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RESPONSE OF THE EUROPEAN UNION TO G/SPS/GEN/2002 ON EU MRLS FOR CERTAIN PLANT PROTECTION PRODUCTS – STC NO. 448

SUBMISSION BY THE EUROPEAN UNION

The following document, received on 18 June 2022, 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/2002 regarding STC 448.

MODIFICATION OF EUROPEAN UNION MRLS FOR PLANT PROTECTION PRODUCTS

The delegations of Colombia, Ecuador, Guatemala and Paraguay would like to ask the European Union the following questions further to the replies received from the European Union in document G/SPS/GEN/1970, and in light of the provisions of Article 5.8 of the SPS Agreement:

The European Union would like to thank the delegations of Colombia, Ecuador, Guatemala and Paraguay for the questions. Since several questions are related to specific aspects of emergency authorizations, the European Union would like to provide some general additional clarifications regarding emergency authorizations complementing document G/SPS/GEN/1970. More information is also available in guidance document SANCO/10087/2013 rev. 1.[1]

Article 53 of Regulation (EC) No 1107/2009 allows the member States of the European Union to authorize the placing on the market of plant protection products, in special circumstances and derogating from the regular authorization process, **for a period not exceeding 120 days and for limited and controlled use**, where such a measure is necessary because of a danger which cannot be contained by any other reasonable means.

Emergency authorizations are granted by EU member States, who should duly notify the other member States and the European Commission through a dedicated IT system, the Plant Protection Products Application Management System (PPPAMS).[2]

For the vast majority of emergency authorizations granted by EU member States, the authorized use is covered by already existing EU maximum residue levels (MRLs). Approximately 90% of emergency authorizations are for plant protection products (PPPs) containing active substances approved in the European Union and many of the specific uses are already authorized in another EU member State, hence EU MRLs already apply. Only in cases where an emergency authorization is granted for a use that would result in residues above the established EU MRL, a national temporary MRL may be needed.

In such cases, consumer safety must be ensured and specific control measures must be put in place. A member State that authorizes the placing on the market of treated food or feed not complying with EU MRLs established by Regulation (EC) No 396/2005, may only do so in **exceptional circumstances and only within its territory** (Article 18(4) of Regulation (EC) No 396/2005).

[1] https://ec.europa.eu/food/system/files/2021-03/pesticides_aas_guidance_wd_emergency_authorisations_article53_post-210301.pdf.

[2] https://ec.europa.eu/food/plants/pesticides/authorisation-plant-protection-products/pppams_en.

This means such food/feed may not be traded, neither to other EU member States, nor to third countries.

Detailed information is required from a member State that takes such exceptional measures on the levels it sets and the control measures put in place. In very rare cases, at a later stage an EU wide temporary MRL may be established if an emergency situation occurs in several member States, the situation cannot be contained by the member State alone, and provided that sufficient data were submitted in the application leading to a favourable risk assessment of the European Food Safety Authority. As the name "temporary MRL" indicates, such measures are limited in time.

It is possible to grant an emergency authorization for a PPP already authorized in the pertinent member State (where the particular danger to plant health exists) but where the authorization does not cover the particular crop/pest combination in question. Usually notifications of this type relate to uses in **minor crops** but it is also possible that new and emerging phytosanitary risks and other phytosanitary issues in major crops need immediate action. Such emergency authorizations are eventually **replaced** by a regular extension of an existing authorization or a new authorization.

1. With regard to the procedures for emergency authorizations (Article 53 of Regulation 1107/2009) and import tolerances (Article 6 of Regulation 396/2005):

a) How long does it take on average to approve an emergency authorization and to approve an import tolerance?

- The evaluation of an import tolerance takes around 24 months.
- Regarding emergency authorizations, as already indicated, they are granted by EU member States and the time for the evaluation process is determined by them.

b) What is the average cost of the emergency authorization approval process and the average cost of the import tolerance approval process?

- For the evaluation of use of an active substance, including import tolerance applications, member States may recover the costs associated with any work they carry out, by means of fees or charges. Fees or charges for evaluations are set by member States and they may vary.
- Regarding emergency authorizations, they are granted by EU member States. Fees to cover these evaluations are set by member States as well and they may vary.

2. With regard to emergency authorizations:

a) Could the European Union please explain why section 11 (concerning temporary MRLs) of an emergency authorization is, in general, left blank? In such cases, what is the applicable MRL?

If section 11 does not include information on a temporary MRL, no t-MRL applies and EU MRL applies. Please see the additional clarifications provided at the beginning of this document.

b) If a temporary MRL is granted, does this mean the product can be marketed in other European Union member States?

Please see point 9a of G/SPS/GEN/1970 and the additional clarifications provided at the beginning of this document.

c) Can third States, which are not members of the European Union, benefit from authorized temporary MRLs?

No, since national temporary MRLs are granted by individual EU member States. Other EU member States which have not granted a national temporary MRL cannot benefit either. Treated food products that do not comply with the applicable EU MRL cannot be imported into the European Union and cannot circulate in the EU internal market either.

d) What MRL is applicable in emergency authorizations for minor crops? How is this MRL determined?

> Please see the additional clarifications provided at the beginning of this document. Regarding your question on the setting of MRLs for minor crops, please see the technical guidelines on data requirements for setting MRLs, comparability of residue trails and extrapolation of residue data on products from plant and animal origin (https://ec.europa.eu/food/system/files/2020-11/pesticides_mrl_guidelines_app-d.pdf).

e) Could the European Union provide some figures regarding the number of emergency authorizations that have been refused?

> Granting (or refusing) emergency authorizations is the responsibility of the EU member States. The available figures on refusals are limited to the start of the IT tool (PPPAMS) in 2016 as follows:
> - Applications rejected: 336 (figures are for all member States including United Kingdom for 2016-2018);
> - Applications withdrawn: 153;
> - Applications completed – authorization cannot be granted: 243.
>
> It should also be noted that – in some cases – member States may have refused an emergency authorization before an application was even added to the respective IT tool PPPAMS (e.g. in the event of pre-discussions where the member State authorities made it clear that emergency authorization would not be possible/granted). In addition, some member States only ask applicants to include information in PPPAMS once a decision to authorize has been made, hence the true number of refusals is likely to be significantly higher.

3. How are import tolerances assessed for minor crops?

> The requirements for setting MRLs as well as the facilities in place for minor crops are the same for European Union and imported products. The European Union acknowledges the insufficient availability of PPPs for minor uses for a number of different reasons. In order to address this, several actions have been proposed, including a commitment from the European Commission to regularly update the Extrapolation Guidelines to facilitate MRL setting for minor crops (https://ec.europa.eu/food/system/files/2020-11/pesticides_mrl_guidelines_app-d.pdf).
>
> These actions are also applicable for import tolerances, as the setting of pesticide residues follows the same procedure regardless of whether the data come from an European Union or a third-country applicant. As an example, some flexibility is allowed in the number of residue trials required and the extrapolation possibilities are maximized.

4. The requirements to be met by an import tolerance applicant are stricter than those to be met by an applicant for an emergency authorization for a new combination of substance and basic product. Is this correct? What is the basis for this distinction?

> As the European Union already explained, it is not possible to compare the requirements for import tolerances and emergency authorizations because these are two completely different procedures (please also see general comments at the beginning of this document). There are different actors involved, the scope is different and there is a limitation in time (120 day) in the case of emergency authorizations. Imported products can circulate in the EU market, while for temporary MRLs granted by EU member States the treated food cannot leave the national territory of that member State.

5. In its reply to question No. 4 in document G/SPS/GEN/1970, the European Union refers to relevant Dispute Settlement Body (DSB) rulings. Which DSB rulings does the European Union consider relevant?

> The European Union would like to kindly refer the Delegations to the WTO website which provides a list of 52 requests for consultations where the SPS Agreement has been cited, with a breakdown by article.

6. It is our understanding that, according to the European Union, its MRL regime does not fall within the scope of Article 5.7 of the SPS Agreement, despite the existence of scientific uncertainty. Is this correct?

> Could the Delegations indicate which EU MRLs they wish to refer to? The European Union would also like to kindly refer the Delegations to its previous replies where Article 5.7 of the SPS Agreement has been discussed.

7. In its reply to question No. 6 in document G/SPS/GEN/1970, the European Union shares a summary table of figures regarding harmonization with the Codex since 2017. We would be grateful if the European Union could provide data disaggregated by:

a) type of plant protection product (e.g. insecticide, fungicide, etc.);
b) active substances in cases where they are not aligned with CXLs;
c) active substances that have benefited from (i) emergency authorizations and (ii) import tolerances.

> The European Union does not have disaggregated the information on CXLs as requested. However, the information is publicly available under the following link: https://ec.europa.eu/food/horizontal-topics/international-affairs/international-standards/codex-alimentarius/ccpr_en.

8. In its reply to question No. 8(a) in document G/SPS/GEN/1970, the European Union notes that around 90% of emergency authorizations are for plant protection products containing active substances that are approved in the European Union. With regard to the remaining 10% of cases:

a) Are stricter requirements applied to the applicant when they request an emergency authorization for an active substance that is no longer approved in the European Union?

> No.

b) What type of scientific evidence is required from the applicant in these cases?

> Please see the additional clarifications provided at the beginning of this document.

c) What MRL is imposed?

> Please see the additional clarifications provided at the beginning of this document.

9. In its reply to question No. 9(a) in document G/SPS/GEN/1970, the European Union states that no exports outside the Union are allowed in the event that food/feed does not comply with the European Union MRL due to an emergency authorization. What mechanisms do member States introduce to ensure that such products are not exported? Could the European Union provide specific examples of these control mechanisms?

> Emergency authorization applications submitted in the Plant Protection Products Application Management System (PPPAMS) must include information on the **measures taken in order to confine the commodities resulting from the treated crop to the territory of the member State** in which the application is submitted pending the possible setting of a temporary MRL at EU level. (PRIMo EFSA calculations to be included). Please also see the additional clarifications provided at the beginning of this document.

10. Further to the European Union's reply to question No. 10 in document G/SPS/GEN/1970, according to which emergency authorizations are limited to European Union member States, what is the explanation for the 27 emergency authorizations granted by Norway?

> According to the European Economic Area Agreement, Norway has to apply EU legislation on pesticides, as laid down in Annex II to the Agreement, with the same obligations and rights as European Union member States.

11. Further to the European Union's reply to question No. 15 in document G/SPS/GEN/1970, which other WTO Agreements, and Articles thereof, would be applicable to MRLs that are set taking into account "other legitimate factors"?

> The General Agreement on Tariffs and Trade (GATT) applies to international trade in goods, unless it is superseded by a more specific agreement, depending on the objective of the measure at stake.

12. Regarding substances considered to be of global concern and for which it has been announced that import tolerances will no longer be granted, could the European Union confirm whether emergency authorizations will no longer be granted either?

> No, please see the additional clarifications provided at the beginning of this document. The European Union would like to reiterate that granting emergency authorization is a member States responsibility and – in any case – any emergency authorization granted must be fully justified. The justifications are followed up closely, and if necessary, the European Food Safety Authority might evaluate the need of granting a specific emergency authorization. Evaluations and guidelines to provide justifications are publicly available.