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REPLIES TO QUESTIONS SUBMITTED BY PARAGUAY ON EUROPEAN LEGISLATION ON ENDOCRINE DISRUPTORS (NO. 382)

SUBMISSION BY THE EUROPEAN UNION

The following document, received on 30 November 2020, is being circulated at the request of the Delegation of the European Union.

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1 How will the European Union determine which peer-reviewed scientific literature is relevant for considering scientific data? Could you provide examples where peer-reviewed literature was used and for which substances?

1. The use of peer-reviewed literature is a standard data requirement under EU law. This requirement is used for all substances which have been assessed during the last years and will be assessed in future. The European Commission has a public database were active substances can be searched for and the relevant information can be retrieved.

2. The Guidance Document published in 2018 jointly by the European Food Safety Authority, European Chemicals Agency and Joint Research Centre sets out the criteria and the definition for the scientific data to be considered as relevant. Also examples are reported in the 'Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009' is available at https://www.efsa.europa.eu/en/efsajournal/pub/5311.

In its reply, the European Union also referred to the "Commission Communications in the framework of the determination of data criteria for active substances and plant protection products" under Regulation 1107/2009 as well as to a "Guidance Document published in 2018 jointly by EFSA, ECHA and JRC". Could the European Union provide copies of these documents?

3. The 'Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market' can be found at the following link: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013XC0403(02).

4. The 'Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009' is available at https://www.efsa.europa.eu/en/efsajournal/pub/5311.

2 Could the European Union elaborate on its assertion that there is no direct link between the assumption of endocrine disrupting property of a substance (as stipulated in Regulation (EU) 2018/605) and the precautionary principle?

5. The EU regulatory framework establishes scientific criteria for the determination of endocrine disrupting properties of active substances, taking into account the current scientific and technical knowledge. The objective is to ensure a high level of protection of both human and animal health and the environment, meaning that substances or products placed on the market have no harmful effect on human or animal health or unacceptable effects on the environment.

6. Article 5.7 of the SPS Agreement applies only to specific situations where, in light of insufficient scientific evidence, a Member has to adopt provisional measures pending more data and a more conclusive assessment. If the conditions provided for in Article 5.7 SPS Agreement are met, risk management decisions concerning particular substances under the EU regulatory framework may be based on the precautionary principle.

3 What are the criteria or requirements considered by the European Union to demonstrate that certain exposure to a substance poses a negligible risk of endocrine disruption?

7. The definition of 'negligible exposure' is reported in Regulation 1107/2009: its Annex II provides in points 3.6.3 / 3.6.4 / 3.6.5 (human exposure) and point 3.8.2 (environment) that active substances, safeners or synergists, classified on the basis of Regulation (EC) No 1272/2008 as carcinogen category 1A or 1B or toxic for reproduction category 1A or 1B, or having endocrine disrupting properties which may cause adverse effects on humans, cannot be approved "unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible".

8. Substances approved considering these provisions will be listed in accordance with Article 24 of this Regulation as candidates for substitution. Therefore, they would be approved for a period not exceeding seven years (Article 24), evaluations for authorisations for plant protection products containing such active substances would be subject to comparative risk assessment (Article 50) and member States may derogate from mutual recognition (Article 41(2.b)). Some qualifying terms (i.e. 'closed systems', 'negligible', and 'excluding contact with humans') are mentioned in the Regulation in relation to negligible exposure.

9. 'Closed systems': Points 3.6.3 to 3.6.5 of Annex II to Regulation (EC) No 1107/2009 point out that "the exposure (…) is negligible" when "the [plant protection] product is used in closed systems". Considering human exposure, it is not possible to demonstrate 'closed systems' throughout the entire life-cycle of a plant protection product. In fact, often cited examples of 'closed systems' relate to a certain phase in the life of a product. For instance, a bulk transfer system may be perceived as 'closed' during mixing and loading but not during application; a bait-box may be perceived as 'closed' during most of the use phase but release into the environment can occur via secondary poisoning of predators or on disposal of the container; high-tech greenhouses, usually perceived to be 'closed systems', may still result in exposure of operators during mixing and loading or workers on re-entry and leakages into the environment are also possible.

10. Even 'closed systems' supported by measurements at the Limit of Detection (LOD) or Limit of Quantitation (LOQ) are not synonymous with no exposure as the active substance, safener or synergist could still be present at levels which cannot be detected using current analytical methods. For these reasons, the following definition is considered appropriate: 'Equipment and procedures designed to reduce as far as technically possible the escape of an active substance, safener or synergist into the environment either during or after the use of the plant protection product'.

11. 'Negligible': 'negligible' is not equal to zero and is defined in the Oxford English Dictionary as "so small or unimportant as to be not worth considering; insignificant". For risk assessment purposes 'negligible' can be considered to be a level so small that it does not appreciably add to the risk and can safely be ignored.

12. 'Excluding contact with humans': this means that residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 4 of the EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments.

4 When does the European Union consider that a risk analysis demonstrates that the protection of European consumers is ensured?

13. The protection of European consumers is ensured when there exists sufficient scientific certainty to establish that substances or products placed on the market have no harmful effects on consumer health.

5 The European Union has stated that maximum residue levels for pesticides (MRLs) can only be established if there is sufficient information to demonstrate that the MRL sufficiently protects consumers, and that the burden of proof to demonstrate that MRLs are safe lies with the applicants.

a. What does the European Union consider as sufficient information?

b. In the absence of sufficient information, does the European Union consider that its measures on MRLs would fall within the scope of Article 5.7 SPS Agreement? If not, could the European Union explain why it considers that the lack of sufficient information would not lead to the application of this Article?

c. Could the European Union explain how the reversal of the burden of proof is compatible with its obligations under the SPS Agreement? In particular, Articles 2.2 and 5.1 SPS Agreement require WTO Members to base their measures on scientific evidence.

14. The data requirements for active substances and plant protection products are set out in Commission Regulations (EU) No 283/2013 and (EU) 284/2013, respectively.

15. SPS measures, such as setting MRLs for pesticides, must indeed be based on sufficient scientific evidence. It is the responsibility of the applicant to provide such evidence. It is justified that the burden of providing scientific evidence is shifted onto applicants because they have a direct or indirect commercial interest in placing the product on the market and – therefore – in actively contributing to risk assessment procedures. This is fully compliant with the SPS Agreement.

6 In its Farm to Fork Strategy, published on 30 May 2020, the European Union has identified "promoting a global transition" as one of its objectives, stating specifically that "the Commission will take into account environmental factors when assessing import tolerances for pesticides that are no longer approved by the European Union". It also ensures that WTO standards and obligations will be respected in doing so. In this sense:

a. Could the European Union indicate whether amendments to Regulation (EU) No 396/2005 are envisaged with regard to import tolerance?

b. Could the European Union provide a definition or list of what it considers to be "environmental factors"?

c. Could the European Union explain how it intends to incorporate these "environmental factors" in the assessment of import tolerances for pesticides?

d. Does the European Union consider that, by taking environmental factors into account in other WTO Members, its regulations would de facto be applied extraterritorially?

16. No amendments to Regulation 396/2005 are currently envisaged.

17. The existing EU legislation does not provide for an exhaustive list of legitimate factors to be taken into account when managers decide on the most appropriate measure to attain a chosen level of protection of human health. So far, the European Union has not resorted to the use of "other legitimate factors" in the setting of pesticide MRLs, including decisions on import tolerances requests.

18. We must not ignore, however, broad consensus that the use of certain pesticides is linked to serious environmental concerns, or effects related to persistent, bioaccumulative and toxic substances. These effects do not stop at national borders and this fact must be considered when defining an appropriate level of protection. In other words, where serious environmental concerns of global nature prevail, national use restrictions may not be sufficient to achieve necessary protection goals and the setting of import tolerances may have to take this situation into account.

19. The European Union will take such decisions on a case-by-case basis, founded on the best available scientific evidence and ensuring that its measures are not more trade restrictive than necessary to achieve their objective. The European Union is committed to continue to fulfil its international obligations and to act according to the WTO rules, with full transparency.

20. The European Union strives to provide its partners with timely and comprehensive information on its policies. With regard to the Farm to Fork Strategy, in September 2020, the European Union organised an information session at which your Delegations participated. In October, the European Union also held – virtually – the first Farm to Fork conference. A more specific seminar on pesticides residues is currently envisaged to take place in early 2021.