WORLD TRADE ORGANIZATION

G/SPS/GEN/2212

20 March 2024

(24-2430) Page: 1/3

Committee on Sanitary and Phytosanitary Measures Original: Spanish

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 COLOMBIA, ECUADOR, GUATEMALA AND PARAGUAY

The following communication, received on 19 March 2024, is being circulated at the request of the delegations of Colombia, Ecuador, Guatemala and Paraguay in response to document G/SPS/GEN/2171 from the European Union.

Reply of the European Union:

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.

1. According to the European Union's reply, "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". Could the European Union clarify why an emergency authorization would be necessary for substances already approved for use and for which there is already an MRL?

Reply of the European Union:

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.

2. We understand that, even if the EFSA concludes that an MRL based on an import tolerance is completely safe, that import tolerance may be rejected for reasons unrelated to food security. Is this correct? What are the reasons why the use of a harmless product would be rejected?

3. Could the European Union clarify how the failure to approve a regulation to establish or modify the relevant MRLs to include an import tolerance, that is supported by scientific data and is safe for consumers, is consistent with Article 2.2 of the SPS Agreement?

4. We are aware of an import tolerance request submitted by Brazil concerning the substance tricyclazole in rice, for which the EFSA found that "the proposed MRL is fully supported by data and safe for consumers". However, this was not endorsed by the SCoPAFF, nor by the Council or by the Parliament. Could the European Union confirm in how many other cases scientific information was not acknowledged and import tolerances with sufficient scientific evidence were rejected, in violation of the SPS Agreement?

5. Further to document G/SPS/GEN/2038, could the European Union update the number of emergency authorizations and import tolerances requested and rejected, as well as the average time for processing such applications?

Reply of the European Union:

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.

6. Could the European Union indicate whether any import tolerance request has been made for MRLs set with environmental objectives?

7. If an import tolerance request is submitted "related to a specific Good Agricultural Practice ... in which it is proven by scientific evidence that [the] risks to pollinators can be excluded", can the import tolerance, by the same token, be rejected for reasons not related to the safety of pollinators? How would this be consistent with Article 2.2 of the TBT Agreement?

Reply of the European Union:

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.

8. Given that, according to the European Union, the granting of emergency authorizations is the responsibility of member States, could the European Union member States provide detailed information on the number of emergency authorizations granted and subsequently renewed, as well as information on the procedure, cost and average processing time for these authorizations?

9. The European Commission has indicated that it "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 ... and will follow this up with the Czech Republic". Could the European Union report on the follow-up with the Czech Republic and how it intends to address similar cases in the future?

10. In document G/SPS/GEN/2139, the European Union stated that the European Commission had mandated the EFSA to develop fit-for-purpose protocols for evaluating emergency authorizations starting with a protocol for insecticides and acaricides by May 2025. If these protocols are not currently in place for evaluating emergency authorizations, could the European Union clarify which parameters form the basis for member States' opinions? In addition, could the European Union indicate whether the criteria to be established in these protocols will also apply to the evaluation of import tolerances?

11. On 18 November 2021, the EFSA published a news item on its web page, entitled "Neonicotinoids: EFSA assess emergency uses on sugar beet in 2020/21". It says in that article that "[t]he authorisations were evaluated using a protocol published by EFSA in 2017 to evaluate requests for use of an insecticide on the grounds that it is necessary to control a serious danger to plant health", and that "[t]he protocol requires all available insecticide and non-insecticide control methods to be included in the assessment". According to this EFSA article, a protocol for insecticides already exists, which was used for the sugar beet evaluation in 2021. Is this correct? Could the European Union indicate whether this protocol has been applied to import tolerance evaluations? Could the European Union also clarify its reply, given in document G/SPS/GEN/2139, in which it refers to the development of fit-for-purpose protocols, starting with a protocol for insecticides and acaricides by May 2025?