

Clear Supply Chain Roles, Responsibilities Help Avoid FIFRA Violations, Attorneys Say

July 23 — Pesticide registrants, companies that produce pesticides under contract for registrants and supplemental distributors should clearly distinguish their related but separate roles and responsibilities to avoid running afoul of the Federal Insecticide, Fungicide, and Rodenticide Act's requirements for supplemental distribution, attorneys from two law firms said July 23.

Lisa Burchi and **Sheryl Dolan**, with **Bergeson & Campbell, P.C.**, and **Jon Jacobs**, cofounder of **Jacobs Stotsky PLLC**, spoke during a webinar, “EPA's Supplemental Distribution: Enforcement Actions Are Buzzing: How to Avoid Getting Stung.” Jacobs spent nearly 26 years in the Environmental Protection Agency's Office of Enforcement and Compliance Assurance before cofounding his law firm.

The webinar was spurred by penalties the agency has assessed since 2012, when its National Program Managers Guidance directed EPA regional inspectors that enforcing compliance with FIFRA's supplemental registration requirements was a mandatory focus area. Similar language is found in the agency's Fiscal Year 2014 guidance.

Compliance with the EPA's requirements is seemingly straightforward and involves following basic business practices such as being clear about who is responsible for what tasks and routine communications among all players, Dolan told Bloomberg BNA after the webinar.

Yet violations can occur unintentionally in the complex supply chain that exists among pesticide registrants, the companies that make the registered pesticide—often toll manufacturers that work under contract with registrants—and supplemental distributors that distribute and sell the product, Dolan said.

Recent Violation

The case of Zep Inc., which recently agreed to pay \$905,000 to settle allegations that it violated FIFRA's requirements for supplemental distributors, illustrates the agency's enforcement efforts.

The EPA accused Zep of selling an inaccurately labeled pesticide product and failing to properly register as a supplemental distributor.

Zep sold an antimicrobial product known as Formula 165 as a supplemental distributor on behalf of the product's registrant, Lanxess Corp., which took over the registration for the product in April 2010 from Clariant Corp., for which Zep had previously distributed the product. Zep, however, didn't get EPA approval to serve as a supplemental distributor for Lanxess until January 2012 (136 DEN A-12, 7/16/14).

Some Violations Easy to Find

A label violations is a pretty straightforward case for the EPA to make, because the agency can easily compare the label it approved for a registered product with the label on the product being sold, Dolan said.

Another fairly straightforward violation for the EPA to enforce is the sale, by a distributor, of a pesticide that the agency has canceled, she said.

During the webinar, Dolan offered participants advice to stay compliant.

For example, pesticide registrants should be aware of what their supplemental distributors are selling and routinely inform distributors of any changes to the product labels, she said.

Registrants also are responsible for telling distributors about cancellations and telling them if the registrant transfers the registration to another company, Dolan said.

For transfers, the new registrant and distributor will need to file a new Notice of Supplemental Distribution of a Registered Pesticide Product (EPA Form 8570-5) with the agency, Burchi said.

Toll Manufacturers, Supplemental Distributors

Another common problem that arises in the pesticide supply chain involves the blurring of the legally distinct responsibilities of a toll manufacturer and a supplemental distributor, Burchi said.

Under FIFRA, supplemental distributors are not allowed to make, package or label a pesticide, she said.

Toll manufacturers can, indeed often do produce, package and label pesticides, Burchi said. They undertake those responsibilities, however, under contracts that are worked out with the pesticide registrant.

Yet sometimes one company may take on the responsibilities of making and distributing the pesticide on behalf of the registrant and fail to ensure it has legally distinguished those obligations, she said.

A contract with a toll manufacturer may spell out specific suppliers of various active and inert ingredients in the pesticide, Dolan told Bloomberg BNA. The contracts also can spell out the concentrations of specific ingredients that the EPA has approved, she said.

Because one division of a toll manufacturer or supplemental distributor may get a better price from different suppliers, that company may start to make a pesticide using those new suppliers or with slightly different concentrations, and therefore violate FIFRA, Dolan said.

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For More Information

The EPA's Fiscal Year 2012 Program Mangers Guidance that made enforcing supplemental distribution a requirement is available at <http://op.bna.com/env.nsf/r?Open=prio-9masnv>.

EPA provided similar direction in its Fiscal Year 2014 guidance, which is available at <http://op.bna.com/env.nsf/r?Open=prio-9matm3>.

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