



April 14, 2016

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

RE: Preliminary Pollinator Risk Assessment to Support the Registration Review of Imidacloprid. 81 FR 2012. January 15, 2016. Docket ID Number EPA-HQ-OPP-2008-0844

Ladies & Gentlemen:

CropLife America (CLA) is the national trade association that represents the manufacturers, formulators and distributors of pesticides. CLA's member companies produce, sell and distribute virtually all of the vital and necessary crop protection and biotechnology products used by farmers, ranchers and landowners. On behalf of our members, we frequently engage with our nation's leaders on Capitol Hill as well as federal, state and local regulatory agencies in pursuit of common-sense policies and regulations. CLA comments on regulatory actions involving individual products when there are issues that have implications for a broad range of pesticide products.

Most of the comments in this letter are of a general nature, along with some specific points to improve the preliminary Pollinator Risk Assessment for Imidacloprid and the on-going assessments of other neonicotinoid insecticides. Detailed technical comments are provided separately by the imidacloprid registrants.

Using Sound Science

We support EPA's general approach to rely on a science-based risk assessment process regarding pollinators. Much of the national and international conversation regarding bees and neonicotinoids has been driven by misinformation, and is not supported by scientific research or practical experience. Protecting pollinators is essential, but it is important that our regulations are based on sound science and not manipulated to satisfy only those voices that cry the loudest. Although there are several specific points that need further refinement, there is much in the risk assessment that we can agree with.

Little Risk to Honey Bees

It is important to note that most uses of imidacloprid pose little risk to honey bee colonies. The Agency's assessment evaluated 37 different use patterns of imidacloprid and found only three that reached even a theoretical level of concern. This finding refutes allegations by those who

claim these products are harming bees. We would note, however, that this important finding is not highlighted in the report and is not even mentioned in the Agency's public communications about the Risk Assessment. Given the strong public interest in bees and the importance of neonicotinoids to agriculture, this point should be more clearly communicated. In particular, the fact that one of the major uses of imidacloprid, the use on corn seed treatments, was found to be of very low risk, was not mentioned or highlighted in media accounts.

Risks Can Be Addressed

Risks for cotton and citrus can be minimized. Of the many use patterns evaluated, only two crops – cotton and citrus – were identified as having “potentially high” risks for some uses. Common sense label restrictions that reduce potential exposures to safe levels can be crafted to address any substantive issues with these current uses. Such label changes would lower risks to bees and allow farmers to continue to protect their crops from destructive pests.

Bee Incidents Are Few

The lack of bee incidents confirms the safe use of imidacloprid. Despite its widespread use over many years, the Report found only 15 incidents involving imidacloprid – and half of those involve uses that are no longer allowed on the label. In fact, *there has not been a single documented bee colony loss* in the United States that can be attributed to exposure following a legal application of imidacloprid.

Honey Bees Are Not in Decline

Honey bees are not in decline; pesticide risks should be put in the proper context. Government records show the number of U.S. colonies has increased since imidacloprid was first registered in 1994. This fact is in contrast to the general public perception that bees are in decline. The EPA should not perpetuate this confusion by enacting unnecessary risk mitigation measures that are disproportionate to the problem, especially when other more important factors are known to affect bee health adversely.

Uncertainty Does Not Imply Risk

The Report noted that more information is needed on some crops to fully complete a colony-level risk assessment, but this is both impractical and unnecessary. An accepted practice in risk assessment allows the bridging of residue data across similar crops and use patterns. The thousands of residue samples collected for this reevaluation was an extraordinarily massive effort – *ten times larger* than the number of residue samples required to support a robust human dietary risk assessment.

EPA Media Statements Are Misleading

EPA's public communications are at odds with the Risk Assessment. While we applaud the science-based approach to this evaluation, we were surprised to see the disparity between the Report findings and the public statements provided in the Agency's press release. Instead of

reassuring the public that most uses of imidacloprid pose little risk to bees, the Agency chose to highlight the few cases of minor risks, which creates the exact opposite impression. While such language may appease anti-pesticide groups, it unnecessarily frightens the public and drives a wedge between those who grow our food and those who eat it.

Imidacloprid Is Not Harming Bee Colonies

The data reviewed to support the conclusion that imidacloprid is not harming bee colonies is extensive. The reevaluation of imidacloprid was a comprehensive approach to pollinator risk assessment, which reviewed 5 years of new data; evaluated multiple use patterns and thousands of new residue samples; and included a thorough review of the available scientific literature. The weight of evidence clearly shows that labeled uses will not harm honey bee colonies. This review, coupled with a documented history of safe use, is good news for the growers who depend on this product, and for the general public as well.

Summary

The EPA should emphasize publicly the relevant facts about imidacloprid and honey bees, as it finalizes the risk assessment. Honey bee populations are not declining, nor is there evidence that labeled uses of imidacloprid are affecting colony health. Most uses of imidacloprid pose little risk to honey bees, and label changes can mitigate potential risks in the two crops that were identified in the Report. Moreover, the number of documented bee loss incidents involving imidacloprid is miniscule, especially when one considers its widespread use on many crops over the past 20 years.

The EPA should speak out against the misperceptions involving imidacloprid and honey bees. In fulfilling its mission to protect human health and the environment, EPA must rely on the best available scientific information. After careful consideration of all the data, it is apparent that this product is not responsible for colony decline. This conclusion has important implications for agriculture and should be communicated plainly and clearly to the general public.

Specific Technical Comments

CropLife defers to more detailed analysis of the assessment by the registrants of imidacloprid. However, there are a number of technical points in the assessment which are relevant generally to how EPA conducted this assessment and that, if addressed, could improve future similar assessments of other insecticides.

Toxicity Endpoint Selection

There appears to be a variety of errors in this section of the imidacloprid assessment which include significant overestimates of contact toxicity. Of greater impact is the decision by EPA to use a flawed bee chronic oral toxicity endpoint. This endpoint comes from a study that has significant methodological deficiencies and that reported results which are contradicted by a

number of higher-quality studies. EPA should use the most reliable data available in an assessment of any pesticide.

Fate and Persistence

The Risk Assessment makes several unsupported and unwarranted statements on the persistence and potential accumulation of imidacloprid in soil. The half-lives estimated by EPA do not represent the field data available to the Agency, and are based on an incorrect selection of the kinetics model. Mistaken estimates could lead to unsupported regulatory concerns.

Exposure Estimates

Imidacloprid is supported by one of the most extensive data sets developed to derive bee exposure estimates. EPA's approach to deriving estimated environmental concentrations (EECs) from the submitted data is overly conservative and tends to use maximum field measurements. In several cases the EPA methodology resulted in EECs more than 10-fold greater than those calculated by registrants. EPA should support using bridging of residue data across crops, so that colony-level assessments may be completed on all use patterns.

Off-field Risk

In assessing the risk of foliar applications to pollinators in off-field habitat, EPA did not follow methodology that has been vetted via the established procedures for developing science policies or new methods, as part of a pesticide assessment. EPA should develop a general methodology for off-field assessment and solicit input from scientists and the public before applying such methodology to a particular product under review. The Agency's current assessment for off-field risk due to spray drift should be viewed as a Tier 1 screening assessment that greatly overestimates the real-world exposure and potential risk. It is not sufficiently rigorous for use to determine label use directions.

Incident Reports

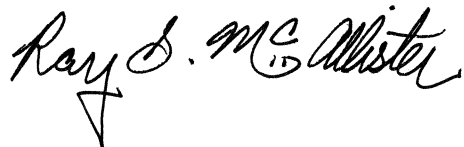
Simply put, more than half (8) of the very low number (15) of incident reports implicating imidacloprid are for uses that are no longer permitted on the current label. That such a low number of incidents have been reported is another indication that this and similar products can be used with minimal risk to honey bees.

Evaluation of Current Labels

There are errors in the label matrix prepared by EPA to summarize current uses of imidacloprid. The registrants will provide corrected information, but inaccurate descriptions of the current use pattern can raise unnecessary concerns. Any EPA assessment should use correct labels to accurately describe the current use patterns, which, in this case, indicate many label restrictions that reduce potential exposures to honey bees and other pollinators.

We appreciate the opportunity to provide these comments on the imidacloprid assessment.

Sincerely,

A handwritten signature in black ink that reads "Ray S. McAllister". The signature is written in a cursive style. Below the signature is a small, simple line drawing of a downward-pointing triangle.

Senior Director, Regulatory Policy
CropLife America