WORLD TRADE ORGANIZATION

G/SPS/GEN/1749

14 November 2019

(19-7751) Page: 1/3

Committee on Sanitary and Phytosanitary Measures Original: English

FLOOR STATEMENTS
NOVEMBER 2019 WTO SPS COMMITTEE - FORMAL MEETING

AGENDA ITEM 3(B)(I): EU MRLS FOR BUPROFEZIN, CHLOROTHALONIL, DIFLUBENZURON, ETHOXYSULFURON, GLUFOSINATE, IMAZALIL, IOXYNIL, IPRODIONE, MOLINATE, PICOXYSTROBIN AND TEPRALOXYDIM

Communication from the United States of America

The following communication, received on 12 November 2019, is being circulated at the request of the Delegation of the United States of America.

---

1. The United States thanks Colombia, Costa Rica, Côte d'Ivoire, Ecuador, Guatemala, India, Panama, and Paraguay for keeping this important issue on the Committee's agenda.

2. Given the serious concerns raised in this forum over the past several years — particularly regarding the profound adverse impacts on producer livelihoods in developing countries — we are disappointed that the European Union continues to lower many MRLs to trade-restrictive levels without clear scientific justification or measurable benefit to human health.

3. In responding to the recent concerns of Members, the European Union has referred to its statements from the November 2018 and March 2019 meetings. We have carefully considered the explanations that were offered, along with those from the July 2019 meeting, and find that they do not address our current concerns. In fact, they raise additional questions about the consistency of the EU explanation with its actions alongside the fundamental provisions of the SPS Agreement.

4. For example, in its November 2018 statement to this Committee, the European Union indicated that the basis for its decision to lower all buprofezin MRLs was its identification of "important consumer health concerns". The European Union alleged that the metabolite aniline was a carcinogen for which a genotoxic mechanism could not be excluded, and no threshold for acceptable exposure could be assumed. The European Union stated that, therefore, a consumer risk assessment was not completed.

5. We note that the European Food Safety Authority (EFSA) evaluated buprofezin and found that aniline only occurs in processed commodities. For commodities that typically do not undergo processing, EFSA stated that a dietary risk assessment for aniline would not be required. We ask the European Union, then, why a risk assessment was not completed for commodities that are typically unprocessed—such as avocados, bananas, grapes, mangoes, and melons—in order to establish MRLs for buprofezin.

6. In November 2018, the European Union also underscored that it based its risk management measures for buprofezin and aniline on the evaluations carried out by its own risk assessment body. We note that the European Medicines Agency (EMA), an EU risk assessment body that evaluates medicinal products, reviewed the available data for aniline and concluded that the weight of evidence supports non-genotoxic mode of action. The EMA established a threshold for use in regulatory risk assessments.

7. In light of the discrepancies between EFSA and EMA's approaches, we ask the European Union how it is achieving consistency in the application of the level of protection it considers appropriate for aniline. We further ask the European Union to explain the basis for the distinctions in its approach to consumer exposure to aniline from different sources. We remind the European Union that such distinctions must not be unjustified or arbitrary.

8. If the European Union seeks to limit consumer exposure to aniline, we ask the European Union to quantify the level of protection and reduction in risk that is achieved by lowering buprofezin MRLs for commodities in which no measurable aniline is present.

9. In November 2018, the European Union conveyed that it would be submitting a concern form to Codex regarding EFSA's findings and conclusions on buprofezin and aniline in order to "raise international awareness".

10. We draw the Committee's attention to the Summary Report of the September 2019 Joint FAO/WHO Meeting on Pesticide Residues, which notes that the JMPR evaluated the EU concern form and determined that aniline is unlikely to be carcinogenic to humans at estimated dietary exposure levels. The JMPR established a reference dose and concluded, on the basis of a risk assessment, that exposure to aniline does not represent a health concern. The JMPR also recommended new and increased MRLs for buprofezin that will facilitate trade of safe food.

11. In November 2018, the European Union also explained that during its evaluation of picoxystrobin, it had identified concerns related to the clastogenic and aneugenic potential of a metabolite, and had not been able to complete an assessment of genotoxicity for the substance. In this case too, the European Union indicated that it would be submitting a concern form to Codex.

12. We again turn to the Summary Report of the September 2019 Joint FAO/WHO Meeting on Pesticide Residues, which notes that the JMPR evaluated the EU concern form. The JMPR's interpretation of the data differed from the European Union's, and the JMPR confirmed that dietary exposure to picoxystrobin is unlikely to represent a public health concern. The JMPR further confirmed that the WHO panel of JMPR included an independent specialist genotoxicity expert.

13. Since the European Union requested that JMPR divert resources towards evaluating its concerns, we ask the European Union how it now plans to take into account the JMPR's responses.

14. In July 2019, the European Union conveyed to the Committee that lowering MRLs for imazalil was considered necessary to ensure its appropriate level of protection. The European Union referenced two evaluations by EFSA which indicated that available data did not support establishment of MRLs sufficiently protective for consumers.

15. We note that EFSA cited uncertainty around genotoxic potential, as well as concerns about a metabolite present in commodities that are treated post-harvest, including citrus fruits, apples, pears, bananas, and potatoes. Consequently, EFSA stated that no MRLs could be recommended for these commodities.

16. Given EFSA's opinion, we ask the European Union to explain its rationale for retaining MRLs for citrus fruits at 4 mg/kg, while lowering the MRL for bananas to the limit of determination, or 0.01 mg/kg.

17. The June 2019 report of the Standing Committee on Plant, Animal, Food and Feed (PAFF) suggests that EU risk managers took into consideration the fact that citrus fruits are peeled, and therefore based consumer exposure estimates on the residues available in the pulp. We ask the European Union why a similar peeling factor was not utilized for bananas.

18. Indeed, the June 2019 PAFF report stated that multiple member State delegations expressed reservations about the lowering of the MRL for imazalil in bananas. One member State asserted that the final position of the Commission on bananas had not been consistent with the approach given to other post-harvest uses in food commodities, even when the scenario was very similar to bananas.

19. We ask the European Union how it is achieving consistency in the application of the level of protection it considers appropriate for imazalil, and how its risk management approach distinguishes

commodities, such as oranges and bananas. We note again that such distinctions must not be unjustified or arbitrary.

20. We also note that during the February 2019 meeting of the PAFF, the Commission and EU member States discussed how to interpret genotoxicity data when all studies show no concern except for one equivocal, or indeterminate, result.

21. Given that uncertainty about genotoxicity has been frequently cited by the European Union as justification for invoking the so-called precautionary principle and basing measures on a priori hazards, and given the apparent divergence of the EU approach to evaluating genotoxicity data from that of the WHO and other national scientific and regulatory authorities, we ask the European Union to provide further details on the outcomes of this discussion, including:

- whether or not it applies an objective weight of evidence approach when considering genotoxicity data;
- how it considers the critical distinction between possibility and probability of exposure; and
- whether it has considered provisional measures, such as temporary MRLs, so that it can avoid unnecessary barriers to trade while still seeking to obtain additional information necessary for its assessment.

22. Chair, the questions we have posed to the European Union speak to the fundamental principles and obligations of the SPS Agreement, and are at the core of the concerns expressed by an unprecedented number of Members in this forum, as well as at the July 2019 meeting of the Council for Trade in Goods.

23. Rather than referencing previous statements that do not address the specific concerns and questions posed by Members, we hope that the European Union will engage productively in future discussions on this important matter so that the Committee can gain a better collective understanding of how the European Union is establishing MRLs in a manner consistent with its obligations under the SPS Agreement.

24. Since the EU implementing regulations for MRLs specify relevance to the European Economic Area (EEA), we also invite Iceland, Liechtenstein, and Norway to respond, as we understand that they operate within the EU's single market and harmonize their MRLs to those of the European Union. We are not clear how or when EU MRLs are adopted by non-EU members of the EEA, as these actions do not appear to be notified to the WTO.

25. Chair, we appreciate the discussions in this Committee on actions to improve transparency and support greater shared understanding of concerns raised in Committee. We will therefore submit this statement to the Secretariat and request its issuance as a GEN document.