



December 11, 2017

European Commission
EU-TBT Enquiry Point
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Re: European Commission WTO TBT notification G/TBT/N/EU/521 proposal to reclassify propiconazole

Submitted to: usatbtep@nist.gov; grow-eutbt@ec.europa.eu

Dear Sir or Madam:

CropLife America (CLA) appreciates the opportunity to provide comments on the European Commission (EC or Commission) World Trade Organization (WTO) notification G/TBT/N/EU/521 announced on October 12, 2017. As described in the WTO notification, the purpose of the draft proposal for an adaptation to technical progress of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) is to amend table 3 (formerly table 3.1) to Annex VI of the CLP Regulation by introducing new and revised entries for the harmonized classification and labelling of 34 substances (including propiconazole), and deleting one substance. CLA comments will reflect concerns about the process which we believe to be inconsistent with the EU obligations under the World Trade Organization (WTO) Rules, including those under the Technical Barriers to Trade (TBT) Agreement.

Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners.

CLA and its member companies support a rigorous, scientific, risk-based approach to regulating pesticides, as conducted by the United States Environmental Protection Agency (EPA). Regulating substances based on risk assessment provides a more predictable regulatory framework that provides for consistency among regulators worldwide. We have significant concerns with the EU draft proposal concerning the proposed amendment to Regulation (EC) No 1272/2008. Propiconazole would be restricted in use due to the EU's hazard-based cut off criteria for regulatory non-approval for plant protection products and pesticide Maximum Residue Limits (MRLs).

In Part 3, Table 3.1, on page 5, the chemical Propiconazole, Index No. '613-205-00-0, has the proposed classification of Repr. 1B. Previous evaluation of the data by the EC, and as supported by regulatory authorities across the globe, would not result in a Repr. 1B classification. The category 2 classification, as proposed by Finland, is more appropriate and consistent with earlier ECHA proposals for similar compounds.

The proposal to classify propiconazole as R1B, which is one of the EC's hazard-based cut-off criteria, is not based on any new studies, data or risk assessments, and would lead to the lowering of the EU MRLs to 0.01ppm. This would lead to major disruptions in US and global trade, and limit the options US growers have for controlling diseases and other pests that impact yield and quality.

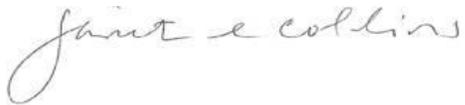
Accordingly, we object to the EC's proposed reclassification of propiconazole and express concerns with the EC's proposed hazard-based pesticide policy which would have broad and significant potential negative implications for US and global trade. Further, the use of a hazard based approach to regulation conflicts with the WTO's agreed and stated policy to use a scientific risk-based process, per Article 5 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

Regulating crop protection products and other chemicals based on risk assessment (rather than hazard-based assessment and use of cut off criteria) provides a scientifically based framework for regulation and an approach that is more predictable and ensures consistent protection of human and environmental health.

If this reclassification of propiconazole is adopted by the EC, as proposed, it could have significant implications for growers of certain specialty and vegetable crops and broader implications for US agriculture and global trade for uses of triazoles which may be at risk for non-renewal and lower MRLs (default of .01ppm) based solely on hazard-based classifications in the EU.

CLA has significant concerns about the classification of propiconazole and other compounds based on the EU use of a hazard-based assessment, and cut off in its MRL development. We believe these reclassification outcomes are inconsistent with the EU obligations under the WTO Rules, including those under the Technical Barriers to Trade (TBT) Agreement.

Respectfully,



Janet E. Collins, Ph.D., R.D
Executive Vice President, Science and Regulatory Affairs