NOTIFICATION

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| **1.** | **Notifying Member:** European Union  **If applicable, name of local government involved:** |
| **2.** | **Agency responsible:** European Commission, Health and Food Safety Directorate-General |
| **3.** | **Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):** Preparation of a kind used in animal nutrition (HS Code: 2309) |
| **4.** | **Regions or countries likely to be affected, to the extent relevant or practicable:**  **[****X]** **All trading partners**  **[ ]****Specific regions or countries:** |
| **5.** | **Title of the notified document:** Commission Implementing Regulation (EU) 2021/968 concerning the renewal of the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species, and repealing Regulation (EU) No 335/2010 (Text with EEA relevance).**Language(s):** English, French and Spanish. **Number of pages:** 4  <https://members.wto.org/crnattachments/2021/SPS/EEC/21_4208_00_e.pdf>  <https://members.wto.org/crnattachments/2021/SPS/EEC/21_4208_00_f.pdf>  <https://members.wto.org/crnattachments/2021/SPS/EEC/21_4208_00_s.pdf> |
| **6.** | **Description of content:** Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation. Zinc chelate of hydroxy analogue of methionine was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EU) No 335/2010. In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of zinc chelate of hydroxy analogue of methionine as feed additive for all animal species in the additive category 'nutritional additives'. The application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003. It results from the opinion of the European Food Safety Authority ('the Authority') of 18 November 2020 that, under the proposed conditions of use, zinc chelate of hydroxy analogue of methionine does not have an adverse effect on animal health, consumer safety or the environment. The Authority also concluded for the additive a risk for the user by inhalation and that it is a skin sensitizer. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The proof of the efficacy of the additive, on which the initial authorisation was based, withstands in a renewal procedure. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003. The assessment of zinc chelate of hydroxy analogue of methionine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed. |
| **7.** | **Objective and rationale: [****X]****food safety, [ ]****animal health, [ ]****plant protection, [ ]****protect humans from animal/plant pest or disease, [ ]****protect territory from other damage from pests.** |
| **8.** | **Is there a relevant international standard? If so, identify the standard:**  **[****X]** **Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:** Code of practice on Good Animal Feeding CAC/RCP 54-2004  **[ ]****World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:**  **[ ]****International Plant Protection Convention *(e.g. ISPM number)*:**  **[ ]****None**  **Does this proposed regulation conform to the relevant international standard?**  **[****X]** **Yes [ ]****No**  **If no, describe, whenever possible, how and why it deviates from the international standard:** |
| **9.** | **Other relevant documents and language(s) in which these are available:** |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** 16 June 2021  **Proposed date of publication *(dd/mm/yy)*:** 17 June 2021 |
| **11.** | **Proposed date of entry into force: [ ]****Six months from date of publication**, **and/or** ***(dd/mm/yy)*:** This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.  **[****X]** **Trade facilitating measure** |
| **12.** | **Final date for comments: [ ]****Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** Not applicable  **Agency or authority designated to handle comments: [****X]****National Notification Authority, [****X]****National Enquiry Point.** **Address, fax number and e-mail address (if available) of other body:**  European Commission  DG Health and Food Safety, Unit D2-Multilateral International Relations  Rue Froissart 101  B-1049 Brussels  Tel: +(32 2) 29 54263  Fax: +(32 2) 29 98090  E-mail: sps@ec.europa.eu |
| **13.** | **Text(s) available from: [****X]****National Notification Authority, [****X]****National Enquiry Point.** **Address, fax number and e-mail address (if available) of other body:**  European Commission  DG Health and Food Safety, Unit D2-Multilateral International Relations  Rue Froissart 101  B-1049 Brussels  Tel: +(32 2) 29 54263  Fax: +(32 2) 29 98090  E-mail: sps@ec.europa.eu |