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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUL 22 2013

To: Registrants of Nitroguanidine Neonicotinoid Products

Subject: Registered Products Containing Imidacloprid, Dinotefuran, Clothianidin or Thiamethoxam

Dear Registrant:

As you are aware, the Environmental Protection Agency (EPA) has been actively involved in pollinator protection. Although research conducted by the U.S. Department of Agriculture has not demonstrated that Colony Collapse Disorder, nor the broader declines in pollinator health, are caused by pesticides, this research has indicated that pesticides in combination with other factors (e.g., pests, pathogens, nutrition, bee management practices) may be associated with the declines. The relative contribution of these factors, however, has not been identified. Based on potential effects of neonicotinoid insecticides on honeybees and other pollinators as well as recent bee kill incidents in Oregon and Canada, which may indicate that applicators are not aware of the potential for harming bees when they use these products, EPA is concerned about potential adverse effects on non-target arthropods, including pollinators. Consequently, EPA is initiating a project to develop clearer language that will strengthen pollinator protective labeling on neonicotinoid products by more effectively highlighting the risks to pollinators. The intent is to achieve clarity and consistency as well as to highlight pollinator protective text to both commercial applicators and general consumers. All registrants of products containing imidacloprid, thiamethoxam, clothianidin and dinotefuran are being notified of this project.

EPA is developing new label language that will apply to all neonicotinoid products registered for outdoor sites, regardless of formulation or intended user. The language being developed will incorporate advice received through the Office of Pesticide Program's Federal Advisory Committee (the Pesticide Program Dialogue Committee). It is essential to this critical effort that registrants adopt these label statements. It is our goal to have this language on as many products as possible by the 2014 use season and we will consider an appropriate regulatory response if registrants decline to adopt the new language. We expect to send you the label statements in early August. To facilitate this implementation it would be helpful if you could provide the following:

- Production cycle for the subject products
- Timeframe of next product label printing

This information would be of most use to the Agency if provided within 7 business days from receipt of this letter.

With this letter we are also informing you that we are requiring the submission of product performance (efficacy) data. While EPA has generally waived the requirement to submit product performance data for non-public health pests, all registrants must ensure through testing that their product is efficacious when used in accordance with label directions. As stated in Title 40 of the Code of Federal Regulations section 158.400(e), test note 1, EPA reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration. At this time we are requesting that you submit product performance (efficacy data) that describes the movement and concentration of active ingredients and major degradates in plant structures, fluids and tissues over the period when efficacy is expected for specified insect pests within 30 working days of the date of receipt of this letter. Based on the data received, EPA may request additional product performance (efficacy) data.

In addition to the efficacy data described above, we are also requesting that you submit a synopsis of your company's pollinator stewardship plan(s) for both agricultural and non-agricultural registrations. All of the information described above should be submitted to Meredith Laws, U.S. Environmental Protection Agency, Office of Pesticide Programs, 1200 Pennsylvania Ave., NW (Mail Code 7505P), Washington, DC 20460. Courier deliveries may be made to Meredith Laws, Office of Pesticide Programs, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA 22202.

Finally, as noted above, OPP is concerned about reports of adverse incidents involving pollinators, particularly honeybees and bumblebees. As a registrant of pesticide products registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), you are required to notify the EPA pursuant to FIFRA section 6(a)(2) of any "*additional factual information regarding unreasonable adverse effects on the environment*."

EPA's implementing regulations at 40 CFR Part 159 identify the types of information that registrants must submit to the Agency pursuant to FIFRA section 6(a)(2). Those regulations include a provision that requires registrants to submit information that "*the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a pesticide or about the appropriate terms and conditions of registration of a product*," 40 CFR 159.195(a), and a provision requiring that information be submitted if "*the registrant has been informed by EPA that such additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product*." 40 C.F.R. §159.195(c). By this letter, OPP is reminding you of your general obligations under 40 CFR 159.195(a), and is informing you of certain specific types of information that it considers reportable under 40 CFR 159.195(c).

If, after the date of this letter, your company, any subsidiary of the company, or any consultant, attorney, or agent who acquired such information while acting as a consultant, attorney, or agent for your company, receives any studies showing that any of imidacloprid, thiamethoxam, clothianidin or dinotefuran is more persistent or is found in greater amounts in any portion of a plant than has previously been reported in a study submitted to the Agency (or is present in any portion of a plant at all if no previous study has been submitted to the Agency), or learns of any incidents or allegations of incidents involving harm or potential harm to pollinators resulting from exposure to imidacloprid, thiamethoxam, clothianidin or, dinotefuran, such information must be reported to EPA's Office of Pesticide Programs as adverse effects information under section 6(a)(2) of FIFRA. The submission of such information must meet the requirements of 40 CFR §159.156, and the information must be received by EPA no later than ten (10) days after you or your subsidiary, consultant, attorney, or agent first receive the study or learn of the incident or allegation. Information on bee kills must not be aggregated, regardless of the number of individual pollinators involved in any incident.

If you or your subsidiary, consultant, attorney, or agent currently have information in your files that would be reportable to EPA under the previous paragraph and that has not yet been provided to EPA, you must provide such information to EPA, following the requirements of 40 CFR §159.156, on the accelerated 10 day schedule. Any information currently in your possession related to an incident previously reported to EPA need not be provided again in response to this letter.

Please note that the requirements to report information to EPA pursuant to section 6(a)(2) continue as long as the product is registered, and must be reported consistent with the terms of this letter unless the Agency notifies you in writing of any modification to the terms of this letter. In addition to submitting the information consistent with the requirements of 40 CFR §159.156, I request that you provide an additional copy of any 6(a)(2) information to Meredith Laws at the address listed above.

If you have any questions about this letter, please feel free to call Lois Rossi at (703) 305-5447 or Meredith Laws at (703) 308-7038.

Sincerely,

Steven Bradbury, Ph.D., Director
Office of Pesticide Programs