March 20, 2017

European Commission EU-TBT
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Re: Notification to WTO – Draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron
Submitted to usatbtep@nist.gov; grow-eu-tbt@ec.europa.eu

Dear Sirs:

CropLife America[1] appreciates the opportunity to provide comment on the European Commission (EC or Commission) WTO notification G/TBT/N/EU/447 which includes the draft Commission Implementing Regulation amending or withdrawing the authorization of plant protection products containing diflubenzuron[2] (Draft Implementing Regulation), in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011.

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 Implementing Regulation concerning the proposed amendment to or withdrawal of the authorizations for diflubenzuron use. Diflubenzuron would be restricted to use on non-edible crops; crops treated with diflubenzuron would not be approved for entry in the food or feed chain.

CLA comments will reflect concerns about the process; concerns 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.

[1] CLA is the not-for-profit national trade association representing the nation's developers, manufacturers, formulators and distributors of plan science solutions for agriculture and pest management in the U.S. Our member companies produce, sell and distribute virtually all crop protection technology products used by American farmers.

[2] Regulation, European Commission XXXX. 2016. Draft Implementing regulation concerning the conditions of approval of the active substance diflubenzuron EU447_EN_1_1 Diflubenzuron. http://ec.europa.eu/info/law/betterregulation/initiatives/ares20163071834/feedback/add_en 3 http://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country_ID=EU&num=437&dspLang=en&basdatedeb=&basdatefin=&baspays=&basnotifnum
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Following amendment of the EU approval (Commission Directive 2010/39/EU) of diflubenzuron, specifically, during the EU evaluation (under Article 21 of Regulation 1107/2009) and peer-review of the confirmatory data provided on diflubenzuron, EFSA reported that it found the metabolite and impurity 4-chloroanaline (PCA) to be an *in vivo* genotoxic and carcinogenic agent. However, the genotoxic and carcinogenic potential were not observed in studies when evaluated using an appropriate animal model for human exposure to diflubenzuron, and hence to the PCA as a metabolite and impurity. Furthermore, in the EU harmonized classification, 4- chloroaniline (PCA) is a category Carc 1B[3], and therefore defined as a 'relevant' impurity, in this case an impurity of diflubenzuron.

During this review, ***a new concern was identified on potential exposure to PCA as a residue, given the genotoxic and carcinogenic properties of PCA.***

The EU Notification (G/TBT/N/EU/447) to restrict use of diflubenzuron is based on the European Food Safety Authority (EFSA) hazard profile of a low-level production impurity and possible plant metabolite PCA. The, EFSA proposed classification,[4] as genotoxic, is not aligned with the Carc 1B determination within the EU harmonized classification, as referenced above. Furthermore, evaluations on the safety of diflubenzuron, conducted by the World Health Organization (WHO) and the European Medicines Agency (EMA) concluded that PCA should be considered as a non-genotoxic carcinogen based on the weight of scientific evidence.

EFSA's review reported that it was not possible to establish any harmful effect of exposure to residues of PCA by consumers, consequent to application consistent with good plant protection guidance, given the absence of a threshold for acceptable exposure. However, the registrant submitted data into the EU Annex 1 renewal review of diflubenzuron to address that question by EFSA. The definitive negative assessment for genotoxic potential ***could be reached*** if the study data from the *In-Vivo Mutation Assay at the cII Locus in Big Blue® Transgenic F344 Rats and Micronuclei Analysis in Peripheral Blood* were to be considered during the EFSA review. In fact, the result of the *in-vivo* mutation assay study provides reliable and robust evidence that PCA is not a genotoxic carcinogen. This failure to consider these newly-derived data provided by the applicant, with relevant comments from the applicant, limit the relevance of the outcomes reported.

Considering the degree of existing scientific support for use of diflubenzuron, we strongly contend that limiting the use and potentially withdrawing the authorization for use of diflubenzuron in the EU, based upon the presence of an impurity in formulation with the active ingredient diflubenzuron, is premature and requires further scientific inquiry. The apparent conclusions of EFSA, drawn from its assessment did not include new data submitted to the EU for specific review of PCA. To confirm the assurance of the safety of the impurity (in the *in-vivo* assays and the definitive *in vivo* mutation assays), the renewal review of diflubenzuron must be opened for a more thorough and relevant assessment that includes all data and commentary submitted into the EU Annex 1.

Per WTO Rules, and under the TBT Agreement, measurements taken under the TBT Agreement must not be "more trade restrictive than necessary," to achieve a policy objective.

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[3] EU Regulation 1272/2008 I. Annex VI.

[4] European Food Safety Authority; 2015; Conclusion on the peer review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA. EFSA Journal 2015: 13(8): 422.

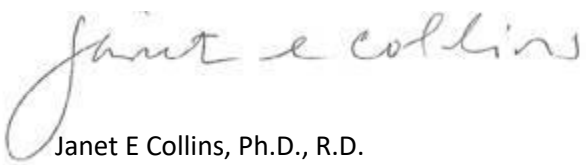
Subsequent trade impacts of such a measure would be significant were there to be the consequent revocation of EU MRL's; for impacted commodities, could be affected for decades to come. Therefore, we strongly believe the notification to WTO needs serious consideration as to the legitimacy of the recommended measure, in view of the lack of a complete scientific assessment, including data submitted in response to questions about potential genotoxicity of an impurity, for the conclusions.

Withdrawing, or limiting use of, diflubenzuron from the market, based on a conclusion not supported by a complete review of available scientific evidence, represents a measure that is more restrictive than necessary. In a process that follows a scientifically based weight-of-evidence approach, any concern regarding perceived absence of data would dictate a renewal review of the data, rather than a conclusion that where data are potentially lacking, there is a negative human health impact.

CLA is strongly opposed to the process followed for the scientific review of the dossier, and the conclusions drawn by EFSA as to the genotoxicity of an impurity in diflubenzuron, but nevertheless used as the basis for the WTO Notification to amend use categories and potential withdraw diflubenzuron from the market in the EU.

Thank you for consideration of these comments. CropLife America is available to address any questions or concerns you might have regarding these comments (jcollins@croplifeamerica.org; +1-202-833- 4474).

Respectfully,



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