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Committee on Sanitary and Phytosanitary Measures Original: English

RESPONSE OF THE EUROPEAN UNION TO G/SPS/GEN/1926 ON EU MRLS FOR CERTAIN PLANT PROTECTION PRODUCTS (CONCERN N° 448)

SUBMISSION BY THE EUROPEAN UNION

The following document, received on 3 November 2021, is being circulated at the request of the Delegation of the European Union.

This document provides the European Union response to the questions raised in G/SPS/GEN/1926 regarding STC 448.

1. **The European Union indicated, in document G/SPS/GEN/1896, that MRLs are set at the lowest level possible to achieve the desired effect, in line with the As Low As Reasonably Achievable (ALARA) principle. The ALARA principle is applied primarily in the field of radiation and not to phytosanitary measures. Would the European Union provide:**
   a) **The basis for the translocation of this principle to non-radioactive substances;**
   b) **The scientific justification for this translocation;**
   c) **The provision of the SPS Agreement covering the ALARA principle; and**
   d) **An explanation of the meaning of "the desired effect" that is sought when determining MRLs at the lowest level possible.**

The ALARA (As Low As Reasonably Achievable) principle is widely recognized and applied in the field of food safety worldwide. In the European Union, in accordance with Regulation 315/93 on food contaminants, contaminant levels must be kept as low as can reasonably be achieved following good practices at all stages. The same principle is laid down in Recital 5 of Regulation 396/2005 on maximum residue levels for pesticides residues. The European Union has the right to take sanitary and phytosanitary measures necessary to ensure the high level of the protection of human, animal or plant life or health.

According to the ALARA principle, maximum residue levels 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. They should never be higher than toxicologically acceptable. Comprehensive field studies, therefore, determine what amount and what application frequency are needed to achieve the intended effect. A maximum residue which occurs under these circumstances is only accepted as a maximum residue level for an agricultural product if it is guaranteed that the concentration does not have any harmful effects on human health according to the latest scientific findings available.

2. **The European Union indicated that it accepts good agricultural practices (GAP) authorized in third countries even though they are different from those established in the European Union, and that third countries may submit a request to review import tolerances in cases where there is evidence supporting the request. According to which principles is the review of the GAP used by third countries incorporated in the process to define import tolerances? What elements of the GAP of third countries are taken into consideration?**

   – A third country can submit an application for an import tolerance with the required supporting evidence, including the GAP used by that third country.

- The data requirements to set import tolerances are the same as for setting MRLs supporting uses in the European Union. Import tolerance requests are assessed against the same strict criteria as applications for MRLs based on uses in the European Union.
- It is the duty of the applicant to prove the safety, and if such evidence cannot be provided or if EFSA finds that that there are open points and uncertainties, an application for a new MRL is not granted or the already existing MRLs are lowered to the limit of quantification (technical zero).
- The data are evaluated first by a member State of the European Union (the "Rapporteur member State") and then by the European Food Safety Authority (EFSA). If the outcome of this evaluation is favourable, an import tolerance can be established.
- For any further information, interested parties may consult the section of the European Commission website specifically dedicated to pesticides: https://ec.europa.eu/food/plants/pesticides_en.

EU legislation and EFSA guidance documents detail how to compile dossiers for submission and the information and studies required for the evaluation. EFSA's guidance is updated regularly so applicants should check at https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance that they are using the latest version before applying.

3. Further to reply 2(a), provided in document G/SPS/GEN/1896, the European Union indicates the situations that, in its opinion, are covered by the precautionary principle referred to in Article 5.7 of the SPS Agreement. Could the European Union provide further details on the difference between its explanation on the measures covered by Article 5.7 and on the action that it is actually undertaking with regard to MRLs?

The European Union would like to kindly refer the Delegations to previous replies where these issues have been explained in detail.

4. Further to reply 2(b) provided in document G/SPS/GEN/1896:
   a) Could the European Union indicate what is meant by "scientific uncertainty"? Is there scientific uncertainty when scientific evidence is insufficient?
   b) Could the European Union indicate what is considered a "reasonable period of time", taking into account the difference between the different approvals and their duration?
   c) Does the existence of scientific uncertainty and the review of measures within a reasonable period of time imply the application of Article 5.7 of the SPS Agreement? What is the opinion of the European Union in this regard?

Regarding the interpretation of Article 5.7 and of other Articles of the SPS Agreement, the European Union would like to kindly refer to relevant Dispute Settlement Body's rulings.

5. We welcome the explanation provided by the European Union for its submission of reservations concerning the MRLs adopted by Codex Alimentarius (CXLs). However, the question posed to the European Union sought clarification as to whether the submission of reservations exempts it, in its opinion, from the harmonization commitments undertaken under Article 3 of the SPS Agreement. We reiterate this question.

As already explained in document G/SPS/GEN/1896, the purpose of raising reservations is to increase transparency and predictability in international trade, and not to exempt the European Union from its obligations under international law.

6. We thank the European Union for the submission of statistics with regard to its level of harmonization with the Codex since 2012. However, the information requested was specifically for the period from 2017 onwards. We would be pleased if the European Union could provide information for the period of time requested.

Existing information on the harmonization figures from 2017 onwards is summarised below:

Year	Total number of CXLs for food adopted by CAC	EU MRLs set at lower values than CXLs	EU MRLs set at the same or higher values[1] than CXLs
2017	417	47%	53%
2018	305	21%	79%
2019	275	32%	68%

7. Furthermore, we appreciate the fact that the level of harmonization of the European Union's MRLs with the CXLs is 70%. We observe, however, that the issue of concern is precisely the remaining 30% of cases, in which the European Union deviates from the CXLs. In these cases, is there a conclusive risk assessment to support each of the MRLs that are not harmonized with the Codex?

Yes, the European Union positions are based on the scientific reports prepared by EFSA. These reports are available at https://www.efsa.europa.eu/en/publications. For each JMPR evaluation, EFSA derived comments on the acceptability of the proposed draft Codex MRLs and the toxicological reference values.

8. We welcome the confirmation that compliance with MRLs must be ensured in order for member States of the European Union to trade with one another. In light of this:

a) Must the MRLs established by the European Union be met by the member State granting an emergency authorization for a specific substance, with regard to imports from other member States of the European Union or third countries?

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 EU level.

See the guidance which provides more details on the considerations for considering emergency use of plant protection products, including product containing substances that are no longer approved in the European Union: https://ec.europa.eu/food/system/files/2021-03/pesticides_aas_guidance_wd_emergency_authorizations_article53_post-210301.pdf.

It should be recalled that around 90% of emergency authorizations are for plant protection products containing active substances that are approved in the European Union.

b) On what criteria is the European Union's analysis based to determine the absence of unacceptable risks for the consumer?

The criteria are established by Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorization of plant protection products.

c) How many countries in the European Union are marketing within their territories products that do not comply with the MRLs established by the European Union?

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 MRLs.

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 EU member States where the authorization was granted.

In February 2020, the 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.

d) Have the member States of the European Union submitted scientific justification to apply MRLs that are higher than those stipulated in European Union standards, which demonstrates that the MRLS do not pose a risk to consumers?

Member States have to apply harmonized MRLs through European Union. If a different MRL application is needed, it should be requested under Article 6 of Regulation 396/2005. The data are evaluated first by a member State of the European Union (the "Rapporteur member State") and then by the European Food Safety Authority (EFSA). If the outcome of this evaluation is favourable, an import tolerance can be established.

e) Could the European Union share the evidence submitted by members of the European Union to justify the application of MRLs that are higher than those stipulated in European Union standards?

Please see answer to question d).

f) How does the European Union conduct controls to ensure that products with higher MRLs produced in member States with emergency authorizations are not marketed in other member States?

Enforcement authorities control products on the market for their compliance with harmonized MRLs. The Rapid Alert System for Food and Feed (RASFF) disseminates information about health risks between the members of the network (Commission, member States, Norway, Liechtenstein, Iceland, Switzerland).

g) In view of the absence of border controls and inspections within the European Union, could the European Union indicate the mechanism used to ensure compliance with the MRLs in intra-Community trade?

All member States have monitoring programmes to ensure that controls are carried out to ensure their compliance with the Regulation. Around 90000 samples are taken in the European Union annually. More information on the results of those inspection programs is available on the dedicated European Union report on pesticide residues in food (e.g. link to the 2019 report: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6491).

9. As regards trade with third countries:

a) What mechanisms exist for the control of the MRLs of substances authorized only for emergencies in the case of exports outside the European Union?

No exports are allowed in the event that food/feed does not comply with the applicable EU MRL due to an emergency authorization granted by a member State. In this situation, the treated food or feed must remain in the territory of the EU member State where the authorization was granted and this must be controlled by that member State.

b) Are there products for export with MRLs that are higher than those authorized for the European Union or specific cases in which they have been exported outside the European Union? Are these products regulated by other standards? Do the MRLs for these products exceed those established by international standards such as Codex?

Please see Article 12(1) of Regulation 178/2002.

c) When a member States grants an emergency authorization for a substance, does the European Union allow the importation of products complying with the same MRLs for that substance which are imposed for domestic products?

No, the only applicable MRLs are the ones set by Regulation 396/2005.

10. Could the European Union explain why there are emergency authorizations for States that are not members of the European Union in its database? Could the European Union also explain how this mirror mechanism works in the case of emergency requests from producers in non-EU countries? Do the same conditions as those for European producers requesting emergency authorizations apply to producers in non-EU countries?

The database only contains information on authorizations issued by the 27 EU member States plus historical authorizations granted by the United Kingdom when it was a member State of the European Union. Only EU member States can produce authorization notifications in the system that populates the database (the Plant Protection Products Application Management System).

Emergency authorizations granted under Article 53 of Regulation 107/2009 concern the placing on the market and the use of plant protection products in the European Union only. Farmers/agricultural producers outside the European Union cannot apply for emergency authorization since they are not part of the European Union. Responsibility for granting authorizations lies with individual member States. Emergency authorizations have to be granted only where necessary because of a danger which cannot be contained by any other reasonable means.

Reference to 'same conditions' for producers outside the European Union is not relevant. Emergency authorizations are for use of products in the European Union only.

More information about emergency use under Article 53 can be found in the following guidance: https://ec.europa.eu/food/system/files/2021-03/pesticides_aas_guidance_wd_emergency_authorizations_article53_post-210301.pdf.

11. How does the European Union reconcile the high level of protection for its consumers with the high number of emergency authorizations issued by its member States? Once the time-limit for an emergency authorization has expired, is there another time-frame in which a new emergency authorization for the same substance may be requested?

There is no time-limit when a request for an emergency authorization of a plant protection product can be made (including if an emergency authorization was previously issued). However, each request must be carefully considered by the applicable member State.

Member States must always ensure protection of consumers when authorizing the use of plant protection products, including from emergency use. Article 53 of Regulation 1107/2009 requires that member States provide information on measures taken to ensure consumer safety.

Crops treated with PPPs for which an emergency use is granted must comply with the applicable EU MRLs. Exceptionally, if a temporary MRL is required for the particular use, treated produce should be restricted to the territory of the member State granting the authorization until such level is set at EU level.

It should be recalled that the vast majority of emergency authorizations are for products containing approved active substances and therefore MRLs are usually already in place.

More information on emergency use under Article 53, including on consumer safety aspects, can be found in the guidance document referred to in reply to question 10.

12. In light of reply 4(a) in document G/SPS/GEN/1896, would the European Union confirm that Article 5.3 of the SPS Agreement applies to MRLs?

Please see the reply provided to questions 4(b) and (c) in document G/SPS/GEN/1896.

13. The European Union indicated, in reply 4(d) provided in document G/SPS/GEN/1896, that there are no objectives for third countries in the Farm to the Fork Strategy. However, this Strategy includes an external dimension as part of the fourth section entitled "Promoting the global transition". The section indicates that the European Union will achieve this objective "through its external policies, including international cooperation and trade policy". European authorities have also indicated that their trade partners must comply with the same standards to level the playing field with European competitors. In this context, could the European Union confirm that it will not require its trade partners to meet the same reduction targets as those required of its producers?

As already explained, also during the information sessions on the Farm to Fork Strategy to which the WTO Members' Delegations were invited, the specific targets concerning the reduction of the overall use and risk of chemical pesticides and of more hazardous pesticides, of nutrient losses, of

sales of antimicrobials for farmed animals or the target concerning the percentage of land under organic farming do not apply to third countries.

14. Would the European Union explain why the assessment of the impact of the Farm to Fork Strategy will be conducted after the implementation of the Strategy?

The targets set out in the Farm to Fork Strategy are aspirational targets, based on ambitious but realistic pathways. The Commission has used available evidence and data to set them, which also includes the 2018 impact assessment for reform of the EU Common Agricultural Policy. Any legislative initiative that will result from the Farm to Fork Strategy will be based on public consultations and on the identification of the environmental, social and economic impacts. Impact assessments will contribute to making efficient and realistic policy choices, based on sound science.

15. In reply 5(b) provided in document G/SPS/GEN/1896, the European Union recognized that "other legitimate factors" fell outside of the scope of the SPS Agreement, even though they apply to food products. Could the European Union indicate the provision of the multilateral trade rules under which these "other legitimate factors" would fall?

Depending on the content of such measures, other WTO Agreements may apply.

16. If the possible consideration of "other legitimate factors" could result in MRLs that are lower than those determined on strictly sanitary and phytosanitary grounds, how would these MRLs be compatible with those stipulated in the SPS Agreement?

Please see the EU reply to question 5(b) in document G/SPS/GEN/1896.

17. If the majority of emergency authorizations are granted for substances the use of which is permitted in the European Union, as stated in document G/SPS/GEN/1894, what is the reason behind the need for these emergency authorizations and their frequent use?

The vast majority of emergency authorizations are for products containing approved active substances.

The key reasons for the use of emergency authorizations are:

- to overcome procedural delays to authorize PPPs and mutually recognize authorizations;
- insufficient availability of PPPs for minor uses - member States are not fully using the existing provisions to facilitate authorization for such uses.

Various activities are ongoing to improve the authorization system, which in turn will lead to less need for emergency authorizations.

18. Could the European Union indicate which MRLs, among those revised since 2017, have been lowered to the limit of detection (LOD)? Could the European Union clarify whether the LOD is a variable or fixed number? Would the European Union indicate which criterion was used to establish the LOD at 0.01 mg/kg in its two regulations?

The MRLs set at LOD are indicated with an asterisk (*) in Regulation 396/2005, as well as in the Pesticides Database. The LOD is not a fixed value, as it depends on substance and matrix for which it is established. While for certain complex food matrices or for substances with more than one element in their residue definitions, LODs can be higher than the default value of 0.01 mg/kg, there are also cases where it can be lower than 0.01 mg/kg, e.g. in the case of highly toxic substances. The EU reference laboratories for pesticides residues provide the scientific support when proposing specific LODs.

Only where no specific LODs have been established, the general default value of 0.01 mg/kg applies.

19. We reiterate our question on the costs at the European level that would result from the withdrawal of plant protection products that have not been renewed to date.

As the economic cost is not part of the considerations of the EU pesticides legislation, which has the main objective of protection of human health and the environment, information on costs is not considered when decisions on non-renewal of active substances used in plant protections products are made.

20. Further to reply 9(b) provided in document G/SPS/GEN/1896, could the European Union indicate which criteria are used to identify sources of data and information?

The EU regulatory criteria set out in Regulation 2018/605 are based on the WHO definition, which is the following:
'An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations.'

The European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) have prepared a joint technical guidance document for the implementation of the criteria that was published in 2018.

21. Further to reply 9(e) provided in document G/SPS/GEN/1896:
- **a) Could the European Union establish an MRL of 0.01 mg/kg in view of "global concerns", despite the existence of a higher CXL?**
- **b) Could the European Union provide an exhaustive list of what constitutes its "global concerns"?**
- **c) Could the European Union share the source of its definition of "global concern", and a definition of the term "transboundary"?**

Please see the replies to question 10 in document G/SPS/GEN/1896.