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H.E. Héctor Marcelo Cima
Ambassador of Argentina to the European Union

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H.E. Justin Brown
Australian Ambassador to Belgium, Luxembourg, the European Union and NATO

H.E. Dan Costello
Canadian Ambassador to the European Union

H.E. Raúl Fernández Daza
Ambassador Extraordinary and Plenipotentiary of the Republic of Chile to the Kingdom of Belgium, the Grand Duchy of Luxembourg and the European Union

H.E. Sergio Jaramillo Caro
Ambassador of Colombia to the European Union

H.E. Aharon Leshno-Yaar
Ambassador of Israel to the European Union and NATO

H.E. David Taylor
Ambassador of New Zealand to the European Union

H.E. Rigoberto Gauto Vielman
Ambassador of Paraguay to the European Union

H.E. Gonzalo Gutierrez
Ambassador of Peru to the European Union

Mr Adam Shub
Chargé d'affaires a.i., United States Mission to the European Union

H.E. Carlos Pérez del Castillo
Ambassador of Uruguay to the European Union

Your Excellencies,

Thank you for your letter of 12 June 2018 in which you expressed your interest in the ongoing evaluation of the pesticide legal framework, your concerns about the management of import tolerances and your suggestions for improving several aspects of our decision making process.

As you noted the evaluation of Regulation (EC) No 1107/2009¹ and Regulation (EC) No 396/2005² are of considerable interest to Member States, stakeholders and also third countries. The workshop that took place on 16 May 2017 allowed for interesting discussion on the main issues related to the application of these Regulations, including the issue of coherence between the two pieces of legislation. We expect to finalise this evaluation during the first half of 2019 and we will publish its results as soon as possible in order to launch the discussion on the best way forward.

Regarding the pending renewals for active substance approvals, I confirm that following the current rules, when an active substance falls under the human health related cut-off criteria laid down in points 3.6.2 to 3.6.4 of Annex II to Regulation (EC) No 1107/2009 (mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction 1A or 1B), following Article 4(1) of the Regulation, the scientific assessment stops and, as a general rule, the active substance cannot be approved. The situation is different for the cut-off criterion laid down in point 3.6.5 (endocrine disruptors), for which the full risk assessment is still needed.

Regarding the management of import tolerances for active substances falling under the human health related cut-off criteria, I confirm that following the non-approval of an active substance, the revocation of national authorisations for plant protection products containing this active substance triggers the application of Article 17 of Regulation (EC) No 396/2005, leading to the deletion of its maximum residue levels (MRLs), including import tolerances. However, I would like to inform you that after having examined the different policy options and taking into account the concerns raised by stakeholders, Member States and third countries, the procedures laid down in Regulation (EC) No 396/2005 for the management of import tolerances requests concerning active substance falling under these cut-off criteria will be followed. These procedures include systematically a risk assessment by an Evaluating Member State and a scientific opinion by the European Food Safety Authority (EFSA). Consequently, the granting of the import tolerances will be considered on a case-by-case basis taking into account all relevant factors. To ensure transparency, this approach for the management of existing and new import tolerances will be published on our website as part of our Guidance on the MRL Setting Procedures.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, (OJ L 309, 24.11.2009, p. 1).

² 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 and amending Council Directive 91/414/EEC, (OJ L 70, 16.3.2005, p. 1).

Concerning your suggestions for improving our decision making process, I would like to underline the following:

- the comments received from third countries in the context of the WTO notification processes are fully considered before the Commission and Member States make their final decision and adopt a Regulation;
- impact assessments are systematically performed for any major regulatory initiatives at EU level. MRLs are established by implementing measures and are based on scientific considerations;
- a schedule of MRL reviews is available on the EFSA website³. The document presents the status of the ongoing and upcoming reviews under Article 12 of Regulation (EC) No 396/2005 and is updated on a quarterly basis. Third countries were informed of this publication via a Communication from the European Union made to the WTO⁴ on 12 June 2017;
- in order to solve the issues of interpretation regarding the applicability of new MRLs, the drafting of the transition measures was recently modified for imported products to clarify that products have to be compliant with EU MRLs at the moment of import into the EU.

As I already mentioned in my letter of 31 March 2016, I am aware of the possible trade implications of our pesticide legislation and would like to assure you that our approach for the management of import tolerances is fully in line with the obligations arising from the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. As Commissioner for Health and Food Safety, I am committed to ensure a high level of consumer protection within the EU and will make sure that MRLs (including import tolerances) will only be set if it can be sufficiently demonstrated that there is no risk to human health.

Yours sincerely,



³ Overview of the MRL review progress under Article 12 of Regulation (EC) No 396/2005

⁴ On going review of maximum residue levels of pesticides in the European Union – Communication from the European Union - G/SPS/GEN/1494/Rev.1