NOTIFICATION

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| **1.** | **Notifying Member:** European Union  **If applicable, name of local government involved:** |
| **2.** | **Agency responsible:** European Commission, Health and Consumers 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):** Flavourings, food |
| **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:** Draft Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione in the Union list of flavouring substances (Text with EEA relevance).**Language(s):** English. **Number of pages:** Act (5 pages) + Annex (2 pages)  <https://members.wto.org/crnattachments/2021/SPS/EEC/21_3602_01_e.pdf>  <https://members.wto.org/crnattachments/2021/SPS/EEC/21_3602_00_e.pdf> |
| **6.** | **Description of content:** The Union list of flavourings and source materials is laid down in Annex I to Regulation (EC) No 1334/3008. It was established by Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances notified in G/SPS/N/EU/13/Add.1 (12 October 2012). This list is now amended by the draft "Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 3‑(1-((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3-hydroxybenzyl) imidazolidine-2,4-dione in the Union list of flavouring substances".  This addendum concerns the addition of the substance mentioned above, with FL n 16.127, to the list of authorised flavouring substances in the European Union.  This inclusion follows an application and the European Food Safety Authority (EFSA) evaluation evaluated this substance. The substance mentioned is included with certain conditions of use. The substance complies with the general requirements for flavourings set out in Article 4 of Regulation (EC) No 1334/2008. |
| **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:**  **[ ]****Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:**  **[ ]****World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:**  **[ ]****International Plant Protection Convention *(e.g. ISPM number)*:**  **[****X]** **None**  **Does this proposed regulation conform to the relevant international standard?**  **[ ]****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)*:** August 2021  **Proposed date of publication *(dd/mm/yy)*:** August 2021 |
| **11.** | **Proposed date of entry into force: [ ]****Six months from date of publication**, **and/or** ***(dd/mm/yy)*:** October 2021  **[ ]****Trade facilitating measure** |
| **12.** | **Final date for comments: [****X]****Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** 20 July 2021  **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 |