WORLD TRADE ORGANIZATION

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Page: 1/2

**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 26 February 2020, is being circulated at the request of the delegation of Paraguay.

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Paraguay wishes to put the following questions to the European Union (EU) regarding specific trade concern No. 382 and the European legislation on endocrine disruptors.

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

1. Could the EU provide a scientific definition of "endocrine disruptors"?

2. Commission Regulation (EU) 2018/605 – on scientific criteria for the determination of endocrine disrupting properties – establishes in recital (3) of its preamble that the implementation of the criteria should be based on "all relevant scientific evidence", including studies submitted in accordance with Regulation (EC) No 1107/2009, which are "mostly based on internationally agreed study protocols". In light of the above:

   (a) Can the EU explain how it distinguishes between *relevant* scientific evidence and *non-relevant* scientific evidence?

   (b) Can the EU indicate which other protocols form the basis for studies that are not based on internationally agreed study protocols?

3. Could the EU explain how the provisions of Commission Regulation (EU) 2018/605 are in conformity with the obligations set out in Articles 5.1 and 5.2 of the SPS Agreement?

4. Could the EU expand on how its risk assessments take account of key elements of risk characterization, such as the strength, severity and reversibility of effects?

5. Commission Regulation (EU) 2018/605 establishes in recital (4) of its preamble that "both known and presumed endocrine disrupting substances" must be identified. Does the EU consider that the application of Commission Regulation (EU) 2018/605 is covered by Article 5.7 of the SPS Agreement?

6. Does the EU consider that the prohibition of substances to which exposure represents a negligible risk of endocrine disruption is scientifically justified?

7. Could the EU provide more details on how the "import tolerance" mechanisms will function that are provided for in Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin?

8. Could the EU explain how it reconciles its assertion that import tolerances will be analysed on a case-by-case basis (in line with its statements in the SPS Committee) if they are to be based on a risk analysis?

9. Could the EU provide detailed information on applications for import tolerances that have already been received and the number of applications that have already been approved?