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OPP Docket
Environmental Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

Ms. Monique Perron
Health Effects Division (7509P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW.
Washington, DC 204060-0001

Re: Docket ID No. EPA-HQ-OPP-2015-0422, Draft Guidance for *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis Purpose*

Dear Ms. Perron:

CropLife America (CLA) appreciates the opportunity to review and comment on the subject notice [EPA-HQ-OPP-2105-0422, Draft guidance for Pesticide Cumulative Risk Assessment: Framework for Screening Analysis Purpose]. Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

CLA represents interests of its member companies by, among other things, monitoring legislation, federal agency regulations, and actions and litigation that impact the crop protection and pest control industries, and participating in such actions when appropriate. CLA is committed to working with the U.S. Environmental Protection Agency (EPA or the Agency), as the primary federal agency responsible for the regulation of pesticides, to encourage practical, science-based regulation of its members' products.

Comments are provided on the following aspects of the document: the framework, exposure refinement options, candidate Common Mechanism Group (CMG) endpoint selection, policy timing and typographical errors.

Framework

CLA supports the general proposed framework for the conduct of screening level cumulative analyses as a practical and tiered methodology which makes use of existing single chemical assessments to address cumulative requirements under the Food Quality Protection Act (FQPA). We appreciate the goal of avoiding both unnecessary complexity and additional resources by EPA and registrants alike, when a screening level assessment provides assurance of meeting EPA's established protection goals. The framework also provides a tiered approach for use of additional information and further refinement, as

needed, rather than prematurely and unnecessarily eliminating products due to over precautious or simplistic calculations.

In particular, we appreciate EPA's emphasis on a weight of evidence (WoE) approach for the construction of candidate Common Mechanism Groups (CMGs), which is principally driven by knowledge of toxicological mode of action (MoA) or adverse outcome pathway (AOP), and that this provides the strongest information and foundation for establishing a CMG. We agree with the Agency that shared chemical structure is not solely sufficient for considering a candidate CMG nor is information on the pesticidal MoA, although both providing possible useful starting points. We support the statements by EPA reaffirming the Agency's position that common mode of action forms the basis of CMGs and not apical outcome or non-specific effects, such as body weight changes.

Exposure Refinement

Within the existing document, one key point is unclear regarding how much refinement could be pursued within the screening level framework. In the introduction and also with the provided example of abamectin, it is implied that higher tiers of dietary exposure data may be used. However, the specific "Tiers" (tiers) described on page 11 indicate that if the existing single chemical assessment was unrefined, no additional information such as percent crop treated (PCT) or United States Department of Agriculture (USDA) Pesticide Data Program (PDP) monitoring data would be used in a screening cumulative level assessment. The inclusion of such data could result in a CMG passing from screening to a standard cumulative assessment with additional toxicology testing to set a common point of departure (POD), without making full use of simple refinements available from existing PCT or PDP information. There may be cases where a cumulative screening assessment does not pass for a particular CMG because the individual chemical assessments are overly conservative (i.e., tolerance level residue values used), but there is no realistic or actual potential for significant cumulative exposure.

We recommend that the finalized document include additional steps to ensure that all existing data for exposure refinement be included in the assessment prior to new toxicological testing requirements. In addition, defining the use patterns of the chemicals within a candidate CMG and a resistance management statement for all products could be considered. If there are use restrictions that limit the number of applications of products within a CMG, those label restrictions may need to be taken into account in the lower tier assessments of this screening assessment framework.

Specifically for the dietary components, the final guidance should provide examples of options that exist between a Tier 4 screening-level cumulative dietary assessment and a highly refined cumulative risk assessment (such as those that have been conducted for OPs, and NMCs). The 5th bullet on page 11 should be expanded to provide examples of additional refinements that could be incorporated into screening-level cumulative assessments.

Below we offer two examples of refinements that could be explored to yield a cumulative assessment that would still be considered 'screening-level:'

- For example, a CMG may contain two active ingredients for which the single pesticide assessments both assume tolerance-level residues and the initial screening-level chronic assessments (Tiers 1 through 4) show unacceptable risks. In this case, it would be appropriate to consider incorporating average residues and/or PCT into each of the single chemical assessments, and subsequently putting those results through the four tiers.

- Another example would be a CMG in which relatively unrefined residue estimates from a single chemical constitutes the dominant source of exposure in a screening-level cumulative assessment. It would be relatively straightforward to refine the residue estimates for that single chemical (e.g., field trial residue data, monitoring data, etc.) and subsequently assess if this refinement would result in a passing screening-level assessment.

Similarly, for the screening-level residential exposure analysis, care should be taken not to sum the exposures from too many separate scenarios. In general, the residential aggregate exposure calculations in a single chemical assessment do not necessarily include exposure estimates for all of the uses for that chemical. Rather, a subset of uses that could reasonably be expected to occur on the same day is included in single chemical aggregate assessments. It is reasonable that the screening level cumulative assessment would be subject to the same constraints.

For example, if the single chemical aggregate residential assessment for Chemical A includes a broadcast turf use, pet spot-on and indoor broadcast spray, and the assessment for Chemical B includes a broadcast turf use, pet spray and indoor fogger, the screening level assessment would include no more than three uses, selected as initially suggested in Tier 1. From the current language in the Tier 1 description, it isn't entirely clear that the screening Chemical A and B cumulative assessment should not include the worst-case broadcast turf use, the pet spot-on and pet spray, indoor broadcast spray and indoor fogger.

The existing text suggests there would be no more than three uses in a screening-level assessment. We recommend that a more detailed explanation for how a reasonably conservative screening level assessment would be constructed be included in any final guidance developed. The draft guidance also does not make clear how co-occurrence information would be incorporated into a Tier 3 residential assessment. We recommend that addition of more explanatory text and an example be added to the final guidance.

Endpoint Selection

The procedures to establish an assessment endpoint for the Candidate CMG should be clarified in the final guidance. There is some ambiguity in the food exposure section regarding the chemical to which the calculated exposure is compared—will it be the *most potent* chemical or a *reference* chemical? Similarly within the residential exposure section the implication is very strong that the index chemical is the most potent chemical (but confusingly also called highest risk/lowest MOE). Perhaps the confusion arises from awareness of the existing guidance for cumulative assessment where the index chemical is defined as the chemical with the most robust toxicological database. Thus, it would be helpful to have a clarification in the final guidance that the reference chemical in the screening assessment may be different from that in the existing guidance, and that in the screening assessment the most potent chemical should be the reference (which appears to be the intent).

Policy Procedures

We recommend that careful consideration be given to the means by which the policy provided in the final guidance document would apply to newly- registered chemicals whereby, for example, a Tier 4 dietary or Tier 3 residential screening analysis did not result in an acceptable screening level cumulative analysis. Recently registered compounds may not have immediately available the refined data (toxicology and/or monitoring data) which would be needed for the Cumulative Risk Assessment according to this proposed policy. We would not want to see EPA decline to register valuable new uses or actives in a Candidate CMG if these screening level analyses are not acceptable. Screening level assessments should be used

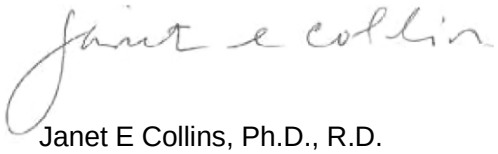
as a method to avoid unnecessary work for lower risk compounds and not as a method for denying regulatory decisions or action.
We continue to support EPA making regulatory decisions based on risk-based and sound science. We strongly believe that it would not serve the interests of the risk assessment process that such new uses or active ingredients to be declined for registration by EPA should these screening level analyses not be acceptable.

Finally, while we appreciate the Agency's transparency in sharing the framework and posting it for public comment, we note that this draft policy was implemented simultaneously with the regulatory cumulative risk assessment for abamectin and emamectin. While an example for the proposed policy is helpful, it is reasonable that any new policy be implemented only after finalization.

Typographical errors
On page 11, in both of the first two bullet points (labeled "Tier 1" and "Tier 2") — the subject of the second sentence in each paragraph should be 'exposure' not 'residue.' "Tier 1" bullet point, second sentence: "The summed residue value…" should be "The summed exposure value value…." "Tier 2" bullet point, second sentence: "This residue value..." should be "This exposure value…. "

In conclusion, CLA appreciates the opportunity to comment on the proposed draft framework for screening level cumulative risk assessments. We generally support the straight forward approach that has been outlined in the document. The approach is consistent with existing guidance for conducting cumulative risk assessments. We applaud EPA's prudent use of critical resources by consistent use of existing data as efficiently as possible.

Respectfully submitted,



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