



17 November 2017

(17-6297)

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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 [], 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 with regard to protein requirements for follow-on formula (and its accompanying annex) (4 pages + 2 pages of annex, in English)
6. Description of content: This draft Commission Delegated Regulation aims to amend Commission Delegated Regulation (EU) 2016/127 which sets, among others, composition and labelling requirements for infant formula and follow-on formula.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health and safety. Commission Delegated Regulation (EU) 2016/127 on infant formula and follow-on formula lays down inter alia compositional and labelling rules for infant formula and follow-on formula. Article 11(2) of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control empowers the Commission to adopt delegated acts in order to update amongst others Delegated Regulation (EU) 2016/127 taking into account relevant technical and scientific progress. The Commission received a request from a company for evaluation of a follow-on formula based on cow's milk intact protein with a protein content of at least 1.6 g/100 kcal, which is below the minimum of 1.8 g protein/100kcal (0.43 g protein/100 kJ) specified in Annex II to Delegated Regulation (EU) 2016/127, so that it could be placed on the market.

The European Food Safety Authority was consulted and on 5 April 2017 adopted its opinion, that the use of follow-on formula, based on cows' milk intact protein or goats' milk intact protein, with a protein content of 1.6 g/100 kcal (0.38 g/100 kJ) and otherwise complying with the requirements of relevant EU legislation is safe and suitable for healthy infants living in Europe with an intake of complementary foods of a sufficient quality. Therefore, it is proposed that the minimum protein content required in Delegated Regulation (EU) 2016/127 for follow-on formula based on cows' milk or goats' milk protein should be lowered to 1.6 g/100 kcal (0,38 g/100 kJ).

8. Relevant documents:

- Codex Standard for follow-up formula CODEX STAN 156-1987
http://www.codexalimentarius.org/download/standards/293/CXS_156e.pdf
- 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 formulae and follow-on formulae and as regards requirements on information relating to infant and young child feeding <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0127&from=EN>
- Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:181:0035:0056:EN:PDF>
- European Food Safety Authority (EFSA), Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6g/100kcal, EFSA Journal 2017; 15(5):4781
<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4781/epdf>

9. Proposed date of adoption: End of January 2018

Proposed date of entry into force: 20 days from publication in the Official Journal of the EU (The provisions shall apply from 22 February 2020)

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/2017/TBT/EEC/17_5142_00_e.pdf

https://members.wto.org/crnattachments/2017/TBT/EEC/17_5142_01_e.pdf