WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures

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RESPONSE OF THE EUROPEAN UNION TO G/SPS/GEN/1885 ON EU LEGISLATION ON ENDOCRINE DISRUPTORS – (CONCERN NO. 382)

SUBMISSION BY THE EUROPEAN UNION

The following submission, received on 26 March 2021, is being circulated at the request of the Delegation of the European Union.

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1. In its reply to question number 2 from Paraguay, the EU indicates that Article 5.7 of the SPS Agreement applies only to specific situations where, in the light of insufficient scientific evidence, the EU's risk management decisions may be based on the precautionary principle. Paraguay notes that a significant number of MRLs have been adopted by the EU as a result of the decision not to renew certain substances found in plant protection products, which is based on inconclusive scientific evidence.

(a) Could the EU please indicate if, in these cases, it applies the precautionary principle in its risk management decisions?

(b) If the answer is no, could the EU please specify how "insufficient scientific evidence" differs from "inconclusive scientific evidence"?

The precautionary principle applies in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists. If these conditions are fulfilled, provisional risk management measures may be adopted if it is necessary to ensure the high level of health protection chosen in the European Union. Whether or not any decision can be referred to as "based on the precautionary principle" must be therefore verified taking into account these specific circumstances.

2. In its reply to question number 4, the EU states that the protection of European consumers is ensured when there exists sufficient scientific certainty to establish that substances have no harmful effects on human health.

(a) Could the EU please provide a definition of when it considers that "sufficient scientific certainty" exists? Specific examples would be useful in order to best demonstrate this.

There is no definition of "sufficient scientific certainty" in European Union law. In order to achieve the general objective of a high level of protection of human health and life, European Union food safety measures take into account the results of risk assessment, which is based on all available scientific evidence and undertaken in an independent, objective and transparent manner.

3. Could the EU please confirm if environmental factors will be taken into account when granting emergency authorizations to member States to use substances prohibited within the EU?

Yes – emergency authorizations are derogations from the standard requirements for authorization, but do not exempt the need to consider safety. When considering whether emergency authorizations can be granted, member States must consider safety for human and animal health and the environment.

In January 2021, the European Commission published the Guidance on emergency authorizations according to Article 53 of Regulation (EC) No 1107/2009, which explains the process to be followed by applications and member States for application for emergency use as well as specifying the information that should be provided in such applications and their resulting authorizations.

Regarding substances which are not approved in the European Union, the Guidance states:

> *"Particular attention should be paid to the reasons underpinning the non-approval of the active substance when assessing applications, taking into account the most recent EFSA Conclusion on the substance, where available. The lack of critical endpoints (such as health-based reference values) for carrying out risk assessments is of particular importance and should be carefully considered, in particular when ensuring consumer safety"* (p. 6).

4. Could the EU please specify the technical criteria used when granting emergency authorizations to member States to use substances prohibited within the EU?

Emergency authorizations are not granted to member States; rather, they are issued by the member States themselves – each member State is responsible individually for granting emergency authorizations. The Commission does not issue emergency authorizations; nor are emergency authorizations issued at European Union level.

The Guidance referred to above in reply to question 3 provides more details on the process of considering emergency use of plant protection products, including product containing substances that are no longer approved in the European Union.

Around 90% of emergency authorizations are for plant protection products containing active substances that are **approved in the EU.**

5. We note that, at the seminar of 20 January 2021 on environmental factors and setting MRLs, the EU stated that exports from one EU member State to another must comply with European MRLs and that few MRLs have been subject to emergency authorizations.

(a) Could the EU please indicate in which cases, for which products and in which member States emergency authorizations have been granted?

There are many authorizations issued each year by member States. The vast majority (around 90%) of emergency authorizations are for plant protection products containing active substances that are **approved in the European Union** and most comply with the EU MRL.

In the event that substances do not comply with the applicable EU MRL, the treated food or feed must remain in the territory of the specific EU member State in which the authorization was granted.

In February 2020, the European Commission launched a public database containing information on the notifications made by member States on emergency authorizations. Users can search to identify emergency authorizations granted from June 2016 onwards.

Third countries can search the database to obtain information on emergency authorizations. The notifications contain details of the use and compliance with the MRL.

(b) We note that the majority of products exported by third countries to the EU are unprocessed natural products (such as sugar cane, maize or beet), while those traded among EU member States are mainly processed products (such as sugar). In this regard, would breaches of the limit of analytical determination be detected in processed products in the same way that they would be detected in an unprocessed raw material?

Yes, the European Union legislation contains specific provisions for maximum residue levels for processed and composite products. EU member States include processed products in their national monitoring programmes and follow up on possible non-compliances in the same way as for raw agricultural products.

6. We reiterate the following questions that were posed by the delegation of Paraguay at the aforementioned seminar and subsequently submitted by note to DG SANTE on 21 January 2021:

(a) Could the EU please explain how it intends to incorporate environmental factors into import tolerances and how this incorporation would be compatible with the obligations laid down for the establishment of sanitary measures under the SPS Agreement?

The SPS Agreement applies only to measures defined in its Annex A.[1] It follows from that definition that the SPS Agreement covers measures aimed to protect human, animal or plant life or health within the territory of the Member. Measures based on other grounds, e.g. environmental, fall outside the scope of the SPS Agreement, even if they apply to food products.

Until now, the European Union pesticides policy has been related to the protection of human health. Under the new approach, however, consideration may be given to issues of global environmental concern when setting import tolerances.

(b) Could the EU please provide a definition and list of the "environmental factors" to be taken into account when assessing import tolerances?

The European Union has replied to this question in document G/SPS/GEN/1871 (point 17).

(c) In October 2020, Paraguay submitted a series of questions to the EU relating to specific trade concerns on MRLs and endocrine disruptors. In its replies, the EU stated that no amendments to Regulation No. 396/2005 are currently envisaged. Could the European Union please confirm whether environmental factors may constitute "other legitimate factors" to be taken into account when determining import tolerances?

The European Union has already replied to this question in document G/SPS/GEN/1872 (point 5).

(d) Can environmental factors determine the imposition of MRLs that are lower than those that would result from the application of purely sanitary factors?

So far, the European Union has not resorted to the use of "other legitimate factors" when taking decisions on the setting of MRLs, including import tolerances. As already explained, environmental concerns of global nature may be taken into account in setting import tolerances. Measures will be taken on a case-by-case basis and founded on the best available scientific evidence. For those specific cases, this may indeed result in lower MRLs.

7. With regard to import tolerances, could the EU please provide a list covering the period from November 2017 to date of all requested import tolerances, the requesting country and whether the requests were accepted or rejected? In cases where requests were rejected, could the EU please provide the reason for this rejection?

This information is publicly available in the European Commission's webpage: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_overview-it-table.pdf.

The table reports the import tolerances requests submitted from 2009 to 2020 and the link to the corresponding Regulations. The table also indicates whether the import tolerances were established in the European Union or if they were rejected. In the latter case, a small remark on the reason for rejection is included. Information related to the country where the GAP is authorized and the MRL value set for each commodity-active substance combination are also reported.

[1] Any measure applied: "(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests".