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Committee on Sanitary and Phytosanitary Measures

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MODIFICATION OF EUROPEAN UNION MRLS FOR PHYTOSANITARY PRODUCTS: MANCOZEB (G/SPS/N/EU/384) – SPECIFIC TRADE CONCERN OF COLOMBIA AND ECUADOR

COMMUNICATION FROM COLOMBIA AND ECUADOR

The following communication, received on 3 July 2020, is being circulated at the request of the delegations of Colombia and Ecuador.

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1. Colombia and Ecuador wish to offer comments and express their concern regarding the measure notified by the European Union (EU) in document G/SPS/N/EU/384 of 24 April 2020 relating to the non-renewal of the approval of the use of the active substance mancozeb, given that this substance is vital for pest control in a wide variety of crops, including bananas, which are the main export of Colombia and Ecuador to the EU.

2. By means of this communication, we wish to bring to the attention of the European Commission and WTO Members an issue that we consider to be of the utmost importance for the global banana sector and, in particular, for Colombia and Ecuador. We would appreciate our comments on this issue being taken into account, with a view to ensuring the continued protection of consumer health and, in parallel, avoiding any effects on the agricultural trade of Latin American countries, for the reasons set out below.

3. The EU has been adopting measures that have resulted in the non-renewal of the approval of the use of crop protection products, thereby affecting the exports of its trading partners. Measures on the suspension or non-renewal of the approval of the use and, thus, marketing of numerous active substances, as well as the subsequent reduction of their maximum residue levels (MRLs) to the minimum detection level, are being taken without any sound scientific evidence and without proof that such measures are the least trade-restrictive means of achieving an appropriate level of protection for consumers.

4. The mancozeb compound was developed in Europe almost 60 years ago to protect crops. It is currently registered for more than 70 crops and over 400 approved uses across the world. It is one of the most robust active substances in that there have been no reports since its registration of a loss of sensitivity, of resistance, or of any harmful effects on treated crops. This is owing to the substance's multi-site properties, which enable it to attack different parts of the fungus without creating resistance. As a result, when used as prescribed in the labelling, it is considered to be a key tool in fungus control programmes.

5. This compound is crucial for pest management and preventing resistance because, owing to the tropical climate in countries like Ecuador and Colombia, pest and disease behaviour follows patterns that are very different from those prevailing in countries with four seasons, such as those in the EU, meaning that the use of certain active substances such as mancozeb and its formulated products is vital in agricultural production. Prohibiting the use of mancozeb could have a very significant economic impact on small-, medium-, and large-scale producers in our countries, as well as on consumers in the EU, because the supply of our food would be affected.

6. In Colombia and Ecuador, the use of the active substance mancozeb is essential in agricultural production for protecting banana crops against pests and diseases such as Black Sigatoka, a devastating disease that attacks the foliar system and is caused by the fungus *Mycosphaerella fijiensis*. This fungus is extremely dangerous and is classed as very high risk by the Fungicide Resistance Action Committee (FRAC) on account of its ability to adapt rapidly to climatic changes and, above all, its inherent capacity to develop resistance to various chemical groups of fungicides. Not only is mancozeb a fungicidal compound, but it is also an integrated management tool that contributes to reducing the risk of fungicide resistance and maintaining the sustainability of the agricultural sector.

7. Black Sigatoka currently shows resistance to three different chemical groups of fungicides used, which is severely limiting the control of the disease. This is why the use of mancozeb is of such importance in banana-producing countries. Recently, the EU also banned the marketing of chlorothalonil (through document "Chlorothalonil-SANTE/10186/2018 Rev. 1 – 22 March 2019, Final renewal report for the active substance Chlorothalonil"), which is the main tool for controlling Black Sigatoka. In this regard, banning mancozeb (an alternative compound) would leave banana-producing countries without any phytosanitary tools for controlling this disease, resulting in significant economic losses in Latin American countries, particularly in Colombia and Ecuador, with bananas being the main export product of both countries.

8. In addition, owing to the limited number of chemical groups of fungicides available or alternatives for the control of Black Sigatoka in banana crops, the risk of the fungus developing resistance is extremely high. Mancozeb has been used effectively, with no signs of resistance reported, thereby reducing the amount and frequency of the applications of this compound on crops. There is evidence that the absence of mancozeb, combined with the lack of products having a similar effect, could cause the resistance shown by the fungus to worsen to the point of no return, making phytosanitary management difficult. This would have catastrophic consequences for banana crops and the agricultural producers whose livelihoods depend on them.

9. Many regions across the world produce bananas and they are a key part of agricultural exports. As a result, the crop must be properly managed in technical and phytosanitary terms and it must be environmentally sustainable. The absence of any of these pillars could mean that banana production would no longer be viable.

10. A review of the EU's draft regulation shows that the scientific justification for the changes or amendments to regulations on the approval of the use of active substances is becoming less relevant, given that, for example, the decision on the non-renewal of the approval of the use of mancozeb has been taken by applying a hazard-based approach and the precautionary principle. This means that the lack of information and sufficient scientific studies in the EU required for making a risk- and science-based decision has been ignored, contrary to the provisions of the WTO SPS Agreement.

11. In Colombia and Ecuador's view, it is a source of concern that the European Food Safety Authority (EFSA), in its final document on the evaluation of the active ingredient mancozeb and the corresponding peer review, refers to developmental toxicity and genotoxicity, yet does so without conclusive studies. Evaluations carried out by agencies such as the United States Environmental Protection Agency (EPA) make the same reference, although the EPA highlights the need to conduct studies on developmental neurotoxicity attributed to ethylenethiourea (ETU) in order to reach sound conclusions.

12. In this regard, it is our understanding that the EFSA decided not to approve the renewal of the use of mancozeb because it classifies the active ingredient in "toxic for reproduction" category 1B and considers it to be an endocrine disruptor in humans and non-target species. However, following the corresponding analysis of the evaluation carried out by the EFSA, we consider that, given the reproductive toxicity hazard profile of mancozeb, it must be taken into account that it is more appropriate to classify mancozeb in "toxic for reproduction" category 2, or even to refrain from classifying it. Consequently, the toxicity classification of mancozeb must be decided on the basis of the active ingredient.

13. We consider that the studies to be taken into account must comply with the analytical and procedural rigour required by EU regulations and the Codex Alimentarius. Moreover, it should be highlighted that mancozeb does not produce adverse effects in experimental species of mammals or humans in doses and concentrations lower than those at which it might be expected to see effects as a result of systemic toxicity. Mancozeb has an effect on the thyroid hormonal system in a number of mammal species, but not in humans. However, thresholds and reversibility have been demonstrated. On this basis, we would be grateful if the EU would take into account the comments made by Colombia and Ecuador, with a view to classifying mancozeb in "toxic for reproduction" category 2 and not as a significant endocrine disruptor in humans.

14. Accordingly, we request the European Commission to take into account: (i) the results recorded in the annual reports issued by the EU-coordinated Control Programme (EUCP), which demonstrate residue levels in fruit such as bananas that are lower than the established MRL; (ii) the information generated at a global level through residue testing, which confirms strict compliance with MRLs; (iii) the established thresholds for mancozeb, particularly since this is a requirement for the non-reduction of MRLs; (iv) the recognition of the MRLs established in the Codex Alimentarius, since we consider that non-recognition would imply disregard for the work of the Codex Alimentarius Commission, and also for consumer health protection policies in countries like our own that adopt Codex standards; and (v) the analytical identification of dithiocarbamate residues, which is covered by the definition of CS2 single residue.

15. In light of the above, we consider that the measure proposed by the EU is neither justified nor supported by sufficient information to establish criteria for the acceptance or rejection of mancozeb. This is because, at the scientific level, its adverse effect on health has not been clearly established, meaning that it is crucial for the EU to adopt a risk assessment approach in the analysis of this regulatory change, given that it lacks sufficient and conclusive scientific studies from EU Member States to determine the various toxicological aspects that may affect human health. There are even some preliminary findings that point to a safe use of mancozeb within the EU.

16. Furthermore, it should be noted that there are scientific opinions at the European level indicating that mancozeb is not an endocrine disruptor. On that basis, a scientifically sound evaluation would only be possible if sufficient time is granted to generate data from countries, in order to conduct a risk assessment with all available scientific studies that include the corresponding levels of exposure for determining the safety thresholds for mancozeb.

17. Colombia and Ecuador support the decision made by globally-recognized expert authorities to authorize the registration of mancozeb for the majority of approved uses, by adopting the necessary risk-mitigation measures to ensure a safe use of the compound through labelling. We consider it highly inappropriate that decisions regarding the reduction of MRLs or restrictions on the use of active compounds continue to be made solely on the basis of the precautionary principle, rather than through a full risk analysis that would provide clear evidence on the compound's danger to human health.

18. In light of this, Colombia and Ecuador consider that the draft technical regulation amending Regulation No. 1107/2009 of the European Union – Non-renewal of mancozeb – must be drawn up in line with the WTO SPS Agreement, particularly with respect to the provisions of Article 2.2 (the SPS measure must be based on scientific principles), Article 5.2 (in the assessment of risks, Members shall take into account: available scientific evidence; banana production processes and methods in the countries that may be affected by the implementation of the regulation; 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).

19. Moreover, with regard to the deadlines established in notification G/SPS/N/EU/384 of 24 April 2020, we would be grateful if the EU could provide greater clarity regarding the timeframe for adoption of the measures. In this respect, we wish to recall that WTO Members must allow a reasonable interval of 36 months between the publication of technical regulations and their entry into force, in order to allow time for producers in exporting Members, and particularly in developing countries, to adapt their products or production methods to the requirements of the importing Member.

20. In view of the arguments presented, Colombia and Ecuador request the EU to renew the approval of mancozeb and maintain its MRLs as a risk management measure to protect the health of consumers in the EU and facilitate trade for its partners, such as Colombia and Ecuador. The ban and consequent reduction of MRLs in the EU for chlorothalonil and mancozeb (an alternative compound) would leave Black Sigatoka management and control programmes without any phytosanitary tools, resulting in highly regrettable consequences for the environment and the economic sustainability of banana crops in all banana-producing countries. Such countries would also see social consequences, bearing in mind that in Colombia, for example, over 45,000 people directly and some 120,000 people indirectly depend on the production of bananas for export to the EU for their livelihoods. In Ecuador, the corresponding figures stand at around 53,200 people and 560,000 people respectively.

21. In addition, the health and scientific authorities in all countries, including Colombia and Ecuador, have been obliged to focus on addressing the situation that has arisen as a result of the COVID-19 global health emergency. Similarly, key sectors such as food producers, organizations and associations are making significant efforts to ensure biosecurity controls in the fruit and vegetable supply chain. This is reducing their capacity to analyse draft regulatory measures and hence also to adjust production methods, and is creating additional burdens on international trade in food products and hampering worldwide economic recovery efforts, particularly in developing countries.

22. Colombia and Ecuador therefore wish to highlight the difficulties being experienced by Latin American countries in handling the many notifications concerning amendments to regulations on compounds and MRLs in the EU during the current COVID-19 global pandemic. The pandemic has become the greatest worldwide health challenge, for which reason we support the request to be submitted by over 30 countries, including Colombia and Ecuador, at the next WTO SPS Committee meeting through document G/SPS/GEN/1778/Rev.2 relating to the suspension of the processes and entry into force of reductions of MRLs for plant protection products in light of the COVID-19 pandemic.

23. We wish to emphasize that the deadline for the receipt of comments is normally a minimum of 60 days (according to the WTO transparency procedure), yet notification G/SPS/N/EU/384 was circulated to all WTO Members on 24 April 2020 and the proposed deadline in the text for receipt of comments is 17 June 2020. In other words, this notification would not be in compliance with the 60-day period recommended by the WTO.