UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON.
D.C. 20460

OFFICE Of' CHE:\IICAL SAFETY A.ND POI.I.I-'TION PREVENTIO:\

February 18,2011

Mr. Steve Ellis
Secretary, National Honey Bee Advisory Board
20591 Co Rd 5
Barrett, MN 56311

Mr. David Mendes
American Beekeeping Federation
3525 Piedmont Road
Building 5, Suite 300
Atlanta, GA 30305

Mr. Kenneth Haff
American Honey Producers Association
604 3rd Avenue, Southeast
Mandan, ND 58554

Mr. Jay Feldman
Beyond Pesticides
70 I E Street, Southeast, Suite 200
Washington, DC 20003

Ms. Heather Pilatic
Pesticide Action Network North America
49 Powell Street, Suite 500
San Francisco, CA 94102

Mr. Justin Augustine
Center for Biological Diversity
P.O. Box 710
Tucson, AZ 85702

Dear Sir or Madam:

Thank you for your December 8, 2010, letter to Environmental Protection Agency (EPA) Administrator Lisa P. Jackson concerning the insecticide clothianidin. Since EPA's

Office of Chemical Safety and Pollution Prevention's Office of Pesticide Programs is responsible for the regulation of pesticides in the United States; I appreciate the opportunity to provide a detailed response to your concerns. I want you to know that EPA continues to advance its regulatory and scientific approaches to ensure honey bees and other pollinators are protected, and if scientific information shows a particular pesticide is posing unreasonable risk to pollinators, we stand ready to take the necessary regulatory action.

Clothianidin was originally evaluated for registration through a North American Free Trade Agreement (NAFT A) Joint Review with Canada and was identified as an alternative to the organophosphate insecticides, a class of insecticides that is generally very highly acutely toxic to bees and, unlike clothianidin, also very highly acutely toxic to humans and wildlife. During the clothianidin registration process, hundreds of studies were reviewed and evaluated. When EPA granted the initial registration for clothianidin seed treatment uses in 2003, the Agency determined that the uses met the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) risk/benefit standard for registration.

Your letter refers to the "imminent hazard" you believe to be posed by clothianidin and urges the Agency to issue a "stop use order" to address the situation. Let me clarify how a stop sale, use and removal order operates. The Agency is authorized to issue a stop sale, use, and removal order under section 13 of FIFRA in response to a violation of FIFRA or after a pesticide has been cancelled or suspended. 7 U.S.C. ~ 136k(a). Since clothianidin has not been cancelled or suspended and there has not been a violation of FIFRA, it is unclear what basis the Agency would have for issuing such an order.

When an actual imminent hazard exists, the Agency may suspend the pesticide registration in accordance with the provisions of section 6(c) of FIFRA. 7 U.S.C. ~ 136a(c). To do so, however, the Agency needs to determine that such an imminent hazard exists based on reliable scientific information. Although your letter references EPA's November 2, 2010 memorandum regarding the reclassification of a clothianidin field study, and "(t)he science that the agency has, [sic] and the independent literature," you provide no explanation, evidence, or data to support an Agency finding of imminent hazard.

Through this letter the Agency is seeking to set the record straight and resolve any confusion about the meaning of the reclassification of the clothianidin field study from acceptable to supplemental. The 2003 registration of clothianidin was conditionally granted based, among other things, on the submission of a field test for pollinators. The registrant addressed this requirement with the field study (MRID 46907801 and 46907802) that you reference in your December 8, 2010 letter. This study has undergone several reviews since its submission and initial evaluation in 2007. The study was originally classified as an acceptable study (that is, a study that fully satisfies a test guideline), but is now classified as a supplemental study (that is, a study that provides scientifically-sound information, but did not follow all protocols set forth in EPA test guideline).

A modification in the Agency's assessment of this study is reflective of EPA's improved understanding of honey bee biology and the recognition in the scientific community of the challenges associated with field pollinator study designs. While elaborate

field studies can be designed, there may be confounding factors which limit, but do not entirely discredit, the utility of a study. It is clear that field pollinator studies cannot be viewed in the same context as laboratory studies where experimental conditions can be strictly controlled. Recognizing the complexity of conducting and interpreting field studies, EPA has made the best use of existing data. Although deficiencies were noted in this specific pollinator field study, including some cross contamination between treated and non-treated (control) plots, there was useful information that has been used to better understand hive survival following exposure to c1othianidin.

The Agency bases pesticide risk characterizations on the entire body of information submitted by the pesticide registrant and open scientific literature data. For c1othianidin, the weight-of-evidence risk characterization was based on 34 studies and not on the findings of a single, specific field study. Therefore, the reevaluation of the study in question does not change the Agency's conclusion that the registered uses of c10thianidin meet the FIFRA risk benefit standard for registration. Clothianidin generally poses less risk to agricultural workers and fish and wildlife when compared to the organophosphate insecticide alternatives. While the acute laboratory data show that clothianidin is toxic to honey bees, as are most insecticides, current labels for clothianidin products used as foliar treatments include bee hazard statements that prohibit applications when plants are flowering and bees are in the area. At this time, we are not aware of any data that reasonably demonstrates that bee colonies are subject to elevated losses due to chronic exposure to this pesticide. Based on EPA's thorough review of the scientific information, EPA does not intend at this time to initiate suspension or cancellation actions against the registered uses of clothianidin.

We know that as science advances, EPA must vigilantly improve our scientific methods to ensure pollinators are protected. We are actively involved in on-going research that is addressing the potential role pesticides may play in the status of honey bees and native bees. EPA proposed a global workshop that was organized by the Society of Environmental Toxicology and Chemistry (SETAC) on January 16 - 21, 2011. This scientific meeting was held to address advances in study designs and improve risk assessment approaches for honey bees. We currently anticipate proposing a revised risk assessment process for pollinators to the FIFRA Scientific Advisory Panel in 2012 for independent external peer-review. [t is our expectation that the open and public process to be used for developing these revised risk assessment methods will increase understanding and strengthen the scientific and regulatory processes for protecting honey bees and pollinators.

Given the concern about the neonicotinoid class of pesticides and protection of bees, the Agency has also accelerated scheduling the comprehensive re-evaluation of these pesticides in the registration review program. EPA's registration review docket for c1othianidin will open this year. We are coordinating re-evaluation of the neonicotinoid insecticides with California's Department of Pesticide Regulation and Canada's Pest Management Regulatory Authority.

I hope this response clarifies the issues raised in your letter of December 10, 20 10. Our office looks forward to working with all interested stakeholders to ensure protection of

honey bees from pesticides. If you have any further questions, please contact Kimberly Nesci at 703-308-8059.

Sincerely,

Steven P. Bradbury, Director Office of Pesticide Programs

cc: Kimberly Nesci, OPP