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Committee on Sanitary and Phytosanitary Measures Original: Spanish

SPECIFIC TRADE CONCERNS - EUROPEAN UNION (EU) MAXIMUM RESIDUE LEVELS (MRLS) FOR BUPROFEZIN, CHLOROTHALONIL, DIFLUBENZURON, ETHOXYSULFURON, GLUFOSINATE, IMAZALIL, IOXYNIL, IPRODIONE, MOLINATE, PICOXYSTROBIN AND TEPRALOXYDIM (NO.448, SEE ALSO RELATED SPECIFIC TRADE CONCERNS NOS. 453, 454, 457, 474, 475)

COMMUNICATION FROM COLOMBIA, GUATEMALA AND PARAGUAY

The following communication, received on 14 October 2020, is being circulated at the request of the delegations of Colombia, Guatemala and Paraguay.

Colombia, Guatemala and Paraguay would like to ask the European Union (EU) the following questions regarding specific trade concern No. 448 and the modification of MRLs.

MODIFICATION OF EU MRLS FOR PLANT PROTECTION PRODUCTS (G/SPS/N/EU/264/ADD.1, G/TBT/N/EU/625 AND G/SPS/N/EU/263/ADD.1)

1. In its replies to the questions posed in document G/SPS/GEN/1760, the European Union states, with regard to its appropriate level of protection (ALOP), that "*it is necessary to ensure that pesticide residues are not present at levels presenting an unacceptable risk to humans. MRLs should be set at the lowest achievable level consistent with good agricultural practice for each pesticide with a view to protecting vulnerable groups such as children and the unborn*".

Meanwhile, paragraph 5 of Annex A to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) defines the ALOP as "*[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk"*."

In the light of its reply, could the European Union:

(a) Define the acceptable level of risk determined for the implementation of its policy regarding the determination of MRLs?
(b) Explain how it has taken into account the objective of minimizing negative trade effects when determining the acceptable level of risk, in accordance with Article 5.4 of the SPS Agreement.
(c) Identify what it considers good agricultural practices (GAPs) to be.
(d) Indicate how GAPs are taken into account when determining the ALOP sought.

2. The European Union stated that between 2012 and 2019, it adopted 1,833 of the 2,567 MRLs established by the *Codex Alimentarius* (CXLs) and that it is therefore aligned with 70% of *Codex* standards. It also replied that "*at times, the European Union deviates from international standards when justified for the protection of public health and on the basis of EFSA's scientific advice*" and that, in doing so, it is acting in conformity with Article 3 of the SPS Agreement.

In light of the foregoing, could the European Union:

(a) Indicate how many CXLs it has adopted to date since November 2017, as well the level of alignment between its MRLs and those established by the *Codex* since the *effective implementation* of its MRL review policies linked to Regulations No. 1107/2009 and No. 396/2005.

(b) Explain the justification for its decision to deviate from the international standards of the *Codex Alimentarius* on the basis of EFSA's scientific advice in cases where EFSA determines that the results of risk assessments are inconclusive or that the scientific evidence is insufficient.[1] In this regard, we note that the EU's reply to question 11(r) submitted by Paraguay within the framework of the EU's Trade Policy Review (TPR), recalls that "*MRL can be set only when there is sufficient information to support a risk assessment demonstrating that the MRL is sufficiently protective for consumers*".[2]

3. The EU "*allows Member States to grant emergency authorisations for PPPs that are not authorised for use on a specific crop*".[3] There has in fact been a "*rise in emergency authorisations [which] has been attributed by some stakeholders to the decreasing availability of effective active substances and the lack of PPPs for specific uses*".[4] In this light, in cases where emergency authorizations are granted within the EU for the use of certain unauthorized pesticides, how does the EU ensure that these emergency measures do not arbitrarily or unjustifiably discriminate between WTO Members with identical or similar conditions as regards the use of these pesticides, as provided for in Article 2.3 of the SPS Agreement?[5]

4. In reply to question 6 in document G/SPS/GEN/1760, on why Article 5.3 of the SPS Agreement[6] is not relevant in the case of the measures stipulated in paragraph 1(b) of Annex A to the SPS Agreement[7], the EU stated that Article 5.3 is not relevant because of the second sentence of paragraph 4 of Annex A to the SPS Agreement[8], which defines risk assessment. However, both paragraph 1(b) and the second sentence of paragraph 4 of Annex A to the SPS Agreement refer to animal health and feedstuffs, in the same way as Regulation (EC) No. 396/2005. We therefore reiterate our request that the EU elaborate on its assertion that Article 5.3 of the SPS Agreement

[1] It should be recalled that the second sentence of Article 3.3 of the SPS Agreement reads as follows: "*all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement*". Therefore, there must be "*scientific justification*" for any sanitary or phytosanitary measure that results in a higher level of protection than would be achieved by measures aligned with the relevant international standards.

[2] Document W/TPR/M/395/Add.1, page 395.

[3] *Commission Staff Working Document Accompanying the document Report from the Commission to the European Parliament and the Council - Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides {COM(2020) 208 final}*, page 31.

[4] *Commission Staff Working Document Accompanying the document Report from the Commission to the European Parliament and the Council - Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides {COM(2020) 208 final}*, page 32.

[5] Article 2.3 of the SPS Agreement: "*Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.*"

[6] Article 5.3 of the SPS Agreement: "*In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.*"

[7] Annex A. Definitions: "*1. Sanitary or phytosanitary measure - Any measure applied: [...] (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".*

[8] Annex A. Definitions: "*Risk assessment - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs*".

(which covers measures to protect animal health) is not relevant in the case of EU measures on MRLs.

5. According to the EU's reply to question 8 in document G/SPS/GEN/1760, "*[c]urrent European Union legislation does not provide for an exhaustive list of [other] legitimate factors*" to be taken into account when determining risks. Could the EU please provide an indicative list, containing specific examples, of what it believes these "other legitimate factors" might be?

6. In reply to question 9 in document G/SPS/GEN/1760, the EU stated that it "*has consistently taken into account comments on the revocation of authorisation on specific substances or on MRLs received by WTO members on measures notified under either the TBT Agreement and/or the SPS Agreement*".

However, the EU has recently acknowledged that, in the substance evaluation dossier, the rapporteur Member State does not always take into consideration comments from other EU Member States concerned and that this may lead to a situation where their concerns are not taken into account.[9]

In light of the foregoing, could the EU:

(a) Explain how it ensures that comments from non-EU trading partners are taken into consideration, when comments from EU Member States themselves are sometimes not taken into consideration during the peer review.
(b) Provide concrete examples of specific cases in which comments from non-EU trading partners have been taken into consideration.

7. We thank the EU for offering to once again provide the link to the EFSA website where details concerning the state of the review of MRLs are published. We note that the EU previously provided the SPS Committee with the link to this website in June 2016 in document G/SPS/GEN/1494. Members are aware of the various websites and the information they contain.

However, as the EU itself expressly points out regarding its database, "[s]imply having information publicly available does not necessarily translate into a better informed public if the information is difficult to find".[10]

For example, the EFSA website https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf refers only to substances that are under review. However, once the review process is complete, substances that are not to be renewed are removed from this portal and moved to the pesticides database on another website: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN.

The fact that available information does not appear on one sole website that provides an overview of the progress of a substance evaluation, from when a substance is included on the list through to when new MRLs are notified, makes holistic and systemic monitoring of the substances evaluated by the EU extremely difficult, particularly for developing countries with limited resources.

We therefore reiterate the request that we made to the EU in paragraph 10 of document G/SPS/GEN/1760 for a single list that clearly indicates all the substances that have already been reviewed and the processes related to, and status of, those for which reviews are ongoing.

8. In the statement made *by* the EU concerning the specific trade concern (STC) raised by the delegations of Colombia and Ecuador regarding *chlorpyrifos and chlorpyrifos-methyl*, the EU noted

[9] *Commission Staff Working Document Accompanying the document Report from the Commission to the European Parliament and the Council - Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides {COM(2020) 208 final}*, page 48.

[10] *Commission Staff Working Document Accompanying the document Report from the Commission to the European Parliament and the Council Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides {COM(2020) 208 final}*, page 61.

that "*given the concerns identified by EFSA, it is not possible to determine MRLs based on a risk assessment and therefore all MRLs must be lowered to the limit of determination*".[11]

Could the EU confirm that the MRLs for both substances will be lowered to the limit of detection (LOD) without a risk assessment?

9. In the same statement, the EU also said that "*European Union legislation prescribes that it is the responsibility of the industry to demonstrate that substances and products they contain do not have any harmful effects on human and animal health or unacceptable effects on the environment*".[12] The EU had already stated this in its replies to questions 8(j) and (k) and 11(q) submitted by Paraguay within the framework of the TPR of the European Union.[13]

According to the European Union, the burden of proof regarding the safety of products falls on the industry. Could the EU explain how this assertion is consistent with its obligations under Articles 2.2 and 5.1 of the SPS Agreement, which require *WTO Members* to base their measures on scientific evidence?

[11] EU statement on the STC regarding MRLs for chlorpyrifos and chlorpyrifos-methyl.
[12] EU statement on the STC regarding MRLs for chlorpyrifos and chlorpyrifos-methyl.
[13] Document W/TPR/M/395/Add.1, pages 392-395.