

Neonicotinoids: EPA's New Get-Tough Measures

Law360, New York (September 25, 2013, 6:27 PM ET) -- Throughout 2013, the issue of the contribution of pesticide use to the decline in honeybee colony health, known as colony collapse disorder (CCD), has been increasingly controversial. Of particular concern is the role that a particular class of pesticides, known as neonicotinoids, may play in CCD.

The neonicotinoids are a new class of insecticides that have seen relatively strong market adoption as the U.S. Environmental Protection Agency has moved to restrict the availability of many previously widely used organophosphate insecticides. The organophosphate insecticides remain effective but have been restricted most commonly due to concerns with the possible risks to workers who apply the pesticides or due to concerns for possible effects of the residues of organophosphates on various food products.

The transition to this newer chemistry for controlling insect pests has been hastened by the more stringent requirements of the Food Quality Protection Act (FQPA), enacted in 1996, as it was designed intentionally to impose enhanced requirements and regulatory scrutiny of possible human health risks in the food supply.

Is it possible that the move away from one class of insecticides to meet tougher food safety standards has led to greater risk to honeybees and other pollinators? Possibly — though the evidence for possible adverse impacts on pollinators from the neonicotinoid compounds is less than definitive, and much new research is underway.

EPA officials have maintained for some years that although pesticide exposures play a role in nontarget effects on bees and other pollinators, pesticide exposures are one of a variety of factors that appear to contribute to colony health and not the dominant factor behind CCD.

The other factors include habitat loss as more acreage is put into production with higher commodity prices, infections by the varoa mite that can severely impact colony health and the discovery of additional pathogens that appear to be affecting the vitality of hives. Stakeholders in the pesticide industry should be aware of new developments that significantly impact the regulatory and legal landscape of this issue.

Two significant regulatory events have occurred in 2013. First, the European Food Safety Authority (EFSA) on Jan. 16, 2013, released risk assessments for three widely used neonicotinoids — clothianidin, imidacloprid and thiamethoxam — finding that all three pose acute risks to bees and that certain uses may not be acceptable.

This led later in the year to a two-year suspension of the registration of these three insecticides. The

suspension of use for these pesticides in the European Union placed even more pressure on the EPA to react to the issue.

While the EPA did generally maintain its view that pesticides, including the neonicotinoids, are one of many factors in contributing to CCD, in July 2013, the EPA took steps to control more stringently the foliar use of neonicotinoid pesticides, including the ones affected by the EU suspension.

The EPA informed the registrants of these products that it sought to impose new label language to better protect pollinators to be in effect for the 2014 growing season. (The EPA also added an additional insecticide, dinotefuran, which was the insecticide involved in a recent bee kill incident in Oregon.)

The EPA described these more-stringent requirements as a goal and sought further information about the timing of production cycles for these compounds to accommodate and coordinate how best to meet this goal for 2014.

At the same time, to emphasize its seriousness, the EPA stated that they “will consider an appropriate regulatory response if registrants decline to adopt the new language.” In EPA-speak, this is a thinly veiled threat of cancellation under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) statute. More specific instructions were sent to the registrants in a separate letter in August 2013 to detail what label language would now be required.

In addition, the EPA’s July letter to the affected registrants required the submission of product performance data to help evaluate the longevity of residues of these pesticides on treated crops, thereby posing a potential exposure to nontarget bees and other pollinators. These data should already be in hand by the companies and generally should not require much new data generation at the present time.

The last mandate in the July letter was to announce that the EPA would interpret current regulations for reporting “adverse effects” as required by FIFRA to include submission of information about “incidents or allegations of incidents involving harm or potential harm to pollinators” from the neonicotinoids, with a requirement that such information be submitted to the EPA within 10 days after learning of the information.

Registrants of the affected insecticides reacted to the pronouncements with general cooperation while expressing some disappointment in the EPA’s tone, especially concerned that it might signal a turn away from the EPA’s conclusion that pesticides should not be singled out as the major cause of CCD.

As one can expect, additional restrictions on these pesticides was welcomed and applauded by those who are convinced the pesticide use is a major, if not the major, contributor to CCD. At the same time, these critics of neonicotinoids cited shortcomings in the EPA’s new approach (e.g., not suspending use of the products altogether as was done in the EU).

The EPA’s most recent “get tough” approach is a new labeling requirement issued Aug. 15, 2013, and available online, and it holds some additional implications. As the label will include more restrictions and mandatory language (e.g., “do not use while bees are foraging” instead of “avoid use while bees are foraging”), such language will present new and additional enforcement and liability issues with the more explicit instructions.

This may especially affect the users and applicators of the pesticides — especially as the language has restrictions that may conflict with a situation needing immediate use of the insecticide or impose timing restrictions that are impractical in a particular setting (e.g., certain crops have the potential for attracting pollinators through much of their life cycle).

There is also concern expressed by some that the EPA's pronouncements indicate a reactive mode or self-imposed mandate to "do something" not consistent with the EPA's previous (and still current) conclusion that pesticides are a possible, but not dominant, contributor to CCD.

In particular, some cite the implied urgency of the need for reporting any bee kill incidents or allegations within 10 days — a time period that is shorter than the EPA allows for reporting for known or alleged incidents of causing a human fatality. This gives credence to the claim that the EPA now seeks "to protect bees more than people" — a claim that the EPA would deny but belies the concern that the EPA is reacting to the situation with more haste than deliberation.

Some see this especially ironic since, as discussed earlier, the adoption of neonicotinoid compounds is to some degree a response to the more stringent regulatory requirements imposed by the EPA to better protect and improve the human health safety of the food supply.

Lastly, there is also concern that the EPA will extend these requirements regarding pollinator protection to broader classes of chemistry (e.g., all insecticides) where there is even less evidence of excessive or novel harm to pollinators (there will likely always be some baseline risk as insecticides are designed to kill insects, and bees are insects).

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