WORLD TRADE ORGANIZATION

G/SPS/N/EU/496

17 June 2021

(21-4974)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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) 2021/969 concerning the authorisation of L-threonine produced by *Escherichia coli* CGMCC 13325 as a feed additive for all animal species (Text with EEA relevance). **Language(s):** English, French and Spanish. **Number of pages:** 4 https://members.wto.org/crnattachments/2021/SPS/EEC/21_4209_00_e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_4209_00_f.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_4209_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 such authorisation. In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-threonine produced by *Escherichia coli* CGMCC 13325 as a feed additive for use in feed for all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation. The application concerns the authorisation of L-threonine produced by *Escherichia coli* CGMCC 13325 as a feed additive for all animal species to be classified in the additive category 'nutritional additives'. The European Food Safety Authority ('the Authority') concluded in its opinion of 18 November 2020 that, under the proposed conditions of use, L-threonine produced by *Escherichia coli* CGMCC 13325 does not have an adverse effect on animal health, consumer health or the environment. It could not conclude on the potential of L-threonine produced by *Escherichia coli* CGMCC 13325 to be a skin sensitiser and irritant to the skin and eyes, and stated an inhalation risk to endotoxins for the users of the additive. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the additive is an efficacious source of the amino acid L-threonine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the additive needs to be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post- market monitoring. It 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 L-threonine produced by *Escherichia coli* CGMCC 13325 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

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:

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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:**

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