WORLD TRADE ORGANIZATION

G/SPS/N/EU/344

11 September 2019

(19-5840)

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 and feed products of animal and plant origin
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:** Regulation (EU) 2019/1381 of the European Parliament and the Council on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance). **Language(s):** English, French and Spanish. **Number of pages:** 28 https://members.wto.org/crnattachments/2019/SPS/EEC/19_4997_00_e.pdf https://members.wto.org/crnattachments/2019/SPS/EEC/19_4997_00_s.pdf https://members.wto.org/crnattachments/2019/SPS/EEC/19_4997_00_f.pdf
6.	**Description of content:** This Regulation - amendment of the Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety ("General Food Law") and eight other sectoral acts - intends to improve the transparency of the EU risk assessment process carried out by EFSA, strengthen the long-term sustainability of EFSA and improve risk communication. Among others, the new Regulation will adapt the existing EU food safety system as follows: – Proactive public disclosure/Confidentiality/Public consultations of submitted studies All scientific data, studies and other information supporting applications as well as other requests for a scientific output by EFSA shall be made publicly available proactively, with the exception of duly justified confidential information, early on in the EU risk assessment process. To that effect, closed lists of clearly-defined information items for which confidentiality may be claimed under certain conditions, with the exception of safety relevant information, are set out in the General Food Law and in seven other sectoral acts. More specifically: When an applicant submits a request for authorisation accompanied by scientific data, studies and other supporting information, it may request certain parts of the submitted data, studies and other information to be kept confidential. This request must be duly justified (proof of "potential harm to a significant degree" in case of public disclosure). The applicant should submit a non-confidential version and a confidential version of the submitted data, studies and other information. Without delay and once an application is found valid or admissible, EFSA would make the non-confidential version of those studies, as submitted by the applicant, public. In parallel, EFSA would assess the

confidentiality claim within ten weeks. Once the assessment is completed, any additional data and information for which confidentiality requests have been considered as unjustified would also be made public (final non-confidential version as assessed by EFSA). Upon receipt of the confidentiality decision by EFSA, applicants would have the right to make a confirmatory application asking EFSA to reconsider its decision. Following public disclosure, EFSA will launch public consultations on the submitted data, studies and other information to ensure access to the widest evidence-base possible before it delivers its scientific output.

The public disclosure of all information supporting applications or other requests for scientific output by EFSA shall be without prejudice to any existing rules concerning Intellectual Property Rights (which may set out limitations on certain uses of the disclosed documents on their content), and "data exclusivity rules". The disclosure to the public shall not be considered as an explicit or implicit permission or licence for the relevant data and information and their content to be used. EFSA shall ensure that clear undertakings or signed statements are given to that effect by those accessing the relevant documents, prior to their disclosure.

– Notification of studies

EFSA shall establish and manage a database of studies commissioned or carried out (at pre-submission phase) by business operators to support a future application or notification in relation to which Union law makes provisions for EFSA to provide a scientific output, including a scientific opinion. Business operators shall, without delay, notify EFSA of the title and the scope of the study, the laboratory or testing facility carrying out the study, and the starting and planned completion dates of any study commissioned or carried out by them to support an application or a notification. The notification obligation shall also apply to laboratories and other testing facilities located in the Union carrying out those studies, and also to laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements. Certain procedural consequences of non-compliance with the notification requirement are also foreseen, e.g. an application or notification shall not be considered valid or admissible where it is supported by studies that have not been notified, unless the applicant or notifier provides a valid justification for non-notification of such studies.

– Fact-finding missions

Within four years after the entry into application of the Regulation, Commission experts shall perform fact-finding missions in member States to assess the application by laboratories and other testing facilities of the relevant standards for carrying out tests and studies submitted to EFSA as part of an application, as well as the compliance with the notification obligation. Commission experts shall also perform fact-finding missions to assess the application of relevant standards by laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements. The Commission, EFSA and the member States shall ensure the appropriate follow-up to these non-compliances. The outcome of the fact-finding missions shall be presented in an overview report, on which basis the Commission shall - if appropriate - submit a legislative proposal as regards any necessary control procedures, including audits.

7. Objective and rationale: [X] food safety, [X] animal health, [X] 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)*: Procedural Manual - Section IV - Working principles for risk analysis for application in the framework of the Codex Alimentarius

[ ] 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? **[X] 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)*:** 13 June 2019 **Proposed date of publication *(dd/mm/yy)*:** 6 September 2019
11.	**Proposed date of entry into force: [ ] Six months from date of publication**, **and/or *(dd/mm/yy)*:** 20 days after publication in the Official Journal of the European Union. **[ ] Trade facilitating measure**
12.	**Final date for comments: [ ] Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** Not applicable **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