



November 1, 2019

Environmental Protection Agency
Office of Pesticide Programs
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Submitted via email to: OPPeco@epa.gov

Re: CLA public comment on EPA’s Draft Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis

CropLife America (CLA), established in 1933, 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 the crop protection and biotechnology products used by American farmers. CLA appreciates the opportunity to comment on Environmental Protection Agency (EPA)’s Draft Guidance¹ for Waiving the Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis referenced in a news release² published on EPA’s website on September 17, 2019.

CLA supports EPA’s decision to waive the sub-acute avian dietary study for some pesticides. Allowing this waiver will increase the efficiency of the pesticide registration process by reducing time and number of animals required for conducting and reviewing pesticide toxicity studies.

The sub-acute dietary study simulates a realistic exposure scenario than the acute oral gavage study (dietary vs. a one-time bolus dose), however, the acute oral gavage study alone provides sufficient information on which risk management decisions can be made, because the sub-acute dietary study rarely changes the outcome of the acute risk assessment. This is supported by the retrospective analysis of avian acute risk assessments for pesticides published by EPA and People for the Ethical Treatment of Animals (PETA).³ The analysis showed that the acute risk assessment conclusions for birds were driven by the results of the acute oral gavage study for 99% of the 119 pesticides analyzed.

¹ “Draft Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registrations,” *United States Environmental Protection Agency*, September 17, 2019. <https://www.epa.gov/sites/production/files/2019-09/documents/draft-waiver-guidance-avian-sub-acute-dietary.pdf>

² “EPA Releases Draft Policy to Reduce Pesticide Testing on Birds,” *United States Environmental Protection Agency*, September 2019. <https://www.epa.gov/pesticides/epa-releases-draft-policy-reduce-pesticide-testing-birds>.

³ Hilton, G.M. E. Odenkirchen, M. Panger, G. Waleko. A. Lowit, A.J. Clippinger. 2019. Evaluation of the avian acute oral and sub-acute dietary toxicity test for pesticide registration. *Regulatory Toxicology and Pharmacology*, 105:30- 35

CLA concurs with the conditions described by EPA under which a waiver for the avian sub-acute dietary study would not be granted. When these conditions are met, there is clearly additional scientific information required that the sub-acute dietary can provide. We are currently preparing recommendations for how a sub-acute dietary study could capture the most scientifically robust information possible, when such a study is warranted.

Thank you for reviewing these comments. Please contact CLA if you have any questions or require additional information.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Manojit Basu', with a long horizontal stroke extending to the right.

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