



26 April 2022

(22-3321)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	<b>Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
2.	<b>Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
3.	<b>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):</b> Preparation of a kind used in animal nutrition (HS code: 2309)
4.	<b>Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> <b>All trading partners</b> <input type="checkbox"/> <b>Specific regions or countries:</b>
5.	<b>Title of the notified document:</b> Commission Implementing Regulation (EU) 2022/653 concerning the authorisation of a preparation of the leaves extract of <i>Melissa officinalis</i> L. as a feed additive for all animal species (Text with EEA relevance). <b>Language(s):</b> English, French and Spanish. <b>Number of pages:</b> 5 <a href="https://members.wto.org/crnattachments/2022/SPS/EEC/22_3045_00_e.pdf">https://members.wto.org/crnattachments/2022/SPS/EEC/22_3045_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2022/SPS/EEC/22_3045_00_f.pdf">https://members.wto.org/crnattachments/2022/SPS/EEC/22_3045_00_f.pdf</a> <a href="https://members.wto.org/crnattachments/2022/SPS/EEC/22_3045_00_s.pdf">https://members.wto.org/crnattachments/2022/SPS/EEC/22_3045_00_s.pdf</a>
6.	<b>Description of content:</b> The leaves extract of <i>Melissa officinalis</i> L. was authorized without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003. In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of a preparation of the leaves extract of <i>Melissa officinalis</i> L. for all animal species. The applicant requested the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. The applicant requested the preparation of the leaves extract of <i>Melissa officinalis</i> L. to be authorized also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorization of flavouring compounds for use in water for drinking. Therefore, the use of the preparation of the leaves extract of <i>Melissa officinalis</i> L. in water for drinking should not be allowed. The European Food Safety Authority ('the Authority') concluded in its opinions of 28 January 2020 and 29 September 2021 that, under the proposed conditions of use, the preparation of the leaves extract of <i>Melissa officinalis</i> L. does not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that the exposure of users to dusts from the additive is not of concern. However, no data was provided on irritant properties for eyes or skin, thus no conclusion could be drawn on these aspects. Due to the nature of the additive, it may be assumed to be potentially both a skin and respiratory sensitiser. 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 Authority concluded, that the preparation of the leaves extract of <i>Melissa officinalis</i> L. is recognized to flavour food and

	its function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
<b>7.</b>	<b>Objective and rationale:</b> <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.
<b>8.</b>	<p><b>Is there a relevant international standard? If so, identify the standard:</b></p> <p><input checked="" type="checkbox"/> <b>Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</b> Code of practice on Good Animal Feeding CAC/RCP 54-2004</p> <p><input type="checkbox"/> <b>World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</b></p> <p><input type="checkbox"/> <b>International Plant Protection Convention (e.g. ISPM number):</b></p> <p><input type="checkbox"/> <b>None</b></p> <p><b>Does this proposed regulation conform to the relevant international standard?</b></p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b></p>
<b>9.</b>	<b>Other relevant documents and language(s) in which these are available:</b>
<b>10.</b>	<p><b>Proposed date of adoption (dd/mm/yy):</b> 20 April 2022</p> <p><b>Proposed date of publication (dd/mm/yy):</b> 21 April 2022</p>
<b>11.</b>	<p><b>Proposed date of entry into force:</b> <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): This Regulation will enter into force on the twentieth day following its publication in the Official Journal of the European Union.</p> <p><input checked="" type="checkbox"/> Trade facilitating measure</p>
<b>12.</b>	<p><b>Final date for comments:</b> <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable</p> <p><b>Agency or authority designated to handle comments:</b> <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: <a href="mailto:sps@ec.europa.eu">sps@ec.europa.eu</a></p>
<b>13.</b>	<p><b>Text(s) available from:</b> <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: <a href="mailto:sps@ec.europa.eu">sps@ec.europa.eu</a></p>