NOTIFICATION

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| **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):** Cereals with the exception of maize and rice; milling products of barley, wheat, spelt, rye and oats, wheat gluten, processed cereal based foods for infants and young children |
| **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 Regulation (EU) amending Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia and ergot alkaloids in certain foods.**Language(s):** English. **Number of pages:** 4+3  <https://members.wto.org/crnattachments/2021/SPS/EEC/21_2660_00.e.pdf>  <https://members.wto.org/crnattachments/2021/SPS/EEC/21_2660_01.e.pdf> |
| **6.** | **Description of content:** The draft Regulation revises the maximum levels set for ergot sclerotia in cereal grains with the exception of maize and rice and establishes maximum levels for ergot alkaloids in milling products of barley, wheat, spelt, rye and oats, wheat gluten, processed cereal based foods for infants and young children. |
| **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)*:** Standard for Wheat and Durum Wheat (CXS 199‑1995) - maximum level for ergot in wheat and durum wheat  **[ ]****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?**  **[ ]****Yes [****X]** **No**  **If no, describe, whenever possible, how and why it deviates from the international standard:** In the Commodity Standard CXS 199-1995, a maximum level for ergot sclerotia of 0.5 g/kg in wheat and durum wheat has been established. The maximum level of 0.5 g/kg in the Codex standard is established as a quality factor. The establishment in this draft Regulation of a maximum level of 0.2 g/kg for ergot sclerotia in unprocessed wheat and durum wheat, which is lower than the Codex level established on quality considerations, has been established on safety considerations to ensure a low the level of ergot alkaloids in wheat and durum wheat derived products for human consumption. The level of 0.2 g/kg for ergot sclerotia in wheat and durum wheat is readily achievable by applying good practices, e.g. by cleaning and sorting of the raw cereal grains before further processing such as milling. The Joint FAO/WHO Expert Committee on Food Additives assessed in its 91st meeting (Virtual meeting 1-12 February 2021) evaluated the risk for human health related to the presence of ergot alkaloids in food and came to the conclusion that certain exposure estimates exceeded the health based guidance value established for ergot alkaloids and that this may indicate a human health concern (Summary and Conclusions available at: [Joint FAO/WHO Expert Committee on Food Additives, Ninety-first meeting (Safety evaluation of certain food additives and contaminants) Summary and Conclusions. Issued 5 March 2021](http://www.fao.org/3/cb3689en/cb3689en.pdf). |
| **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)*:** 1 January 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)*:** 13 June 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 |