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 (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 [****], 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 Regulation amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards iron hydroxide adipate tartrate used in the manufacture of food supplements (3 pages, in English), (annex - 2 pages, in English) |
| **6.** | **Description of content:** This draft Commission Regulation concerns the authorisation of the addition of Iron Hydroxide Adipate Tartrate, as a source of iron to food supplements in line with EFSA's relevant scientific opinion. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The proposed measure aims at allowing the addition of Iron Hydroxide Adipate Tartrate as a source of iron to food supplements. The draft measure reflects the favourable outcome of the safety assessment by EFSA. In order to allow the addition of the substance to food supplements it is necessary to amend Annex II to Directive 2002/46/EC on food supplements; Protection of human health or safety |
| **8.** | **Relevant documents:**  Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements  <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2002:183:SOM:EN:HTML>  Safety of iron hydroxide adipate tartrate as a novel food pursuant to Regulation (EU) 2015/2283 and as a source of iron in the context of Directive 2002/46/EC  [Safety of iron hydroxide adipate tartrate as a novel food pursuant to Regulation (EU) 2015/2283 and as a source of iron in the context of Directive 2002/46/EC | EFSA (europa.eu)](https://www.efsa.europa.eu/en/efsajournal/pub/6935) |
| **9.** | **Proposed date of adoption:** 3rd quarter 2023  **Proposed date of entry into force:** The proposed measure shall enter into force on the 20th day 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](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/2023/TBT/EEC/23_0893_00_e.pdf>  <https://members.wto.org/crnattachments/2023/TBT/EEC/23_0893_01_e.pdf> |