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Committee on Sanitary and Phytosanitary Measures

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SPECIFIC TRADE CONCERNS - EUROPEAN LEGISLATION ON ENDOCRINE DISRUPTORS (NO. 382)

COMMUNICATION FROM PARAGUAY

The following communication, received on 14 October 2020, is being circulated at the request of the delegation of Paraguay.

Paraguay wishes to put the following questions to the European Union (EU) regarding specific trade concern (STC) No. 382 and European legislation on endocrine disruptors, under Article 5.8 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

EUROPEAN LEGISLATION ON ENDOCRINE DISRUPTORS (G/SPS/N/EU/166/ADD.2)

1. In its statement of 25 and 26 June 2020 pertaining to STC No. 382, the EU replied that in order to determine the relevance of scientific data, scientific peer review literature could also be used, if relevant.

In the light of this reply:

(a) Could the EU please specify the criteria used to determine that this type of literature is relevant?
(b) Could the EU also confirm whether it has used this type of source when analysing relevant scientific data? If so, could it provide specific examples of the studies used and indicate which substances with endocrine properties the studies were used for?

In its reply, the EU also referred to the "*Commission Communications in the framework of setting out the data requirements for active substances and plant protection products*", in accordance with Regulation No. 1107/2009, and a "Guidance Document published in 2018 and developed by EFSA, ECHA and JRC".

(c) Could the EU please provide copies of these documents?

2. Could the EU elaborate on its assertion that there is no direct link between the *presumed*[1] existence of the endocrine disrupting property of a substance (as stipulated in Regulation (EU) 2018/605) and the *precautionary principle*?

3. What criteria or requirements does the EU use to demonstrate that exposure to a substance represents a negligible risk of endocrine disruption?

4. In the EU's view, when does a risk analysis demonstrate that the protection of European consumers is ensured?

[1] "Presumed" is not the same as "confirmed".

5. The EU has affirmed that maximum pesticide residue levels (MRLs) can be set only where there is sufficient information to demonstrate that the MRL adequately protects consumers, and that the burden lies with the applicant to show that the MRLs are safe.

(a) In the EU's view, what constitutes sufficient information?
(b) If the information available were insufficient, would the EU's measures concerning MRLs fall within the scope of Article 5.7 of the SPS Agreement?[2] If not, could the EU please explain why it believes that insufficient information would not entail the application of that Article?
(c) Could the EU please explain how the reversal of the burden of proof is consistent with its obligations under the SPS Agreement and, in particular, with Articles 2.2 and 5.1 thereof, which require *WTO Members* to base their measures on scientific evidence?

6. In its "Farm to Fork Strategy", published on 30 May 2020, the EU identified "promoting the global transition" as one of its objectives, and specifically stated that "[t]he Commission will take into account environmental aspects when assessing requests for import tolerances for pesticide substances no longer approved in the EU".[3] The EU also provides assurances that WTO standards and obligations will be respected in the process. In this light:

(a) Could the EU please indicate whether it plans to make any changes to Regulation (EC) No. 396/2005 in respect of import tolerances?
(b) Could the EU please provide a definition or list of what it views as "environmental aspects"?
(c) Could the EU please explain how it intends to incorporate these "environmental aspects" into the assessment of requests for import tolerances for pesticide substances?
(d) In the EU's view, would taking into account environmental aspects in other WTO Members mean applying its Regulations extraterritorially on a de facto basis?

[2] Article 5.7 of the SPS Agreement provides as follows: "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

[3] Farm to Fork Strategy, page 18.