WORLD TRADE ORGANIZATION

G/SPS/N/EU/491

26 May 2021

(21-4381)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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):** Food supplements
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 Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice (Text with EEA relevance). **Language(s):** English. **Number of pages:** 8 https://members.wto.org/crnattachments/2021/SPS/EEC/21_3686_00_e.pdf
6.	**Description of content:** This draft Commission Regulation concerns the inclusion of monacolins from red yeast rice (RYR) in Annex III of Regulation (EC) No 1925/2006 ('the Regulation'). EFSA, in its scientific opinion adopted on 28 June 2018, considered that monacolin K in lactone form is identical to lovastatin, the active ingredient of several medicinal products authorised for the treatment of hypercholesterolemia in the European Union. EFSA concluded that monacolins in RYR when used as food supplements were of significant safety concern at the use level of 10 mg/day, and that individual cases of severe adverse reactions had been reported at intake levels as low as 3 mg/day. Furthermore, EFSA noted that the profile of adverse effects to RYR was similar to that of lovastatin. Therefore, pursuant to the procedure of Article 8 of the Regulation, this substance should be included in Annex III (Part B) to the Regulation. Furthermore, as EFSA could not identify a safe dietary intake of monacolins from RYR, and therefore, there is still the possibility of harmful effects on health but scientific uncertainty persists in this regard, this substance should be placed under Union scrutiny (Part C of the 'Regulation').
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:** Regulation (EU) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0026:0038:EN:PDF
10.	**Proposed date of adoption *(dd/mm/yy)*:** Foreseen in the fourth quarter of 2021. **Proposed date of publication *(dd/mm/yy)*:** Foreseen in the fourth quarter of 2021.
11.	**Proposed date of entry into force: [ ] Six months from date of publication, and/or *(dd/mm/yy)*:** 20 days from publication in the Official Journal of the European Union. **[ ] Trade facilitating measure**
12.	**Final date for comments: [X] Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** 25 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