

(25-4556)

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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:** EUROPEAN UNION **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** European Commission EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: https://technical-barriers-trade.ec.europa.eu/en/home
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 codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Food
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Draft Commission Delegated Regulation amending Delegated Regulation (EU) 2016/127 as regards the protein-related requirements for infant and follow-on formula manufactured from protein hydrolysates; (4 page(s), in English), (10 page(s), in English) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://members.wto.org/crnattachments/2025/TBT/EEC/25_04621_00_e.pdf https://members.wto.org/crnattachments/2025/TBT/EEC/25_04621_01_e.pdf 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 Website: https://technical-barriers-trade.ec.europa.eu/en/home
6.	**Description of content:** This delegated Regulation aims to amend Commission Delegated Regulation (EU) 2016/127 by amending the compositional requirements set out in that Regulation for the protein content, protein source, protein processing and protein quality for infant and follow-on formula manufactured from protein hydrolysates, based on the relevant EFSA scientific opinion.

7. **Objective and rationale, including the nature of urgent problems where applicable:** Regulation (EU) 2016/127 provides that infant and follow-on formula manufactured from protein hydrolysates are to comply with the requirements for protein content, protein source, protein processing as well as with the requirements for protein quality as set out in point 2.3 of Annex I and Annex II of that Regulation. These requirements correspond to the composition of the four protein hydrolysates used in infant and follow-on formulae that had been positively evaluated by EFSA so far. The requirements of the Regulation apply to infant formula and follow-on formula manufactured from protein hydrolysates as of 22 February 2022.

Regulation (EU) 2016/127 also provides that these requirements may be amended in the future to allow the placing on the market of formulae manufactured from protein hydrolysates with a composition different from the ones already positively assessed, following a case-by-case evaluation of their safety and suitability by EFSA.

In this context, the Commission has received a request from Fonterra Co-operative Group Ltd for the evaluation by EFSA of the safety and suitability of two products, an infant formula as well as a follow-on formula manufactured from a protein hydrolysate the composition of which does not comply with the requirements laid down in Regulation (EU) 2016/127.

In its opinion published on 28 November 2024, EFSA concluded that the protein hydrolysate in question is a nutritionally safe and suitable protein source for use in infant and follow-on formula. Taking into account the conclusions of that opinion, it is appropriate to allow the placing on the market of infant and follow-on formulae manufactured from that protein hydrolysate and amend Regulation (EU) 2016/127 accordingly. ; Protection of human health or safety

8. **Relevant documents:**

Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (EUR-Lex - 32016R0127 - EN - EUR-Lex (europa.eu))

EFSA NDA Panel. Nutritional safety and suitability of a specific protein hydrolysate manufactured by Fonterra Co-operative Group Ltd derived from a whey protein concentrate and used in infant formula and follow-on formula, https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2025.9160

9. **Proposed date of adoption:** first quarter 2026

Proposed date of entry into force: The proposed measure shall enter into force following its publication in the Official Journal of the EU.

10. **Provision of comments**

Final date for comments: 14 September 2025

[X] 60 days from notification

Contact details of agency or authority designated to handle comments regarding the notification:

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