

Registration Transfer Challenges for Pesticide Supplemental Distributors and Registrants

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) allows pesticide registrants to distribute their registered pesticides through supplemental distributor arrangements. See 40 C.F.R. § 152.132. These arrangements allow the supplemental distributor to sell the registered product under his/her own name and product brand without having to obtain their own registration. The ability to utilize a supplemental distributor arrangement under the U.S. Environmental Protection Agency's (EPA) regulations provides registrants and distributors a flexible means to expand their market reach. But, pesticide registrations are licenses and assets that are bought, sold, and transferred when product lines and businesses change hands. As demonstrated by recent enforcement efforts by EPA, these registration transfers can create significant regulatory risk for both registrants and supplemental distributors if the transition from one registrant to another is not handled carefully.

Supplemental Distributor Authorizations

EPA allows a registered product to be distributed and sold under another supplier's name (*i.e.*, a distributor) if certain conditions are met. Such distribution is termed "supplemental distribution" under EPA's regulations. To create the arrangement, the registrant first must submit a notice to EPA (Form 8570-5) that is signed by both the registrant and the supplemental distributor. See EPA Form 8570-5, Notice of Supplemental Distribution of a Registered Product, available at <http://www.epa.gov/opprd001/forms/8570-5.pdf>. In signing the form, registrants affirm that they agree to allow the supplemental distributor to sell the registered product under the distributor's name. The notice form also includes basic information about the registrant and the supplemental distributor, the product

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name under which the distributor product will be sold, and the EPA registration number of the product.

Under the regulations, the supplemental distributor product must bear a label identical to the registered product label, except that the producer name and address may be different and the supplemental distributor may delete (but not add) certain claims made for the product. In addition, the distributor's product must be "produced, packaged and labeled in a registered establishment operated by the same producer (or under contract in accordance with 40 C.F.R. § 152.30) who produces, packages, and labels the registered product." 40 C.F.R. § 152.132(b).

In addition to submitting the supplemental distributor notice (Form 8570-5) to EPA, registrants and supplemental distributors frequently enter into contractual arrangements that reiterate regulatory requirements and establish additional terms under which the distributor's product may be manufactured, repackaged, and sold. EPA considers the supplemental distributor to be the agent of the registrant, and both parties are held liable for any violations related to supplemental distribution. For this reason, these agreements often include detailed provisions on sale, distribution, labeling, indemnification, and liability to ensure that the supplemental distributor's products are distributed and sold in compliance with EPA's regulations and allocate the risk if there is ever a problem with the product.

In some cases, the supplemental distributor is also a toll formulator or repackager of the product. In that case, the distributor must be under contract with the registrant to formulate, package, and label the product. For this reason, the registrant and the distributor may have a separate toll formulation/packaging agreement that is separate from the supplemental distribution agreement covering the commercial terms of sale and distribution.

Effect of Registration Transfers on Supplemental Distributorships

Registrations are often sold as part of the sale of a business or product line. Under those circumstances, EPA allows for a transfer of the registrations from the existing registrant to the new owner. Before a registered product may be transferred to another entity, the transferor and transferee must both sign and submit to EPA certain transfer documentation. The documentation must include, among other things, both the names and addresses of the parties and the EPA registration number(s) of the product(s) being transferred. Unlike supplemental distributor notices, which become effective at the time of submission to EPA, registration transfers are not effective until EPA approves them. See 40 C.F.R. § 152.135(e).

FIFRA regulations are silent as to when EPA is required to decide whether to approve the transfer and the process often takes several months after the documentation is submitted. The regulations also say nothing about the effect of a transfer of a registration on the continuing validity of an existing supplemental distributor arrangement. However, EPA takes the position that "[i]f the basic registered product is transferred to another company, supplemental distributorships do *not* transfer with the section 3 registration," and that "if the new registrant wishes to continue any supplemental distributorship . . . , the registrant must fill out a new . . . Form 8570-5." EPA Pesticide Registration Manual, Chapter 9, *available at* <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>. Thus, supplemental

distributors who are unaware of the transfer and have not formalized new supplemental distributor agreements with the new registrant face the risk of enforcement by EPA if they continue to produce, package, and sell distributor product under the old registration number after the transfer becomes effective at EPA.

A significant problem arises for the supplemental distributor in a transfer situation because the supplemental distributor has no control over—and may have no knowledge of—when or to whom a registration is transferred or whether the new registrant will continue a distributor agreement with them. Moreover, state registration authorities treat the supplemental distributor products as requiring their own registration. Thus, when the EPA registration is transferred, new state registrations for the supplemental distributor product must be obtained that align with the new registration number assigned to the EPA-registered product. Registration processes vary from state to state and it may take some time for state authorities to issue the approvals. In addition, new State registrations cannot be obtained until after U.S. EPA approves the transfer of the registration, further compounding the delay. So, even where supplemental distributors are aware of transfers, they may find themselves facing unexpected interruptions of their ability to sell the products involved.

EPA's regulations and policy do not provide significant help for supplemental distributors facing this dilemma. The guidance only allows for continued sale of existing stocks of products after the time of the transfer. EPA has taken the position in recent enforcement actions, that any production (formulation/packaging) after the time of the transfer under the old registration number is disallowed.

Contractual Protections for Supplemental Distributors

Given the regulatory hurdles to lawful continued production of supplemental distributor products after the sale or transfer of a product registration, supplemental distributors should ensure that their contracts put them in the most favorable position to transition smoothly. Ideally, the contracts should require that supplemental distributors are given significant advance notice of any potential transfer of the registration. They also should allow the supplemental distributor to be in contact with the potential new registrant early to begin negotiating the continuation of the supplemental distributor relationship before any regulatory notice or application filing is due. That way, the supplemental distributor product can continue with minimal interruption.

One way for a supplemental distributor to achieve this goal is to include provisions in its contract with the original primary registrant to require the registrant to (1) notify the distributor when certain transfer events occur and (2) facilitate communications between the supplemental distributor and the new registrant to continue the supplemental distribution arrangement. Ideally, the supplemental distributor should be notified prior to the sale of a product or business that includes a product registration, but this may be difficult given the constraints on the registrant to keep such pending business transactions confidential.

At a minimum, the supplemental distributor should be notified when the registrations are sold (*i.e.*, the sale of the business/product line is announced to the public) and specifically when the registration transfer documentation is submitted to EPA. This will assist the supplemental distributor in planning how it will continue to obtain and distribute the affected products in the interim before the transfer becomes effective. Finally, it is imperative that the original registrant notify the supplemental distributor when the transfer is approved by

EPA. Under EPA's current view, this date becomes the cut-off for the existing supplemental distribution arrangement. After this date, the supplemental distributor and the new registrant must establish a new supplemental distributor arrangement and go through the state registration process as outlined above.

These contractual provisions highlight the importance of continuing communication between registrants and supplemental distributors to ensure ongoing compliance with FIFRA regulations after contracts have already been signed. All parties—the original registrant, the supplemental distributor, and the new registrant—could benefit from the continuity of production and market awareness of distributor products that these contractual provisions make more possible.