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Committee on Sanitary and Phytosanitary Measures

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EUROPEAN UNION AMENDMENTS OF MRLS FOR IMAZALIL (G/SPS/N/EU/319) – CONCERNS OF COLOMBIA AND ECUADOR

COMMUNICATION FROM COLOMBIA AND ECUADOR

The following communication, received on 27 June 2019, is being circulated at the request of the delegations of Colombia and Ecuador.

The Republics of Colombia and Ecuador would like to express our concern with respect to the draft Commission Regulation amending Annexes II and III to Regulation (EC) No. 396/2005 of the European Parliament and of the Council as regards maximum residue levels for imazalil in or on certain products.

1. By means of this specific trade concern, we wish to make the European Commission and WTO Members aware of an issue that we believe to be of the utmost importance for global agricultural production and, particularly, for agricultural production in developing countries such as Colombia and Ecuador. We are grateful for the consideration given to our views on this issue, which are aimed at promoting the agricultural development of banana producing countries worldwide.

2. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures provides that Members shall ensure that measures are not more trade-restrictive than required to achieve their appropriate level of protection, taking into account technical and economic feasibility. The above-mentioned European Union regulation, however, reduces the maximum residue levels (MRLs) for imazalil in bananas from 2.0 to 0.01 mg/kg. This would, in practice, make its use unfeasible despite its recent evaluation and approval at European level barely five years ago.

3. Imazalil is a fungicide used by banana producing countries as a key post-harvest tool for preserving product quality and safety and keeping the product free from mould and fungus during storage and transport and the period when it is available for sale before reaching consumers on the European market. We see that there are currently no phytosanitary alternatives available on the market that can be used in bananas (nor are there other alternatives comparable in quality and efficacy). The loss of this tool for preserving crops would make it unfeasible for producers to be able to respond to market demand.

4. It follows from the foregoing that the draft regulation must take into account the scientific evidence generated from studies in experimental animals as well as epidemiological studies on exposed populations to clearly establish disruption as an effect, thereby eliminating the presumption of adverse effects.

5. In Colombia, 50,000 hectares are dedicated to the production of bananas for the European market, and the marketing and distribution of those bananas in the European Union could be affected by this measure. They produced a total of 1,700,000 tonnes in 2016, which accounted for 90% of total domestic banana production.

6. Colombia's banana exports to the European Union account for 80% of all its agricultural exports to that market. They amounted to USD 665 million in 2018 and benefited remote areas of the

country where the armed conflict had taken place. The main destinations are Germany, Belgium, Spain and the Netherlands.

7. Ecuador is the world's leading banana exporter, with trade with around 87 markets internationally, including the European Union. Bananas are Ecuador's main export to that bloc, representing 30% of the total exported. In Ecuador, banana exports account for 2% of overall GDP and around 35% of agricultural GDP. Banana production in Ecuador falls mainly in the realm of the household economy and the "popular and solidarity economy", which means the sector contributes to job creation and poverty reduction.

8. A review of the Codex Alimentarius reveals an MRL of 2.0 mg/kg for imazalil in bananas. The European Union's amendment of the MRL for imazalil deviates unjustifiably from the Codex Alimentarius standard and lacks any scientific basis.

9. We believe that any measure applied by the European Union must be prepared in accordance with the WTO SPS Agreement, particularly Article 2.2 (the SPS measure shall be based on scientific principles), Article 5.2 (in the assessment of risks, Members shall take into account available scientific evidence, relevant processes and production methods, and relevant inspection, sampling and testing methods) and Article 5.3 (Members shall take into account as relevant economic factors the potential damage in terms of loss of production or sales).

10. In light of the foregoing, it is clear that the "default" MRL of 0.01 mg/kg set for imazalil in bananas lacks a technical or scientific basis and creates a restriction on access to the European Union, which will have a significant economic and social impact on banana producing countries.

11. It should be noted that, in 2010, the EFSA (European Food Safety Authority) published a report containing the conclusions of the risk assessment of the active substance imazalil (EFSA, 2010). From the mutagenicity studies presented, it was concluded that imazalil was not genotoxic. In evaluating other effects, it was concluded that imazalil was neither a reproductive toxicant nor a teratogen.

12. The European Union's reasons for proposing this amendment are not based on the identification of a risk to consumers, but rather on the lack of the necessary studies that would allow certain risks to be dismissed. Those studies could not be conducted beforehand by the producer of the substance, but the EFSA indicated that it needed them in order to be able to to conclude its scientific evaluation. Consequently, the EFSA's two Scientific Opinions on MRLs for imazalil do not propose a specific MRL and indicate that more studies need to be done before a decision can be reached. However, the Commission has interpreted the lack of a conclusion by the EFSA as a health risk.

13. We understand that the Netherlands, the evaluating member State, authorized the initiation of the necessary vertebrate studies identified by the EFSA. Those studies are expected to be available in the first quarter of 2020, at which time they will be evaluated by the Netherlands and then sent to the EFSA.

14. We are quite concerned about the proposal to change the MRL for imazalil in bananas from 2.0 to 0.01 mg/kg, as risk analysis had not been taken into account as a methodological tool in the decision-making process; according to the EFSA's review, there was insufficient scientific evidence of genotoxicity for three metabolites of imazalil (R014821, FK-772 and FK-284) although negative results from *in vitro* tests were reported in an FAO/WHO document.

15. According to the calculations and under the scenarios contemplated for acute and chronic intakes in the two diets evaluated for citrus fruits and bananas, in conservative scenarios, no health risk was found, indicating that the existing MRLs are safe.

16. Changing the value of the MRL to the limit of quantification of residues according to the analytical technique, when those values are determined on the basis of supervised trials and require validation of toxicological safety, would make it irrelevant given the absence of information.

17. This decision would run counter to the most recent work done, in 2018, on Codex MRLS, which included MRL values well above the limit of quantification. The WHO/FAO JMPR (Joint Meeting on Pesticide Residues) evaluated the same group of studies on imazalil as the Netherlands and the EFSA

and found that there was no type of risk to consumers and recommended new MRLs for the substance even higher than those currently agreed under Codex. The JMPR is the leading international body of experts for the evaluation of pesticides and residues and constitutes the scientific arm for risk management.

18. It should also be noted that the European Union's comments regarding the effects in bananas were considered at the last meeting of the Codex Committee on Pesticide Residues, which took place in April 2019. Nevertheless, that Committee recognized the 2018 JMPR report and seemed favourable to increasing MRLs for bananas from 2.0 to 3.0 mg/kg.

19. With respect to the European Union's argument regarding an excess in the acute reference dose (ARfD) for bananas, we kindly request that the European Union consider the new scientific evidence from Spain, as that would resolve the issue.

20. The initial studies on bananas were conducted on samples treated with a 600 ppm dose of imazalil (the dose used in Latin America, not 300-375 ppm, the dose used in the European Union), which presented a risk to consumers, on the basis of EFSA models, because the ARfD was exceeded. Recently, however, studies conducted in Spain using a 300 ppm dose have come to light. Those studies would show that the ARfD is not exceeded with this dose, which would allow the Directorate-General for Health and Food Safety to set safe MRLs for European consumers.

21. We believe that the amendment of the MRL for imazalil in bananas to 0.01 mg/kg lacks a scientific basis and deviates unjustifiably from the international reference set in the Codex Alimentarius (2.0 mg/kg). We therefore call on the European Union to maintain the current MRL of 2 mg/kg for the imazalil molecule in bananas, as set in the Codex Alimentarius, until the European Union develops and evaluates new studies. We ask that the MRL only be applied through a scientific assessment of the risk, as set forth in the WTO SPS Agreement, providing real health protection and not constituting a disguised barrier to trade.

22. This request is grounded in the WTO SPS Agreement, which provides that, in determining the appropriate level of sanitary or phytosanitary protection, Members should minimize negative trade effects and that sanitary and phytosanitary measures should be scientifically and technically justified, be based on risk assessment and not constitute unjustified barriers to trade.

23. We are very concerned that the European Union's regulatory amendments regarding MRLs do not have adequate technical or scientific support and are based on hazard, not risk. We therefore highlight the need to use "risk analysis" as a methodological tool for making decisions on pesticide use, under its three components of assessment, management and communication, in order to protect public health and the environment, and as a tool for facilitating international trade in agricultural products. A review of the European Union's proposal shows that risk assessment is losing ground, with the decision to accept or allow the use of substances being made under a hazard based approach and the conditions of use that can define risk scenarios and lead to scientifically based decisions being neglected.

24. To conclude, we would also like to express our deep concern regarding the "transition periods" granted by the European Union for provisions amending maximum residue limits (MRLs). It should be noted that in view of harvesting periods and the times when agrochemicals are applied, the six month period prior to the implementation of the provision, as provided for in the SPS Agreement, does not give enough time to make the necessary adjustments to production so as to ensure that agricultural products comply with the new MRLs. For processed and/or frozen products, the situation can be even more problematic.

25. Transition periods should be examined in a light that differs from the general rule of a reasonable interval of six months under Annex B.2 of the SPS Agreement (Ministerial Decision WT/MIN(01)/17), as farmers need more time to adapt to MRL requirements, since it takes 36 months on average to develop a new phytosanitary pest control product. Colombia notes, in this regard, that Article 10.2 of the SPS Agreement provides for the granting of longer time frames for compliance with sanitary and phytosanitary measures for products of interest to developing country Members, with a view to maintaining opportunities for their exports.