July 27, 2018

Michael Goodis, Director
RD/OPP/EPA
1200 Pennsylvania Ave
Washington, DC 20460

Anita Pease, Acting Director
AD/OPP/EPA
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Formulation with preservatives

Dear Mr. Goodis and Ms. Pease:

CropLife America (CLA), the Center for Center for Biocide Chemistries (CBC), and RISE (Responsible Industry for a Sound Environment) wish to provide details on an urgent product formulation issue. Preservative products containing the active ingredient 1,2-benzisothiazolin-3-one (BIT; CAS Reg No. 2634-33-5) are used in the formulation of many hundreds of agricultural pesticide products by many registrants to manage potential bacterial growth. Without it, registrants cannot maintain quality end-use product that meet specifications and can be applied.

The precursor chemical o-nitrochlorobenzene, essential to the manufacture of BIT products, is sourced almost exclusively from China. As part of a random facility inspection process, the Chinese government has recently shut down key production facilities of this precursor for an extended and unknown period of time. We are concerned that other Chinese facilities producing o-nitrochlorobenzene may be subject to the same fate.

Some suppliers of BIT preservative products have recently provided *force majeure* notices to customers that supplies are likely to be interrupted and supply contracts cannot be met. As a result, registrants are scrambling to find alternate sources. Many Confidential Statements of Formula (CSFs) for crop protection products may now list sole suppliers for BIT. Wholesale amendment of hundreds of CSFs in a short period of time to designate alternate suppliers, even by notification, would be an unmanageable burden, both for EPA and the registrants. From a limited number of respondents, we have already determined that more than 600 products are affected. Without resolution, the situation portends disruption of supplies of crop protection products, and consequent threats to food production.

We recommend, as a short-term solution, allowing registrants to self-certify the necessary changes to CSFs, in order to avoid market disruptions by these unforeseen circumstances. Such self-certification could be limited strictly to adding alternate comparable sources for this specific ingredient, and should apply equally to the crop protection products using the BIT preservative products, and to the preservative products themselves, whose registrants may need to seek alternate sources of the BIT active ingredient. Subsequent routine changes to any of the CSFs could highlight the previous self-certification for attention by reviewers.

This urgent approach could serve as a robust pilot project for a broader policy of self-certification for CSF amendments, with the goal of improving efficiency, reducing regulatory burdens, and reducing workload of EPA reviewers.

Due to the urgency of this situation and the large number of products potentially impacted, we are seeking resolution on behalf of the industry as soon as possible. Please let us know if there is any additional information that you need in order to address this request promptly. We are sharing this letter with our colleagues in other registrant trade associations, and anticipate they may contact you as well.

Sincerely,

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American Cleaning Institute (ACI)