



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

APR 02 2015

To: Registrants of Nitroguanidine Neonicotinoid Products

Subject: New and Pending Submissions for Outdoor Uses of Products Containing the Nitroguanidine Neonicotinoids Imidacloprid, Dinotefuran, Clothianidin or Thiamethoxam

Dear Registrant:

You are receiving this letter because your company has submitted an application for a new outdoor use and/or holds registrations for products containing imidacloprid, dinotefuran, clothianidin or thiamethoxam that have use directions for outdoor application.

## I. Background

EPA is committed to developing a robust and science-based understanding of the implications of the use of nitroguanidine neonicotinoid pesticides. To that end, as you know, EPA has required that the registrants of these pesticides submit data (pollinator hazard and exposure) to inform this issue. EPA will specifically receive data on potential impacts of a pesticide on developing bees (larvae, pupae), oral exposures and data which examine potential adverse effects on honey bee colonies. These data are being generated now under the Registration Review program for this class of pesticides. The Registration Review schedule for these chemicals has been accelerated.

Separately, the Agency is also in receipt of a number of new use registration applications for these same pesticides. In the absence of the new studies, the Agency does not believe it has sufficient information to support a determination that new outdoor uses will meet the FIFRA registration standard for the pesticides imidacloprid, clothianidin, thiamethoxam and dinotefuran. EPA believes that until the data on pollinator health have been received and appropriate risk assessments completed, it is unlikely to be in a position to determine that such uses would avoid "unreasonable adverse effects on the environment" as required under FIFRA to support further regulatory expansion of these pesticides in outdoor settings. Affected actions include:

- New or Modified Uses (including crop group expansion requests)
- Changes to Existing Use Patterns (ex. adding aerial or soil application or significant formulation changes)
- Experimental Use Permits
- New Special Local Needs Registrations

Accordingly, until EPA receives and assesses the outstanding pollinator health data, EPA is unlikely to be in a position to grant any submitted registration action that involves a request with one of these pesticides for a new outdoor use or use expansion. However, EPA acknowledges that the merits of individual actions may differ and that, for example, a pest management need could arise during this interim period that would support the issuance of an emergency exemption request under FIFRA section 18. EPA will assess such requests by relying on currently available information and risk mitigation strategies. This announcement does not preclude the approval of products that are identical or substantially similar to existing uses (i.e., “me-too” products).

## **II. Products affected**

This letter applies to any future submissions or submissions that are currently under review in the Agency for outdoor use(s) (excluding “me-too applications/products and FIFRA section 18 submissions that are consistent with EPA regulations) for pending and existing products containing the active ingredients imidacloprid, thiamethoxam, clothianidin, or dinotefuran.

## **III. What you need to do**

For your registered nitroguanidine neonicotinoid products with a pending new outdoor use/expansion and/or any pending nitroguanidine neonicotinoid registrations with a new outdoor use, EPA requests that registrants withdraw or modify those impacted actions (where applicable by deleting the outdoor new use) by April 30, 2015. If your company does not have any pending outdoor use applications (excluding “me-too applications/products or FIFRA section 18 submissions) then no action is needed.

### **A. Address**

For impacted actions that can be modified by deleting the pending outdoor use, you may send the revised cover letter and CD/DVD containing the revised label(s) by courier service to the Document Processing Desk address listed below by April 30, 2015.

### **Personal/Courier Service Deliveries (e.g., FedEx)**

The following address should be used for resubmissions that are hand-carried or sent by courier service Monday through Friday, from 8:00 AM to 4:30 PM, excluding Federal holidays.

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
ATTENTION: Resubmission/Revision to a Nitroguanidine Neonicotinoid

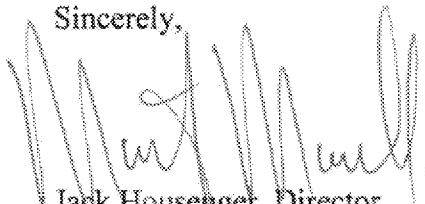
**B. Email withdrawal request to Product Manger**

For pending affected actions with the EPA, it is requested that the registrants email the withdrawal request directly to the product's Product Manager (PM) by April 30, 2015.

For imidacloprid, clothianidin and thiamethoxam -- please direct your email to Venus Eagle, PM01: eagle.venus@epa.gov. For dinotefuran -- please direct your email resubmission to Mark Suarez, PM07: suarez.mark@epa.gov.

EPA considers the completion of the new pollinator risk assessments for these chemicals to be an agency priority. Following that review, the agency expects to be in a position to make determinations under FIFRA Section 3 for new outdoor use applications for products containing imidacloprid, dinotefuran, clothianidin and thiamethoxam. Updates to this position, and EPA's assessments will be added to the Registration Review docket for each chemical. If you have any questions about this letter, please feel free to call Susan Lewis at (703) 305-8009 or Meredith Laws at (703) 308-7038.

Sincerely,

B-1  *acting*  
Jack Householder, Director  
Office of Pesticide Programs