



NOTIFICATION

1. Notifying Member: <u>EUROPEAN UNION</u> 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: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Commission Implementing Regulation (EU) 2021/719 concerning the authorisation of L-valine produced by <i>Corynebacterium glutamicum</i> CGMCC 7.358 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_3289_00_e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_3289_00_f.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_3289_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-valine. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation. The application concerns the authorisation of L-valine produced by <i>Corynebacterium glutamicum</i> CGMCC 7.358 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'. The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2020 that, under the proposed conditions of use, L-valine produced by <i>Corynebacterium glutamicum</i> CGMCC 7.358, when supplemented to diets in appropriate amounts, does not have an adverse effect on animal health, consumer health or the environment. With respect to the safety of the user of L-valine produced by <i>Corynebacterium glutamicum</i> CGMCC 7.358, the Authority could neither exclude a risk by inhalation, nor that the substance is irritant to skin or eyes, or a dermal sensitiser. Therefore, appropriate protective measures should be taken for this additive to prevent adverse effects on human health, in particular as regards the users of the additive. Furthermore, the Authority concluded that the substance is considered an efficacious source of the essential amino acid L-valine for animal nutrition and that, in order to be efficacious in ruminants, it should 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 reports 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-valine produced by <i>Corynebacterium</i>

<p><i>glutamicum</i> CGMCC 7.358 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 substance should be authorised as specified in the Annex to this Regulation.</p>
<p>7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.</p>
<p>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input checked="" type="checkbox"/> 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</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
<p>9. Other relevant documents and language(s) in which these are available:</p>
<p>10. Proposed date of adoption (dd/mm/yy): 30 April 2021</p> <p>Proposed date of publication (dd/mm/yy): 3 May 2021</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> 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.</p> <p><input checked="" type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>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</p>
<p>13. Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>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</p>