Page numbers: 3; 6-32; 34-35; 42-43 and 46-47 have been entirely redacted as out of scope

EUROPEAN COMMISSION

Directorate-General for Trade
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

MISSION REPORT

Subject: WTO/TBT Committee meeting – written procedures - May 2020

Art. 4 (1)(b) TRADE F.3
Art. 4 (1)(b) TRADE F.3
Art. 4 (1)(b) TRADE F.3
Art. 4 (1)(b) TRADE F.3
Art. 4 (1)(b) TRADE F.3

Art. 4 (1)(b) GROW B.1
Art. 4 (1)(b) GROW B.2
Art. 4 (1)(b) GROW B.2
Art. 4 (1)(b) Geneva DEL

1. Highlights

Out of scope

Out of scope

- Colombia, Brazil, Costa Rica and the US questioned the **non-renewal in the EU of the active substance Mancozeb** used in plant protection products, supported by Ecuador, Paraguay, Guatemala, Indonesia and Nicaragua.

Out of scope

- EU measures on **Maximum Residue Levels (MRL) of plant protection products and the non-renewal of Chlorothalonil** continued to draw a lot of attention by members, with 11 and 10 interventions respectively. The non-renewal of Picoxystrobin was again included in the agenda. The EU **approach to plant protection products** related to **endocrine disruptors** and the **setting of import tolerances** in case of non-renewal of pesticides provoked the reaction of 12 members.
- In a joint statement of 12 May 2020 addressed to the TBT and SPS Committees (Documents G/TBT/GEN/296 and G/TBT/GEN/1778) in light of the COVID-19 crisis, 13 Members, including **Argentina, Colombia and Israel,** asked the EU to **suspend** for 12 months **all review processes for Maximum Residue Levels** (MRL) in plant protection products among others. They further urged all WTO Members in the process of reviewing or modifying MRLs to comply with international standards and recommendations. The Commission is currently preparing a reply.

Out of scope

2. Specific Trade Concerns

Out of scope

As to **defensive cases**, there were 4 new defensives cases against the EU: the **non-renewal** of the active substance **Mancozeb**,

Out of scope

Out of scope

Art. 4(1)(b)

Out of scope

CC: Ms Weyand, Ms Konig, Art. 4(1)(b) Mr Redonnet,

Art. 4(1)(b)

Mr Tynan (Cabinet Hogan).

Art.4 (1)(b)

(AGRI).

Mr Nunes de Almeida, Art.4 (1)(b)

(GROW).

Art.4 (1)(b) (ENV).

Art.4 (1)(b)

(SANTE).

(ENER).

(JUST).

(CLIMA).

Art.4 (1)(b) (CONNECT).

(LS).

(UKTF).

Art.4 (1)(b)

(EU Delegations).

ANNEX 2 – SPECIFIC TRADE CONCERNS AGAINST THE EU (EU DEFENSIVES)

Out of scope

Out of scope

4. European Union – Hazard-based approach to plant protection products and setting of import tolerances

In total, **12 Members** raised deep concern with the EU measures for the identification of endocrine disruptors (questioning in particular, the hazard-based approach instead of the risk based approach and the lack of scientific criteria/evidence). It is important to note that, in view of the situation with COVID-19, several Members asked the EU to suspend, for a period of 12 months, all review processes of market approvals for plant protection products and the entry into force of Regulations in this area planned for 2020 (Document G/TBT/GEN/296).

The **US** reiterated concerns on endocrine disruptors and called the EU to provide a satisfactory response. The US was disappointed about the hazard-based approach and the lowering of Maximum Residue Limits (MRLs) to trade-restrictive levels. Contrary to what the EU had stated, the EU seems not to conduct risk assessments for MRLs and import tolerances for substances triggering its hazard criteria. The US also noted that the EFSA does not set risk endpoints even for substances for which other authorities, including Codex, have successfully completed risk assessments and set MRLs.The US repeated its concerns about the scientific underpinnings, non-discrimination, transparency, and predictability in application of the EU's process.

Brazil, stressed that EU approach to limit the use of pesticides is more trade restrictive than necessary to fulfil its legitimate objectives under the TBT Agreement. It also disregards risk analysis in the setting of regulatory measures that may have serious impact on trade. Serious evaluations must be able to separate chemicals that have the potential to cause harm due to their endocrine mode of action from those substances that do not pose a threat to human health. **Canada** welcomed EU's commitment to host seminars with third countries and stakeholders and asked for any additional information that will help ensure predictability of trade. Canada would like to have information on implementing measures and calls for coherence and transparency. **Australia** asked for guidance material on the procedures for handling requests for import tolerances and information sessions with third countries and stakeholders. Australia requested that MRLs for active substances which were not renewed in the EU be maintained at existing levels to minimize trade disruption and allow producers and exporters to make timely business decisions. Alternatively, Australia requested the setting of temporary MRLs in order to allow any scientific studies necessary for supporting an MRL to be undertaken and evaluated. **Costa Rica** asked the EU to shift from a hazard-based approach to a risk-based one and pointed to the need for sufficient scientific evidence, in line with TBT commitments. Similarly, **Colombia** considered that the EU proposal must take into account scientific evidence, production processes and methods, the international recommendations of the Codex Alimentarius, and the relevant ecological

and environmental conditions in countries that may be affected by the implementation of the measure, in order to avoid creating an unnecessary technical barrier to trade. **Uruguay** maintained that the evaluation of real risks is important for preparing legislation an noted that certain products are withdrawn from the market even if they are not dangerous, which has an important impact on sustainable agriculture and food protection. Codex Alimentarius work should be the reference to guarantee health protection and trade. The EU should pay attention to Members' comments and reconsider its regulatory approach.

According to **Panama,** the TBT Agreement allows deviations, but based on risk assessment and scientific evidence. Certain studies on some of the substances were based on risk assessment, but the EU called them inconclusive and it is necessary to have a conclusive analysis. It has to be taken into consideration the type of measure that developing countries can take, in accordance to their climate. It also called for a suspension of the measure in light of the COVID-19 pandemic. **Ecuador** noted that EU decisions are not provisional and therefore, they are difficult to modify; even if the reviewed MRLs are based on non-conclusive opinions, there is a lack of information, and the EU follows a precautionary approach by reducing the limits to minimum detection limits. In case no information is available, the EFSA should not make recommendations, but maintain current levels. **Guatemala** considered that the EU should provide scientific evidence to countries exporting agri-products and that their specific situation should be taken into consideration (different climate conditions, control of plagues, time and distance for exports). **Paraguay** regretted that the EU forces the implementation of its standards in other Members, without considering the economic, climatic and political consequences and explained in details the negative impacts for its economy of the EU hazard-based approach, in particular, for small producers. Finally the **Dominican Republic** asked the EU to avoid implementing this type of unnecessary trade barrier given the importance of the EU's market to developing countries.

The **EU** explained that the scientific criteria to identify endocrine disruptors for plant protection products based on the WHO definition are applicable since 10 November 2018 onwards and included in Regulation (EU) No 2018/605. The EU is aware of general concerns on the EU policy on plant protection products for the definition of scientific criteria to identify endocrine disruptors, as well as of more specific concerns, in particular, on whether import tolerances can be established for substances that are not authorised in the EU, due to the so-called "cut-off" criteria in Regulation (EC) No 1107/2009. After having examined the different policy options and taking into account the concerns raised by stakeholders, Member States and third countries, the EU decided to follow the procedures laid down in Regulation (EC) No 396/2005 for the management of import tolerance requests concerning active substances falling under these cut-off criteria. These procedures include a risk assessment by an Evaluating EU Member State and a scientific opinion by EFSA. The granting of the import tolerance will then be considered in line with risk analysis principles on a case-by-case basis and taking into account all relevant factors. The EU reiterated its commitment to act in full transparency and agreed to keep Members duly informed about further developments.

5 European Union – Chlorothalonil (pesticide active substance), G/TBT/N/EU/625

In total, **10 Members** raised their concerns on this issue. It is important to note that, in view of the situation with COVID-19, several Members asked the EU to suspend, for a period of 12 months, all review processes of market approvals for plant protection products and the entry into force of Regulations in this area planned for 2020 (Document G/TBT/GEN/296). **Colombia** stated that the measures for the suspension or non-approval of the marketing of a number of active substances, and the subsequent reduction of their MRLs to the minimum detection level, are being taken without any solid scientific evidence and without demonstrating that they are the least trade-restrictive means of achieving an appropriate level of protection for consumers. EFSA publishes opinions even in case of insufficient, non-conclusive information and the Commission, following a precautionary approach decided not to renew the approval of the substance. Commission decisions are final and there seem to be no effort to get additional information. The proposed measure is a violation of Article 2.2 of the

TBT Agreement, since there should be less restrictive measures to achieve legitimate objectives, such as consumer protection. Colombia asked for the EU to suspend for a period of 12 months all review processes of market approvals for plant protection substances, and the entry into force of Regulations in this area, planned for 2020, including the non-renewal of the active substance Chlorothalonil.

Panama stressed that that the six-month transition period set by the EU is inadequate, as the production typically lasts from 9 to 12 months, without taking into account the transit time for fruit from origin to destination and finally to the point of sale. In other words, during the process of adapting cultivation methods to the new measures, losses amounting to more than a year's production could be generated. Panama reiterated its request to the EU to suspend the entry into force of the new MRLs for plant protection products during the COVID-19 pandemic. **Brazil** regretted the EU decision banning the substance and the hazard-based approach, instead of a risk-based approach. The reduction of MRLs by the EU would affect Brazilian exports of papaya, coffee and watermelon and would create systemic concerns. Brazil stated that the non-renewal of approval for Chlorothalonil did not duly consider that it is currently authorized in more than 100 countries and that the MRLs allowed by Codex could reach up to 70 mg/kg. **Costa Rica** referred to its request for suspension of the processes and entry into force of reductions of MRLs for plant protection products in light of the COVID-19 pandemic.

Ecuador detailed previous concerns for the non-renewal of authorisation for this substance. The reduction of MRLs would be affecting the commercialisation of bananas, in spite of their high efforts to produce high quality products. It noted that EU measures limiting the use of key phytosanitary tools such as Chlorothalonil pose an additional challenge to existing difficulties caused by the coronavirus. In addition, the process of looking for replacements for Chlorothalonil will take longer because field tests are being hampered by infection prevention protocols. Before reducing MRLs for this substance, a risk assessment would appear necessary, as provided for in the SPS Agreement and in Codex. Therefore, Ecuador suggests that the EU suspends for a period of 12 months its measures. **Guatemala** joined the Members asking for a risk assessment of this measure and pointed to the lack of sufficient scientific evidence on its impact on human health and of proof of product contamination. The lack of alternative pesticides is of great concern in the fight against plagues. **El Salvador** shared the Members' concerns on the negative impact of the EU measure on exports of agriproducts from developing countries, the same as the **Dominican Republic**, who stressed that these types of measures have a direct socioeconomic impact not only in the Dominican Republic, but throughout the region and called for the re-establishment of the registration of this substance. **Paraguay** pointed to related issues of concern, such as the lack of alternative substances and the inconclusive data on which the decision of the EU was based. Nicaragua echoed the concerns of other Members and urged the EU to suspend the application, taking into account the negative impact that the current pandemic has had on global supply chains, food production and the economies of farmers in developing economies.

The **EU** proposed not to renew the approval of Chlorothalonil and notified third countries of the draft Regulation via the TBT procedure. The measure did not lead to immediate disruptions in trade, as it does not amend the maximum residue levels (MRLs) and provides for a grace period. The possibility for granting transitional measures will be considered when proposing any changes to existing MRLs, which will not take place before expiry of the grace period. Furthermore, the EU reiterated that any action to reduce MRLs in the future will be subject to a separate notification under the WTO/SPS procedure. Chlorothalonil was evaluated in accordance with Regulation (EC) No 1107/2009 on the placing of plant protection products on the market. The EFSA conclusion on Chlorothalonil, following assessment by the "rapporteur" Member State and an extensive peer review process, was published in January 2018. During this peer review process, the approval criteria provided for in Article 4 of the Regulation were not satisfied with respect to one or more representative uses of at least one plant protection product. During the assessment: (i) a critical concern was identified by EFSA in relation to the contamination of groundwater by certain metabolites of Chlorothalonil; (ii) EFSA could not exclude a genotoxicity concern for residues to which consumers will be exposed and identified a high risk to amphibians and fish for all the uses evaluated; (iii) several areas of the risk

assessment could not be finalised due to insufficient data in the dossier, and (iv) it was noted that Chlorothalonil is classified as carcinogen category 2 in accordance with Regulation (EC) No 1272/2008, while the EFSA conclusion of the Authority indicated that Chlorothalonil should be classified as carcinogen category 1B. In light of the above, the EU proposed not to renew the approval of Chlorothalonil in accordance with Article 20(1)(b) of the plant protection products Regulation. On 29 April 2019, the Commission adopted Implementing Regulation (EU) No 2019/677 concerning the non-renewal of the approval of the active substance Chlorothalonil. Grace periods shall not be set beyond 20 May 2020 Import tolerance requests however remain possible and will be assessed on a case-by-case basis by the "rapporteur" Member State and the European Food Safety Authority. Such requests would have to be supported by substantial new data addressing the concerns.

6. European Union – Transitional periods for MRLs and international consultations

In total, **11 Members** expressed deep concerns on this issue.

Colombia refers to the non-renewal of certain substances to be used in pesticides in the EU and reiterates that there is no alternative to replace those products for South American producers of foods and vegetables. More inclusive technical discussions are needed, involving stakeholders and measures should not act as technical barriers to trade. Producers bear an important burden and need to take action to protect their crops at least one year in advance, which is very challenging. Colombia referred to the short transitional period granted by EU measures and to the discrimination faced by products imported in the EU. WTO notification of technical rules should not only be a procedural step and Members must be able to effectively present their views and that they are taken into account. It is not sufficient for the EU to say that, by the time the EFSA decision is known, the concerned countries have to do the relevant adjustments.

The **US** shared the concern that the EU's transition measures do not provide adequate time for producers to modify their pest management programs to clear the channels of trade. Furthermore, EU policies appear to establish arbitrary differences in the treatment of domestic and imported products, and do not appear to account for obstacles posed to imported products compared with generally non-existent risks of non-fulfilment with their described legitimate objectives of human health and safety. The US noted the notification by the EU to both the TBT and SPS systems of its active substances non-renewal decisions, but stressed that this does not adequately address the inherent problems with the EU's approach to regulating crop protection products and establishing MRLs. Trading partners still do not know with certainty the impact of the non-renewal decision on future MRLs, nor can foreign growers make informed decisions on their food production practices in the present. Rather, it places foreign growers who comply with existing EU MRL standards at the time of production in jeopardy of facing future rejection at EU borders—a damaging prospect that EU growers do not face under the current regulatory provisions. According to the US, the EU explicitly acknowledged that non-EU countries would have a shorter time to comply with new MRLs compared to EU Member States but did not clarify how such shorter timeframes do not arbitrarily or unjustifiably discriminate between its own territory and that of other Members. The US reiterated its request that the EU conduct a risk assessment prior to resetting MRLs and it is asked that the EU extends its MRL transitional measures to account for realistic production and processing times for food and agricultural products.

Panama reiterated its concerns, in particular, on the non-renewal of Chlorothalonil and asked to continue discussions on how the EU can take health measures in line with the SPS and TBT Agreements without unduly interrupting international trade. **Brazil** referred to Article 2.12 of the TBT Agreement, according to which an interval of time shall elapse between publication and enter into force except in cases of public health, or urgency. Brazil noted that the scientific evidence is inconclusive and is concerned that the transitional period is incompatible with the planting and production process. Brazil expressed concern on the short grace period of 3 months granted for the active substance Chlorpyrifos. **Ecuador** claimed that developing countries are mostly affected and

asked for reasonable transitional periods, taking into account harvest time. Farmers need more time for MRLs, since developing a new pesticide takes a long time and a minimum of 36 months as a transitional period especially due to the COVID-19 pandemic. **Canada** acknowledged the necessity of applying food safety measures, but highlighted that a longer transitional period would be needed for exporters to adapt to new requirements, claiming that the same conditions should apply for domestic producers and importers. **Paraguay** supported the Members as regards the insufficient nature of transitional periods for the transformation of production systems and urged the EU to suspend processes in light of the COVID-19 pandemic. EU measures have great impact on **Costa Rica**, as the country's agricultural production is not expected to adjust to the new requirements in such a short time period. **Uruguay** asked the EU to consider harvest times and ensure the registration of alternative substances. Measures should be based on international standards and conclusive scientific evidence. **Guatemala** reiterated the importance to give transitional periods in line with stages of production of crops in tropical countries and to give time for finding alternative substances. Guatemala defends producers and exporters that are affected by the change of EU conditions and asks the EU for a real dialogue in the search of solutions. The **Dominican Republic** associated itself with the statements of other Members regarding international consultation processes and the transition periods granted prior to the entry into force of relevant provisions.

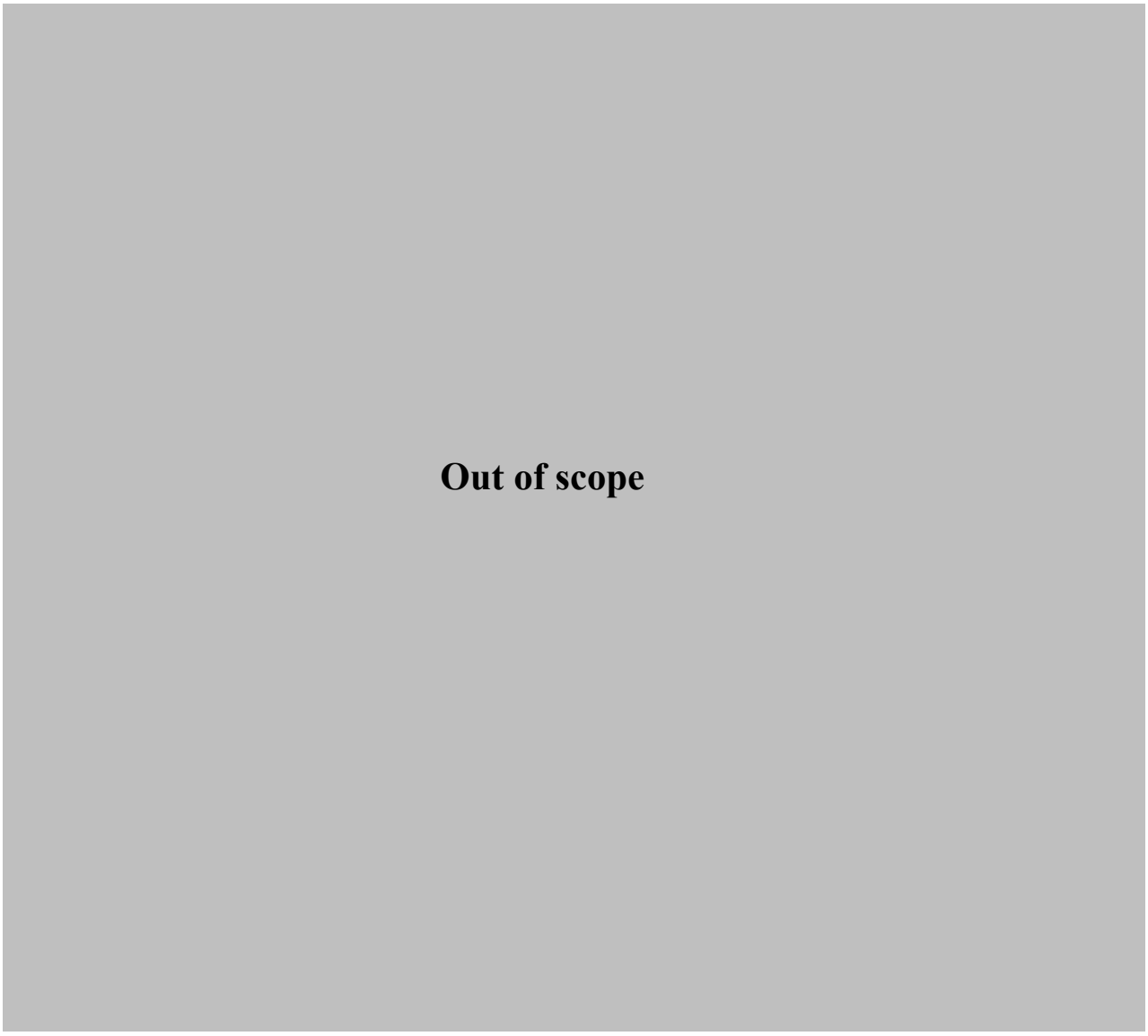
The **EU** explained that, as a matter of principle, it considers concerns on the setting of MRLs for pesticides – and any details regarding their implementation – to be a matter for discussion at the SPS Committee, rather than at the TBT Committee. Further to requests by some Members, and in the interest of transparency, the EU decided to notify all draft measures on pesticide active substances that are relevant for the TBT Committee additionally also to the SPS Committee. In practice, it means that future draft acts on the non-approval or restriction of approval of an active substance will be notified to both Committees. However, in the interest of efficient proceedings in both Committees, and in line with the respective Agreements, the EU continues to consider that matters on approvals of active substances should be discussed exclusively in the TBT Committee, and matters on the setting of MRLs for pesticides should be discussed exclusively in the SPS Committee. The EU fulfils all its obligations under both the TBT and the SPS Agreement, including notifying its trading partners about planned measures that fall within the scope of either of these agreements. Information and comments received in response to these notifications are duly considered and taken into account before final decisions are taken, as explained in EU replies to trading partners. As regards possible transitional periods when MRLs are lowered, the EU would like to remind the Committee about two key provisions of such measures. First, following the formal adoption, publication and entry into force of an act lowering MRLs, a deferred date of application is set. The date of application is the date from which the new/lower MRLs are effectively enforced. The length of the deferral is 6 months after entry into force, in the vast majority of cases. This deferral of the application date permits *inter alia* third countries and food business operators to prepare themselves to meet the new requirements that will result from the modification of the MRLs. Second, products produced in the EU or imported into the EU before the aforementioned application date may continue to benefit from the old/higher MRLs and remain on the market if information shows that a high level of consumer protection is maintained. This is regularly not the case where MRLs are lowered because the safety of consumers could not be demonstrated.

7. European Union – Regulation (EC) No 1107/2009 – Non-renewal of approval of the active substance Picoxystrobin

Brazil explained that the EU had notified the non-renewal of this substance to the TBT Committee in July 2017 and that the MRLs, which are extremely low, had been notified to the SPS committee. Brazil considers that the transitional period granted is unreasonable and that the measure is based on inconclusive EFSA studies. The non-renewed substance is in fact used in more than 65 countries. Brazil called the EU to consider aligning its decision on renewal of approval of active substances with scientific consensus regarding the safety of substances and their use to protect crops. **Paraguay**

referred to its previous statements and reiterated its concerns about the non-renewal of the substance and the criteria used.

As the **EU** explained in detail at previous TBT Committees, the European Commission decided not to renew the approval of Picoxystrobin through Commission Implementing Regulation (EU) 2017/1455. Authorisations for plant protection products containing Picoxystrobin in the EU were required to be withdrawn by 30 November 2017. Member States were permitted to allow for a grace period until 30 November 2018 at the latest. The EU notified third countries of the draft Regulation via the TBT procedure. The measure did not lead to immediate disruptions in trade, as the measure itself does not amend the MRLs and provides for a grace period for use of products containing Picoxystrobin. Given the issues identified by EFSA, the existing MRLs were reviewed in a separate measure in view of their safety to consumers. A draft measure lowering the MRLs for Picoxystrobin to the limit of quantification (LOQ) was prepared and presented to the Standing Committee on Plants, Animals, Food and Feed. The EU notified third countries of the draft Regulation via the SPS procedure. Comments received from non-EU countries and stakeholders were available to the Standing Committee, where a summary of the key points raised was presented. The Standing Committee gave a favourable opinion on the draft. The European Commission formally adopted the revised MRLs in January 2019. The revised MRLs are applicable since 13 August 2019. Import tolerance requests however remain possible and will be assessed on a case-by-case basis by EFSA. Such requests would have to be supported by substantial new data addressing the concerns.



Out of scope

13. European Union - Non-renewal of the approval of the active substance Mancozeb NEW

In total, 9 Members raised concerns on this issue. In general, Members underlined the importance of Mancozeb for management of fungicide resistance and the lack of alternatives. They also criticized the lack of scientific evidence and the short time frame for the application of the measure.

Colombia expressed concerns about the measure notified on 17 April 2020 relating to the non-renewal of the approval of the active substance Mancozeb and asked the EU to reconsider. Colombia emphasised the significance of Mancozeb as a fungicide used to prevent fungi from developing resistance to curative fungicides thus allowing fungicides to remain effective. It stressed that the ban

of Mancozed, which comes after the EU ban of Chlorothalonil, would leave banana producing countries without the tools to control certain diseases which affect banana crops, as for instance Black Sigatoka. It referred to 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 increase to the point where phytosanitary management is difficult. Colombia criticized the hazard-based approach taken by the EU, noting the lack of a scientific basis. It asked for clarity regarding the timeframe for the adoption of the measures and a reasonable interval between the publication of technical regulations and their entry into force, in order to allow time for producers in exporting Members to adapt. **Brazil** echoed Colombia's concerns and inquired into the scientific basis of the Regulation and potential less trade-restrictive alternatives. It finally urged the EU to consider establishing transition periods that are adequate to the production cycle of the affected crops. **Costa Rica** called for the postponement of the non-renewal process and subsequent reduction of Maximum Residues Levels (MRLs) for Mancozeb, so as to give the national sanitary and phytosanitary authorities a reasonable period of time to respond to the numerous challenges posed by the COVID-19 pandemic and find an alternative substance. **Ecuador** joined calls for the EU to base its measures on conclusive studies, to refrain from introducing definitive measures on the basis of the precautionary principle, and to establish transition periods of at least 36 months for the registration of alternative substances, in view of the current shortage of tools available to control pests. **Paraguay**, **Indonesia** (referring to the acknowledgment by the FAO of Mancozeb as an active substance for plant protection products)**, Nicaragua** (referring to relevant international rules) and **Guatemala** echoed the views expressed by the above Members.

The **US**, joining the Members in reiterating its concerns about then new Regulation, considers that the EU continues to ignore international standards and fails to provide adequate rationale of the risk of non-fulfilment to justify the non-renewal of substances. The US referred to prior WTO interventions on the EU's hazard cut-off criteria for possible endocrine disruptors and stated that non-renewal due to hazard potential creates excessive uncertainty for agricultural trade. If MRLs are lowered, the US requested that the EU establish transitional measures that allow all foods, including those with long shelf lives, to go through the complete channels of trade before enforcement. The US will submit written comments regarding the non-renewal of approval of Mancozeb and requested that the EU takes these comments into consideration and responds in advance of the closing of the WTO comment period on 16 June.

The **EU** pointed out that the non-renewal of the approval is based on a scientific assessment conducted under Regulation (EC) No 1107/2009 by experts from Member States and the EFSA. In order for an active substance to be approved in accordance with Regulation (EC) No 1107/2009, it must be demonstrated that the substance is not harmful to human health, animal health or the environment. Specific criteria, listed in Article 4 of the Regulation (and further detailed in Annex II), must be met to enable approval. During the evaluation and peer review of Mancozeb, the following concerns were identified by EFSA: (i) a reprotoxic potential of Mancozeb, classified as Toxic for reproduction category 1B in accordance with the criteria set out in Commission Regulation (EC) No 1272/2008;(ii) the non-dietary exposure estimates exceed the reference values for tomatoes, potatoes, cereals and grapevines.; (iii) moreover, endocrine disruptors criteria are met for humans and likely for non-target species. In light of the above, EFSA concluded that Mancozeb does not meet the approval criteria as outlined in Article 4 of Regulation (EC) No 1107/2009 and cannot be currently approved. The EU stressed that Member States must withdraw existing authorizations for plant protection products containing Mancozeb at the latest by three months from the date of entry into force of the Commission Implementing Regulation. The grace period in line with Article 46 of Regulation 1107/2009 shall expire, at the latest, after six months from the entry into force of the Implementing Regulation. Following non-approval and the expiry of all grace periods for stocks of products containing this substance, separate action will likely be taken on MRLs and a separate notification will be made in accordance with SPS procedures.