From: Ray McAllister
To: Laws, Meredith
Subject: RE: Neonic label questions for EPA
Date: Wednesday, September 04, 2013 3:54:04 PM

Registrants have received differing responses on some of these questions, leading to some confusion. We want to maintain a level playing field for registrants so that they all have consistent answers, as well as minimize confusion for product users and applicators. Therefore, a written response would be most helpful. Alternatively, would it work better for a few of us to call you to discuss the answers to these questions?

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From: Laws, Meredith [mailto:Laws.Meredith@epa.gov]
Sent: Wednesday, September 04, 2013 12:40 PM
To: Ray McAllister
Subject: RE: Neonic label questions for EPA

Hi Ray:

Thank you for the email, however I'm a little surprised by it. We have been meeting individually with these and other companies and have been answering questions during the meetings. As we continue with the meetings, we will make sure we address each of these concerns.

Meredith

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From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, September 04, 2013 8:54 AM
To: Laws, Meredith
Subject: Neonic label questions for EPA

Meredith:

Representatives of Bayer, Syngenta, Valent, and Landis (on behalf of Mitsui) are working together to seek consistency and/or clarity regarding the new label requirements for foliar uses of neonicotinoid insecticides. The work group has asked me to send these questions of clarification, and to request that the answers be provided also to the various state regulators through SFIREG or other appropriate means. We are sharing this message also with other registrants of neonicotinoid products. We anticipate that there may be other questions in the next few weeks.

1. **Must the bee icon be printed in color on the labels?** Adding color to a label that is currently black and white is expensive, and could potentially lead to delays in getting the new labels into the market place. A very preliminary inquiry indicates that addition of the colors to the label can increase label costs by 30% to nearly 90%. If a company chooses to put the bee icon in color on the label, we need more details on the specific requirements, such as the number of colors, possibility of using alternate icon images, etc.

2. **Must all three use instruction statements be included on each label?** Some registrants have received indications that it is not necessary to print all three 'Direction For Use' statements on products labels with no agriculture uses. We understand that it will be acceptable to include only the non-agriculture 'Direction For Use' language [i.e. Statement #3] for products intended solely for non-agricultural uses. Please confirm.

   If this practical approach is taken for the non-agricultural use products, we would like to propose that instruction #3 be excluded from labels that have only agricultural uses.

3. **Can use instruction statement number two be clarified to specify that pre-bloom applications are permitted?** It is our understanding from EPA personnel that pre-bloom applications are not restricted. However, we have heard conflicting interpretations of the statement from state regulators. Some see no problem in applying pre-bloom applications, as the language is written. Others had not thought of the potential problem in interpretation. And still others say that, as written, the language clearly precludes the use of pre-bloom applications. Prohibiting pre-bloom applications can lead to serious gaps in insect pest protection for some crops. Growers, EPA, beekeepers, and registrants cannot afford the confusion that would lead to differing interpretations by state regulators in enforcing the new label language. We are seeking written clarification from EPA on this point.

4. **Can exceptions be added to use direction statement number three?** Three of the exceptions allowed for 'Direction For Use' statement #2 could and should be pertinent for non-agricultural uses, particularly for treating commercially grown ornamental plants. These exceptions include: after sunset, below 55F, and government-initiated public health response.

5. **How can we make existing pollinator-protective information in crop-specific use directions compatible and consistent with the new label language?** Dr. Bradbury's letter of August 15 states:
   "EPA acknowledges that these labeling changes are generic in nature and that

there may be existing pollinator safety information on your current label that may not be fully compatible with the generic statements attached to this letter. We also recognize that there could be product-specific pollinator language that provides additional protection and EPA does not intend that this language be removed."

Many labels currently use the following statement in crop-specific use directions: "Do not apply this product while bees are foraging" or "Do not apply pre-bloom or during bloom or when bees are (actively) foraging". In order to be consistent with the new label statements, we would propose either deleting that statement from crop-specific use direction (in deference to the new statement, which makes it redundant), or adding to it the following statement: "Do not apply this product until flowering is complete and all petals have fallen unless one of the conditions specified under point 2 of the Bee Hazard Direction for Use is met."

6. The instructions from Dr. Bradbury's letter state: "At this time these statements are not intended to be placed under each crop or site." At the registrant's discretion, would it be permissible to place the bee icon adjacent to foliar uses on the label, as a means of referring the user to the pollinator protection instructions, or should the icon only appear with the pollinator 'Directions For Use' language?

7. **How much time will be allowed to get amended labels into the marketplace, once they are approved by EPA?** The Agency should allow a specific, reasonable time for this transition, rather than a blanket requirement of "next label printing." While we understand the urgency of this need, it would be reasonable to specify the next label printing following approval by all relevant state regulatory agencies. Details of the time allowed should not introduce a penalty for those registrants who quickly comply with the label requirements. Several reasons make this approach necessary:
   a. Registrants should not be asked to assume the liability of printing labels, packaging products, and releasing them for shipment, absent approval from all states where the products are sold. Otherwise, the registrants risk fines levied by state enforcement personnel for misbranded products.
   b. We anticipate that EPA will use its influence to expedite the approval by states of the amended labels. Nevertheless, this would provide no guarantee that the process will proceed without a hitch.
   c. The next production cycle and label printing for some products may come as early as November. Completing the approval process in the states by that time would be impossible, even assuming everything goes smoothly in the EPA approval process.
   d. Many products have sub-registrations. The label printing and product packaging processes must be propagated through these channels.

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