



June 12, 2018

CropLife America (CLA) appreciates the opportunity to provide comments to the European Food Safety Authority (EFSA) on its scientific report, “Establishment of cumulative assessment groups of pesticides for their effects on the nervous system.” CropLife America supports science-based efforts to harmonize regulatory actions between countries to prevent unnecessary adverse trade impacts and to support the consumers’ confidence in regulatory actions taken by competent governmental authorities globally.

CLA was established in 1933 and 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 vital and necessary crop protection and biotechnology products used by farmers, ranchers and landowners in the United States. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products can be used without causing unreasonable adverse effects to either human health or the environment both in the United States and around the globe.

CLA has three primary concerns with the EFSA’s proposed approach to cumulative assessment of pesticide groups. First any cumulative risk assessment grouping should be based on a common mode of action among the pesticides in the grouping. The proposed “effects” categories are too broad to permit toxicologically meaningful groupings. Therefore, this grouping will result in cumulative risk cups being inappropriately “full,” and uses and products will be unnecessarily lost.

Our second concern is that it is very unclear how exposure will be considered in EFSA’s approach. Common (i.e., concomitant) exposure is a key part of any cumulative risk assessment. There must be a transparent and scientific method and basis for concluding that there is any common exposure between chemicals that have been identified to have a common mode of action before they are included in a cumulative risk assessment.

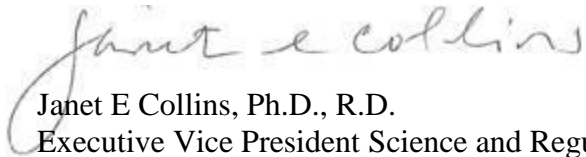
Finally (our third concern), the approach being proposed by EFSA is an exclusionary rather than an inclusionary approach. The chemical is to be included in the cumulative assessment unless the registrant provides data to show it can be excluded. A more appropriate alternative approach would be that the chemical only is included when it is clearly demonstrated that there is a common mode of action and common exposure.

The United States Environmental Protection Agency (EPA), upon passage of the Food Quality Protection Act (FQPA), has over the last two decades taken a great deal of time establishing and conducting cumulative risk assessments for chemicals that act by a common mechanism (i.e., or mode) of action.

We strongly encourage EFSA to consider addressing these concerns related to a common mode of action, and concomitant exposure to prevent the loss of uses, products and import MRLs that will adversely affect trade with no additional protection of human health. Under separate cover, CLA is providing a listing of documents with hyperlinks to support the CLA positions outlined.

In sum, CLA appreciates this opportunity to provide comments to EFSA on the approach it proposed to use in conducting cumulative risk assessments and the grouping of chemicals. We hope our comments will be considered to further harmonize approaches among regulatory authorities, and which could assist to avoid actions that unnecessarily impede global trade.

Respectfully,

A handwritten signature in cursive script that reads "Janet E. Collins". The signature is written in black ink and is positioned above the printed name and title.

Janet E Collins, Ph.D., R.D.

Executive Vice President Science and Regulatory Affairs