WORLD TRADE ORGANIZATION

G/SPS/GEN/2076

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Committee on Sanitary and Phytosanitary Measures Original: Spanish

QUESTIONS FOR THE EUROPEAN UNION CONCERNING DOCUMENT G/SPS/GEN/2002 ON EUROPEAN UNION MAXIMUM RESIDUE LEVELS (MRLS) FOR CERTAIN PLANT PROTECTION PRODUCTS – STC NO. 448

COMMUNICATION FROM COLOMBIA, ECUADOR, GUATEMALA AND PARAGUAY

The following communication, received on 1 November 2022, is being circulated at the request of the delegations of Colombia, Ecuador, Guatemala and Paraguay.

FOLLOW-UP TO: G/SPS/GEN/2038

1. Could each European Union member State please indicate:

   (a) How many emergency authorization applications it receives, on average, each year?

   (b) How many of these applications are approved?

   (c) How many are sent for mutual recognition to other European Union member States? Please indicate all the approved applications that have been sent for mutual recognition and to which member States.

   (d) How many emergency authorizations have been approved each year?

2. Could each European Union member State please indicate how long, on average, it takes to approve an emergency authorization in its territory?

3. Could each European Union member State please indicate the disaggregated and total cost of active substance evaluations, including import tolerances, and emergency authorizations?

4. Could the European Union please provide a list of the active substances (in combination with the relevant product) for which it requires an MRL that is not harmonized with the Codex? With regard to these substances, could the European Union please indicate how many emergency authorizations and import tolerances have been granted?

5. How many import tolerance applications have been submitted? How many have been rejected?

6. Regarding the reply to question 9 in document G/SPS/GEN/2038:

   (a) Could the European Union please explain what information is required from member States concerning the steps taken to confine to their territory products that have been treated with substances not authorized in the European Union and that have benefited from emergency authorizations?

   (b) Could each European Union member State please explain what sort of information it provides to meet this requirement?

7. Could the European Union please indicate which specific GATT articles are applicable for the establishment of MRLs under other specific factors?

8. We have searched through the EFSA publications on emergency authorization evaluations on the websites indicated by the European Union in document G/SPS/GEN/2038 and have only found 18 dossiers (eight for 2018 and 10 for 2021) on emergency approvals for neonicotinoids. Could the European Union please indicate:

(a) Whether these dossiers constitute all the emergency authorization evaluations conducted by EFSA?
If not, please provide copies of any other evaluations related to the products covered by this STC.

(b) In what circumstances might EFSA evaluate the need to grant or maintain an emergency authorization?

(c) How many times can a member State renew an emergency authorization? Is there a limit on the number of renewals?

(d) How does the European Union [the Commission?] use the technical information in the dossier provided by member States when granting an emergency authorization?

(e) Why does the evidence submitted by members States in their dossiers not provide sufficient justification for EFSA to re-evaluate MRLs?

(f) At what point does the EFSA evaluation take place? When an emergency authorization is being requested from a member State, or once a member State has already approved the emergency authorization?

(g) Could the European Union please explain why an emergency authorization is justified even in cases where highly effective alternatives (chemical or non-chemical) exist?
We refer to EFSA's evaluations, conducted in 2021, of the emergency authorizations granted by Belgium, Croatia, Denmark, Germany, Slovakia and Spain for the use of the active substances thiamethoxam, clothianidin and imidacloprid in sugar beet crops.

(h) Why are emergency authorizations for using certain active substances justified when EFSA notes that for certain crop/pest combinations their use is not/may not be necessary when the good agricultural practice of crop rotation is used?
We refer, by way of example, to EFSA's 2021 evaluations of the emergency authorizations for thiamethoxam, clothianidin and imidacloprid granted by Belgium (for the combination sugar beet/*Agriotes lineatus* and *Tipula sp.*); by Denmark (for the combination sugar, fodder and energy beet/*Atomaria linearis*,*Pegomya hyoscyami*, *Thrips angusticeps*); and by Slovakia (for the combination sugar beet/*Aphids*, *Atomaria linearis* and *Chaetocnema tibialis*).

(i) What consequences are there for a member State if EFSA considers the emergency authorization to be unjustified?
We note that, in Romania's case, the emergency authorization for the active substances thiamethoxam, clothianidin and imidacloprid, for the combination maize/*Tanymecus dilaticollis,* was considered unjustified by EFSA in 2018, and yet a new authorization was granted by Romania in January 2022.

(j) In cases where member States fail to provide EFSA with the information needed to determine whether the emergency authorization is justified, are there any consequences such as, for instance, greater scrutiny or a control system for the emergency authorizations granted by those member States following the EFSA evaluation?
For example, we note that in relation to the active substances thiamethoxam, clothianidin and imidacloprid, the required information was not submitted by Croatia in 2021 for sugar beet/*Alphididae*; by Bulgaria in 2018 for maize and sunflower/*Tanymecus dilaticollis* and *Agriotes* spp.; or by Hungary in 2018 for maize/*Tanymecus dilaticollis*, *Agriotes* spp. and *Melonthina melonthina* and sunflower/*Agriotes* spp.

9. We refer to notifications G/SPS/N/EU/394 – *Maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine*; G/SPS/N/EU/319 – *Maximum residue levels for imazalil*; and G/SPS/N/EU/264 – *Maximum residue levels for buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim*.

We note the following text in the "Description of content" section of the notification: "Lower MRLs are set after updating the limits of determination and/or deleting old uses which are not authorised any more in the European Union or for which a human health concern **may** not be excluded."

10. According to the replies previously received from the European Union regarding this STC, the European Union claims that its MRL measures do not fall within the scope of Article 5.7 of the SPS Agreement, despite the absence of categorical scientific evidence concerning health risks ("a human health concern may not be excluded"). Is this correct?