wiley

NEWSLETTER

Little-Noticed Provision of National Pollinator Strategy May Lead to Most Impact

June 2015

Many in the agricultural chemical industry greeted the Administration's May 19th "National Strategy to Promote the Health of Honey Bees and Other Pollinators" with relief, because it did not focus on pesticides until page 47 of a 53-page report. The measured nature of the Administration's approach indeed merits commendation. But buried in the document was announcement of an initiative that will trigger broad impacts far beyond recent attention to neonicotinoids. It is EPA's intention to restrict the use of 76 active ingredients considered "acutely toxic to bees." And with a May 29th *Federal Register* notice (80 Fed. Reg. 30644), the Agency opened a 30-day comment period on that initiative. That notice merits much wider attention than it has been receiving.

Most of the pesticide-related actions in the "National Strategy" and its appendices had been telegraphed by earlier EPA actions. For example, in August 2013, the Agency imposed new bee-protective language on neonicotonoid products. More recently, the Agency announced its intention not to grant label expansions of four neonicotinoid pesticides until new bee-impact assessments are completed. (The products are imidicaloprid, clothianidin, thiamethoxam, and dinotefuran.) And expansion (and thus necessarily delay) of registration review analyses to incorporate pollinator effects studies hardly comes as a shock.

But the new strategy also announced EPA's proposal to prohibit foliar application of "acutely toxic pesticide products during bloom for sites with bees on-site under contract." The May 29th *Federal Register* notice describes the affected products as those with an acutely lethal dose to 50% of bees tested of less than 11 micrograms per bee, based on acute contact toxicity testing. The more comprehensive

Authors

David B. Weinberg
Senior Counsel
202.719.7102
dweinberg@wiley.law

Practice Areas

Environment & Product Regulation

Extended Producer Responsibility and Recycling

document made available for comment identifies 76 active ingredients as meeting that test. *EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products* at 17 (May 28, 2015). The list appears in the below table.

Appendix A – List of Registered Active Ingredients That Meet the Acute Toxicity Criteria

EPA's proposal is to require registrants of products containing these active ingredients to add a label prohibition of use "from onset of flowering until flowering is complete when bees are on-site under contract," except in limited cases. The approach harkens back to 15 to 20 years ago, when EPA requested that registrants "voluntarily" drop uses asserted to create unacceptable risks to children as part of the Agency's implementation of the Food Quality Protection Act (FQPA). That pressure resulted in a series of immediate cancellations and phase-outs, often documented in "memoranda of agreement" between the Agency and product registrant.

Many of the same issues that arose under FQPA are likely to arise here: questions about the validity of the pertinent testing, timing of label changes to avoid disadvantaging competitive products and—perhaps potentially most disruptive commercially—possible decisions by some registrants who have taken a lead on product defense to finally throw in the towel.

Registrants and user groups thus should consider the implications of EPA's proposal carefully. Far more than consensus on appropriate label language (as to which EPA has requested comment) is at issue. For example, in some FQPA cases, user groups who failed to adequately explain to the Agency the vital need for particular products found a vital crop protection tool canceled. In others, market segmentation led to different views among registrants of the substantially similar products as to what limitations would be acceptable, or even whether continued registration remained economically viable. Some companies with dominant positions as to particular active ingredients, but patented alternatives in their portfolios, were inclined to enter into "phase out" agreements covering the older products, and negotiated draft agreements before only belated notice of impending changes was received by generic registrants. Even if such situations do not arise here, the inclusion of so many older products on the target list means that a generic registrant or set of generic registrants may have succeeded to the role of principal product steward, but may not be staffed adequately to evaluate or respond on a timely basis to this challenge.

In short, from the registrant's perspective, this proposal merits careful evaluation by both regulatory and commercial teams. Potential responses may differ among companies and, within individual companies, with regard to alternative products.