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Page: 1/2

Committee on Sanitary and Phytosanitary Measures

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RESPONSE OF THE EUROPEAN UNION TO [G/SPS/GEN/1740/REV.1](#)

COMMUNICATION FROM THE EUROPEAN UNION

The following communication, received on 19 November 2019, 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/1740/Rev.1](#) regarding [STC 448](#).

1. The risk assessment carried out by the European Food Safety Authority (EFSA) provides the scientific rationale for the current EU MRL for imazalil in bananas as defined in Commission Regulation (EU) 2019/1582 of 25 September 2019.¹ See EFSA's relevant reasoned opinions of 2017,² 2018³ and 2018⁴. These opinions revealed unacceptable risks in respect of the previous EU MRL, noting an exceedance of the acute reference dose (ARfD) of 157%. For the existing Codex MRLs (CXL) at the time of assessment, the exceedance was of 184%. No safe fall-back options could be identified by EFSA since the other GAPs⁵ considered in the review also led to exceedances of the ARfD or were not supported by data.

2. The EU MRL for imazalil in bananas is based on EFSA's risk assessment and, therefore, consistent with Article 2.2 of the WTO SPS Agreement. EFSA's risk assessment is consistent with the requirements of Article 5.1 of the WTO SPS Agreement (see reasoned opinions cited above). For products where no safe use could be identified from the available data, MRLs were set at the limit of quantification (LOQ), in the case of bananas, 0.01 mg/kg. An LOQ, as opposed to zero tolerance, provides legal certainty to the operators.

3. EFSA's risk assessment takes into account all relevant factors in accordance with Article 5.2 of the WTO SPS Agreement (see reasoned opinions cited above). It is worth noting that EFSA's risk assessment also took into account the existing CXLs at the time of assessment, based on the use of imazalil as assessed by the JMPR (FAO 1977, 1984, 1985, 1994).

4. Article 5.3 is not relevant in the case of SPS measures as defined in Annex A, paragraph 1.b.

5. The EU MRL for imazalil in bananas, as defined in Commission Regulation (EU) 2019/1582 of 25 September 2019, is consistent with the provisions of Articles 5.4 and 5.6 of the WTO SPS Agreement in that no safe alternative options could be identified to ensure the EU level of protection as defined in Article 4 of Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009.⁶ Applications for new MRLs/import tolerances can always be submitted under

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019R1582&from=EN>.

² European Food Safety Authority; Review of the existing maximum residue levels for imazalil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(9):4977.

³ European Food Safety Authority; Modification of the existing maximum residue levels for imazalil in various commodities. EFSA Journal 2018;16(6):5329; European Food Safety Authority.

⁴ Reasoned Opinion on the updated review of the existing maximum residue levels for imazalil according to Article 12 of Regulation (EC) No 396/2005 following new toxicological information. EFSA Journal 2018;16(10):5453.

⁵ Good Agricultural Practices.

⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009R1107&from=EN>.

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

6. The measure establishing EU MRLs for imazalil as defined in Commission Regulation (EU) 2019/1582 of 25 September 2019 is consistent with the provisions of Article 5.5 of the WTO SPS Agreement. The MRLs are justified by the risk assessment carried out by EFSA, where safe fall-back options could be identified for certain foods.

7. Article 5.7 of the WTO SPS Agreement is not relevant in that the results of EFSA's risk assessment provide appropriate scientific justification for the measures adopted in Commission Regulation (EU) 2019/1582 of 25 September 2019.
