



13 September 2022

(22-6764)

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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 amending Commission Delegated Regulation (EU) 2016/127 as regards the protein requirements for infant and follow-on formula manufactured from protein hydrolysates.; (5 page(s), in English), (7 page(s), in English)
6. Description of content: This delegated Regulation aims to amend Delegated Regulation (EU) 2016/127 by amending the compositional requirements set out by that Regulation for the protein content, protein source, protein processing and protein quality for infant and follow-on formula manufactured from 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 two protein hydrolysates used in infant and follow-on formulae that had been positively evaluated by the Authority so far. The requirements of the Regulation are applicable 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 in order 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 meyer.science GmbH on behalf of HIPP-Werk Georg Hipp OHG and Arla Foods Ingredients 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 9 March 2022, EFSA concluded that the protein hydrolysate for which the dossier has been submitted 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 the protein hydrolysate in question 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 \(europa.eu\)](#))

Nutritional safety and suitability of a specific protein hydrolysate derived from whey protein concentrate and used in an infant and follow-on formula manufactured from hydrolysed protein by HIPP-Werk Georg Hipp OHG (dossier submitted by meyer.science GmbH) | EFSA ([europa.eu](#))

9. Proposed date of adoption: 4th quarter 2022

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

10. Final date for comments: 60 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/2022/TBT/EEC/22_6117_00_e.pdf

https://members.wto.org/crnattachments/2022/TBT/EEC/22_6117_01_e.pdf