WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures Original: English

SPECIFIC TRADE CONCERNS – EUROPEAN UNION MAXIMUM RESIDUE LEVELS (MRLS), EUROPEAN LEGISLATION ON ENDOCRINE DISRUPTORS AND IMPORT TOLERANCES FOR CERTAIN PESTICIDES TO ACHIEVE ENVIRONMENTAL OUTCOMES IN THIRD COUNTRIES – STC NOS. 448, 382 AND 534

COMMUNICATION FROM THE EUROPEAN UNION

The following communication, received on 10 November 2023, is being circulated at the request of the delegation of the European Union in reply to Colombia, Ecuador, Guatemala and Paraguay. This document provides the European Union response to the questions raised in G/SPS/GEN/2140.

According to the minutes of the Standing Committee on Plants, Animals and Food and Feed (PAFF) of 10-11 May 2023, "*[t]he Commission presented Revision 4 of the draft Regulation, which clarifies that the MRLs for tricyclazole should be set in Annex II to Regulation (EC) No 396/2005. [The Commission] proposes modifying the MRL for tricyclazole in rice from 0.01* mg/kg to 0.09 mg/kg, based on an import tolerance request based on a Brazilian GAP, for which EFSA confirmed that the proposed MRL is fully supported by data and safe for consumers*". Despite this, several EU member States did not support the draft Regulation presented by the Commission, and no qualified majority was reached. The following reasons were given by those member States voting against the measure: (i) the non-acceptability of import tolerances for substances no longer approved in the European Union; and (ii) a negative impact on the competitiveness of European rice farmers that are deprived of using the same tools as third countries for effective control of certain pests.

1. In the light of the above, could the European Union please indicate:

   a) Which Annex(es) of Regulation (EC) No 396/2005 did the Commission propose to amend? We note that the *text* of the minutes of the PAFF refers to **Annex II** (EU MRLs), but the *title* of the minutes refers to **Annex III** (Temporary MRLs).

   b) In practical terms, what is the difference between Annex II and Annex III of Regulation (EC) No 396/2005?

   c) How are temporary MRLs established? What is their period of validity?

   d) When an import tolerance is accepted, does this generate a new EU MRL that is set in Annex II to Regulation (EC) No 396/2005?

   e) If an import tolerance is accepted for a given substance and crop, what MRL applies to domestic crops in the European Union?

   f) If an import tolerance is granted and an emergency authorization is granted by a member State:

   – Is the establishment of a temporary MRL necessary — as indicated in item 11 of the emergency authorization notification form — or does the MRL set for the import tolerance apply?

   – If the MRL for import tolerance is applied, is the product authorized to be placed on the market throughout the European Union?

EU reply:

a) The draft Commission Regulation intended amending Annex II of Regulation (EC) 396/2005, as the safety of the MRL was recently confirmed by the European Food Safety Authority (EFSA). The agenda mentioned Annex III erroneously.

b) Annex II mostly contains 'definitive' MRLs following the full review of existing active substances according to Article 12 of Regulation (EC) No 396/2005. Annex IIIA contains 'temporary' MRLs that were to a large extent taken over from the previous MRL Directives in the past, mostly for active substances that are awaiting a decision on the inclusion in the Annex to Commission Implementing Regulation (EU) No 540/2011 and/or the evaluation according to Article 12 of Regulation (EC) No 396/2005.

c) The temporary MRLs that are set in Annex IIIA were established at the moment of the entry into force of Regulation (EC) 396/2005 for active substances that were awaiting a decision on the inclusion in the Annex to Commission Implementing Regulation (EU) No 540/2011 and the evaluation according to Article 12 of Regulation (EC) No 396/2005. No specific period of validity is defined for the temporary MRLs that are set in Annex IIIA.

d) e) and f) When a Regulation setting a new MRL based on an import tolerance is adopted, the MRL established in Regulation (EC) No 396/2005 is modified accordingly and this new MRL applies to domestic and imported products equally. However, if the import tolerance concerns a substance not approved in the European Union whatever the reasons, health or environmental concerns, the use of that substance is nevertheless not authorized in the European Union and EU producers cannot benefit from it.

If an emergency authorization is established by an EU member State, in the vast majority of cases (around 85%) this concerns substances approved in the European Union and the uses are covered by already existing EU MRLs. In exceptional cases, and only if the uses are not covered by the existing MRL (including MRLs based on import tolerances), a temporary national MRL according to Article 18(4) of Regulation (EC) No 396/2005 may be necessary, but this is only very rarely the case. In this case, the concerned member State must make sure that the products are safe for consumers, remain on its national market, and enforcement authorities control that this is the case.

2. If an import tolerance is proposed for an MRL that "*is fully supported by data and safe for consumers*", how would rejecting such an import tolerance because of "*a negative impact on the competitiveness of European producers*" be compatible with the obligations of the SPS Agreement?

EU reply:

In cases when EFSA concludes that an MRL based on an import tolerance is safe, the European Commission, in accordance with the EU legislation and with its obligations under the SPS Agreement, drafts a Regulation to set, or modify the relevant MRLs. However, under EU legislation on the control by member States of the Commission's exercise of powers conferred on it by the Council, the draft Regulation must then be presented for vote to EU member States representatives in a regulatory committee. In case of a favourable opinion by the EU member States, and if subsequently no objection is received from either the European Parliament or the Council of the European Union, the draft regulation shall be adopted by the Commission. In case of a negative opinion by the member States on the draft Regulation, or in case of a "no opinion" (neither an opinion in favour, nor against the draft Regulation with a qualified majority), the Commission shall submit the draft to the Council of the European Union and to the European Parliament for their opinion. If either the Council of the European Union or the European Parliament deliver a negative opinion, the Commission shall not adopt the draft Regulation.

3. With respect to MRLs set with the objective of protecting human health, if member States do not vote in favour of import tolerances, how can the Commission argue that requesting import tolerances is a feasible way forward for MRLs set with environmental outcomes (e.g. neonicotinoid substances)?

EU reply:

If after assessment EFSA confirms that a new MRL does not pose a risk to EU consumers, the Commission has the obligation to draft a Regulation and submit it to the member States in the respective committee.

In addition, the recent Regulation lowering MRLs for clothianidin and thiamethoxam takes into account the risk for pollinators which is an environmental concern of global nature. As indicated in the Recital 20 of the Regulation (EU) No 2023/334 "*applications for import tolerances for clothianidin or thiamethoxam maybe be submitted pursuant to Article 7 of Regulation (EC) No 396/2005 and should provide relevant information to demonstrate that the GAPs applying for the specific uses of the active substances are safe for pollinators. That information, if submitted, would be assessed on a case by case basis within the time period provided for in that Regulation. In the context of the assessment of a request for an import tolerance, if an applicant provides scientific evidence that the use of these neonicotinoids does not adversely impact pollinators, if all requirements are met, an import tolerance could be set by the Commission.*"

Hence, if an import tolerance request related to a specific Good Agricultural Practice is submitted in which it is proven by scientific evidence that such risks to pollinators can be excluded, such an import tolerance can be proposed by the Commission in a draft Regulation, whose adoption will follow the procedure described in the reply to question 2.

4. In response to repeated challenges to the excessive use of emergency authorizations by member States, the European Union indicated, in this and other committees and councils at the WTO, that in light of the ruling of the Court of Justice of the European Union (CJEU) of 19 January 2023 (Case C-162/21), member States may no longer grant emergency authorizations for plant protection products containing banned neonicotinoids. In this regard, we note the following:

a) There are a number of emergency authorizations that were approved *before* the CJEU judgment, but whose application covers a period *subsequent* to that ruling. Will these emergency authorizations remain valid for the entire period for which they were approved, in light of the CJEU judgment?

b) On 4 April 2023, subsequent to the CJEU ruling, the Czech Republic granted an emergency authorization for the banned substance thiamethoxam between 20 April 2023 and 16 July 2023, using as justification and as a mitigation measure that "*the product will only be used on the crop intended for export to countries outside the European Union*".

   i. How can the export of the crop for which thiamethoxam has been used be considered a mitigation measure that protects European pollinators?

   ii. How is the emergency authorization granted by the Czech Republic compatible with the outcome that the European Union claims to pursue with Regulation (EU) No 2023/334, i.e. to protect pollinator populations worldwide?

   iii. Regulation (EU) No 2023/334 refers to the ban of *outdoor* uses of clothianidin and thiamethoxam in the Union and sets MRLs for these substances. At what point and in what way does it take into account the fact that the imported products may have been produced in *greenhouses*?

EU reply:

a) The granting of emergency authorizations is the responsibility of member States and therefore it is primarily the role of member States' judicial systems to ensure the compliance with applicable rules which is a general principle of European Union law.

   The judgment of the Court answers questions about the interpretation of Article 53 of Regulation 1107/2009 by a national court. The Court's judgment clarifies the meaning of that rule as it ought to have been understood and applied from the time of its coming into force. Compliance with it is the responsibility of member States. Nonetheless, the Commission may act if member States grant emergency authorizations that are unjustified or contravene the applicable legislation. Thus, the Commission has in the past requested two member States to stop granting emergency authorizations for the two neonicotinoids and has requested EFSA to analyse if other emergency authorizations were justified. Regarding this instance, in principle, member States' administrative bodies must

apply the Court's interpretation to emergency authorizations granted before the Court ruling. However, whether emergency authorizations already granted may/need to be withdrawn depends, essentially, on national administrative provisions and on the application of the principles of primacy of EU law and legal certainty. The essential element is whether review of a decision is possible, or even mandatory, under national law, which is left to the procedural autonomy of member States. Thus, the Commission has invited the member States concerned to withdraw those emergency authorizations in compliance with their national law as soon as possible.

b) I and II. The Commission agrees that an emergency authorization for the outdoor use of thiamethoxam seems not compatible with Article 53 of Regulation (EU) No 1107/2009 as interpreted by the Court of Justice in the above-mentioned judgement and will follow this up with the Czech Republic.

III. See reply to question 3.

5. We remind the European Union that it has not yet responded to the questions submitted in document G/SPS/GEN/2076, dated 2 November 2022.

EU reply:

The European Union informs that its reply to G/SPS/GEN/2076 was provided through G/SPS/GEN/2139.