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European Crop Protection

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Dear [redacted]

Policy on the setting of Import Tolerances for substances impacted by hazard criteria

In a world where the production and supply of food and feed are largely globalized, the setting of import tolerances is vital as part of the internationally agreed rules to govern their trade. Since the introduction of the hazard based criteria in Regulation 1107/2009, the relevance of these criteria (the 'cut-offs') for the setting of Maximum Residue Levels (MRLs) and Import Tolerances (ITs) has been under discussion.

In the minutes of the SCoPAFF residues meeting of 12-13 June, further information was provided about the legal services' thinking on the setting of import tolerances for active substances falling under the cut-off criteria. The Legal Services seem to favour the interpretation that MRLs and ITs cannot be set above the LOD for those active substances. That interpretation is surprising and **we strongly believe it is not in line with the EU's legislative and international obligations.**

It should be stressed that this restrictive interpretation would have a substantial impact on international trade, without providing any additional safety to European consumers. With many potentially impacted active substances being currently authorised in the EU and in third countries, the reduction of relevant import tolerances to the LOD would result in a situation where growers in third countries would no longer be able to export to the EU some of the food and feed they produce. Recent studies have shown a significant impact on trade – with many EU jobs being reliant on the imported products (e.g. food processors and livestock farmers). **Given such a substantial potential impact, we believe that the EU's Better Regulation principles should apply to such a measure – and this should include a full socio-economic impact assessment of the proposed measure.**

We fail to understand the conclusion reached by the legal services. Looking at Regulation 396/2005, there is no reference to hazard based criteria. Applying hazard based restrictions on the setting of import tolerances would be contrary to the EU's own legislation on the setting of maximum residue levels, which relies on consumer risk assessments and is independent of the active substance intrinsic properties while providing the highest levels of protections to consumers. In the setting of import tolerances for international trade, it is only the provisions of Regulation 396/2005 that apply. The provisions of Regulation 1107/2009 (including the specific cut-off criteria provisions) should not prevent the legal decision making process in setting import tolerances in the EU. **We would ask that legal clarity be provided to explain which provisions of Regulation 396/2005 require the application of hazard based criteria and not the accepted risk based approach.**

When setting import tolerances, consideration must also be given to the EU's obligations to comply with the provisions of the WTO Sanitary and Phytosanitary Agreement. In particular, we would highlight Article 5.1 of the SPS agreement which states that SPS measures must be based on risk consideration:

> *"Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."*

The SPS agreement does not include hazard-based criteria that would justify any measure restricting trade. The decision to use hazard classification properties as cut-off criteria in the context of an active substance approval applies for European approvals only, and has no legal endorsement outside the EU. Within the WTO context, we are extremely concerned that a violation of the agreement by the EU could only encourage other WTO members to use their own 'protectionist' criteria - and this presents a significant threat to the future use of the SPS agreement itself. This should be given due consideration by the European Commission. **We would therefore ask that legal clarity be provided to explain the EU's compliance with the provisions of the SPS agreement.**

As a final point, we would also highlight that a restrictive EU interpretation would also raise issues in the implementation of the EU's legislative frameworks for both pesticides and biocides. While the hazard based criteria are introduced in both pieces of legislation, derogations are in place in both Regulations; and the derogation allows authorisations where products comply with a full risk based evaluation and where there is a socio-economic need. While the provisions vary between the two Regulations, we would underline that such approvals would require the setting of MRLs to allow the continued use of the product[1]. It is therefore illogical to introduce an automatic refusal of applications to set import tolerances when the setting of EU MRLs will be required in similar situations for EU uses. **Further consideration and clarification is required regarding the future need for EU MRLs for substances impacted by the hazard criteria.**

To conclude, we believe that the trade restrictive policy, denying import tolerances for cut-off crop protection active substances, is contrary to EU principles and policy priorities. It is not required by EU legislation, will not make imported food safer, will unnecessarily disrupt the global trade of food and feed and is not compatible with the EU's international obligations. Import tolerances should be set when necessary to support the trade of food and feed, and are proven to be safe for consumers - based on the evaluation of an appropriate data. This policy should be independent of the authorisation status of the active substance in the EU.

We urge the European Commission to review its current position and would request an urgent response to the issues raised in this letter. If you require clarification on any of the issues raised, please let me know.

Yours sincerely

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[1] An MRL would be required to uses granted under Article 4.7 of Regulation 1107/2009. For biocidal uses, MRLs will be required in future for certain uses.