NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** European Union  **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](mailto: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 vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula (5 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.  Concerns have been raised that high consumption of formula containing 3 μg/100 kcal of vitamin D, combined with additional vitamin D intakes through supplementation, could lead some infants to consume vitamin D at amounts that could pose safety risks.  The European Food Safety Authority was consulted and on 28 June 2018 adopted its opinion, that the use of infant formula containing vitamin D at 3 μg/100 kcal may lead some infants aged at about 4 months to consume amounts of vitamin D above the tolerable upper intake level from formula alone. It further concluded that the use of a maximum vitamin D content of 2.5 μg/100 kcal in infant formula does not result in intakes of vitamin D above the tolerable upper intake level from formula alone. Therefore, it is proposed that the maximum vitamin D content permitted under Delegated Regulation (EU) 2016/127 for infant formula should be lowered to 2.5 μg/100 kcal.  Maximum levels for erucic acid have been established in several foodstuffs, including infant formulae and follow-on formulae by Commission Regulation (EC) No 1881/2006. The same maximum levels for erucic acid in infant and follow-on formula are provided in Delegated Regulation (EU) 2016/127. For reasons of legal certainty and clarity, especially in view of future amendments to Regulation (EC) No 1881/2006 as regards erucic acid, it is proposed that the provision on the maximum content of erucic acid in Delegated Regulation (EU) 2016/127 should be deleted. |
| **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 update of the tolerable upper intake level for vitamin D for infants, EFSA Journal 2018;16(8):5365 <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5365> * European Food Safety Authority (EFSA), Scientific Opinion on euric acid in feed and food, EFSA Journal 2016;14(11):4593 <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4593> |
| **9.** | **Proposed date of adoption:**  End of February 2019  **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](mailto: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/2018/TBT/EEC/18_6512_00_e.pdf>  <https://members.wto.org/crnattachments/2018/TBT/EEC/18_6512_01_e.pdf> |