



29 April 2025

(25-2950)

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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> Foodstuffs of animal origin
4.	<b>Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5.	<b>Title of the notified document:</b> Commission Implementing Regulation (EU) amending Regulation (EU) No 37/2010 as regards the classification of the substance fluralaner with respect to its maximum residue limit in foodstuffs of animal origin. <b>Language(s):</b> English. <b>Number of pages:</b> 4 <a href="https://members.wto.org/crnattachments/2025/SPS/EEC/25_03105_00_e.pdf">https://members.wto.org/crnattachments/2025/SPS/EEC/25_03105_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2025/SPS/EEC/25_03105_01_e.pdf">https://members.wto.org/crnattachments/2025/SPS/EEC/25_03105_01_e.pdf</a>
6.	<b>Description of content:</b> This draft legislation will establish a maximum residue limit (MRL) in the Union for the pharmacologically active substance fluralaner, intended for use in veterinary medicinal products for food-producing animals.  This draft legislation will amend the existing entry for fluralaner in Table 1 of the Annex of Commission Regulation (EU) No 37/2010 on pharmacologically active substances and its classification regarding maximum residue limits in foodstuffs of animal origin.
7.	<b>Objective and rationale:</b> <input checked="" type="checkbox"/> food safety, <input checked="" 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.
8.	<b>Is there a relevant international standard? If so, identify the standard:</b> <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): <input checked="" type="checkbox"/> None <b>Does this proposed regulation conform to the relevant international standard?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, describe, whenever possible, how and why it deviates from the international standard:</b>

<b>9.</b>	<b>Other relevant documents and language(s) in which these are available:</b>
<b>10.</b>	<b>Proposed date of adoption (dd/mm/yy):</b> July 2025 <b>Proposed date of publication (dd/mm/yy):</b> August 2025
<b>11.</b>	<b>Proposed date of entry into force: [ ] Six months from date of publication, and/or (dd/mm/yy):</b> This Regulation shall enter into force on the twentieth day following its publication in the Official Journal of the European Union.  <b>[ ] Trade facilitating measure</b>
<b>12.</b>	<b>Final date for comments: [X] Sixty days from the date of circulation of the notification and/or (dd/mm/yy):</b> 28 June 2025  <b>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:</b>  European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: <a href="mailto:sps@ec.europa.eu">sps@ec.europa.eu</a>
<b>13.</b>	<b>Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b>  European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: <a href="mailto:sps@ec.europa.eu">sps@ec.europa.eu</a>