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Committee on Sanitary and Phytosanitary Measures

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RESPONSE OF THE EUROPEAN UNION TO G/SPS/GEN/1847 ON EU MRLS FOR CERTAIN PLANT PROTECTION PRODUCTS

SUBMISSION BY THE EUROPEAN UNION

The following document, received on 2 December 2020, is being circulated at the request of the Delegation of the European Union.

This document provides the EU response to the questions raised in G/SPS/GEN/1847 regarding STC 448.

1. As already explained previously, MRLs 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.

EU legislation acknowledges the dual role of MRLs in consumer protection and trade facilitation. It provides for the possibility to set MRLs for imported products to meet the needs of international trade and requires the consideration of good agricultural practices authorised in third countries as well as of MRLs set by the Codex Alimentarius Commission.

In accordance with the EU legislation applicable to MRLs, 'good agricultural practice' (GAP) is the nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed. It also implies the application of the principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained. 'Critical GAP' means the GAP, where there is more than one GAP for an active substance/product combination, which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for establishing the MRL.

Information on the toxicity and metabolism of an active substance as well as on the residue levels present in crops following application of plant protection products in accordance with GAP are taken into account, not to determine the level of protection, but to ensure that a given GAP, and in extension the setting of an MRL based on that GAP, is acceptable without compromising the pre-determined level of protection.

2. The European Union is the only Codex member openly raising reservations and communicating to Codex every time when not in a position to adopt a new Codex MRL. The European Union also provides scientific reasons for the reservations and consequent non-alignment. To increase transparency and predictability in international trade, the European Union strongly encourages other Members to do likewise.

In order to set a maximum residue level (MRL) a risk assessment from the European Food Safety Authority (EFSA) must demonstrate that the MRL is safe for consumers. This requires that a minimum of supporting data is provided in line with the EU data requirements allowing EFSA to reach a conclusion on the safety of the MRL. If such supporting evidence is lacking or insufficient, EFSA cannot conclude that the MRL is safe.

3. The European Union ensures the absence of any discrimination by applying the same MRL for a given substance-commodity combination to all relevant food products on the market in the European Union, regardless of their origin, i.e. whether they were produced domestically or imported from third countries.

4. The EU prior response needs to be properly contextualised. The point we are making is that Article 5.3 of the SPS Agreement applies to the assessment of risk to animal or plant life or health and to determining the measure to be applied for achieving the appropriate level of protection from such risks. Consequently, measures established to protect human health from risks, as opposed to risks to animal or plant life or health, fall outside the scope of this Article.

5. Scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls. So far, the European Union has not resorted to the use of "other legitimate factors" when taking decisions on the setting of MRLs, including import tolerances. Therefore, the European Union does not have any specific examples.

6. All the comments received in response to these notifications are duly considered and taken into account before a final decision is taken. Detailed replies are sent to all trading partners that submit comments. The European Union always provides a reply to all the comments submitted by another WTO Member on an EU notification and explains in details the planned measures and their rationale.

7. The European Union would like to thank Colombia, Guatemala and Paraguay for this suggestion, which is being noted and will be considered in terms of feasibility.

8. The European Union has carefully studied all the information available and confirms that there is sufficient evidence to conclude that both substances pose serious concerns for human health. The available regulatory studies and scientific literature, including epidemiological data, provide evidence of developmental neurotoxicity, leading to adverse neurological outcomes in children. In addition, a genotoxic potential cannot be excluded for the two substances, in particular concerning the ability of the substances to damage DNA.

The Regulations concerning the non-renewal of approval received a favourable opinion at the Standing Committee on Plants, Animals, Food and Feed on 6 December 2019, after being duly notified under the WTO/TBT procedure. The Regulations were adopted and published on 10 January 2020.

On 18 February 2020, member states endorsed a Commission proposal to lower the MRLs of chlorpyrifos and chlorpyrifos-methyl in food and feed to the Level of Quantification, which was duly notified to the WTO SPS Committee.

Notwithstanding the serious health concerns identified by EFSA, the Regulation includes a deferral period for the application of the lower MRLs - three months from the date of entry into force of the Regulation. Therefore, it has not led to immediate trade disruptions as the new MRLs became applicable on **13 November 2020**.

It is important to note that given the concerns identified by EFSA, it is not possible to determine MRLs that are protective for consumers based on a risk assessment and therefore all MRLs must be lowered to the limit of analytical determination.

For the same reason, no additional transitional measures can be provided for products that have been produced in the European Union or imported into the European Union before the Regulation became applicable.

Chlorpyrifos was originally evaluated by JMPR in 1972. It was evaluated for toxicology in 1982 by JMPR and for residues in 1995 and it was reviewed for toxicology in 1999 and for residues in 2000, 2004 and 2006.

There is a 20 years' gap since chlorpyrifos was last reviewed by JMPR, as it is also indicated in General considerations (point 2.6) of the 2019 Report of the extraordinary FAO/WHO Joint Meeting on Pesticide Residues (JMPR).

The European Union has recently submitted a concern form to the Codex secretariat and the JMPR to raise awareness on its latest findings. The European Union considers that a re-evaluation for toxicology and residues of chlorpyrifos and all the CXLs is necessary and this task should be prioritised in the JMPR calendar.

9. It is the responsibility of the applicant to provide relevant information and data needed to carry out risk assessment. It is justified that the burden of providing scientific evidence is shifted onto applicants because they have a direct or indirect commercial interest in placing the product on the market and – therefore – in actively contributing to risk assessment procedures. This is fully compliant with the SPS Agreement.