Pesticide Registration Manual:

Chapter 9 - Supplemental Distribution of a Registered Pesticide

Supplemental Distribution of a Registered Pesticide

According to 40 CFR 152.132, registrants may distribute or sell their registered product under another company's name and address instead of (or in addition to) their own. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "supplemental registration" or "distributor product." The distributor, also known as a "subregistrant," is considered an agent of the registrant, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product.

Detailed information on the supplemental distribution or supplemental registration of another federally registered product can be found in 40 CFR 152.132.

Important Note: Supplemental registrations are only an extension of a currently federally registered pesticide product. They are a duplication of the basic registered product and must reflect any changes in formulation or labeling made to the basic registered product within the same timeframe imposed on that product.

- If the basic registered product is canceled, the supplemental registration is automatically canceled effective on the same date as the basic registered product, and existing stocks must be sold in the same time period (40 CFR 152.132(e)).
- If the basic registered product is transferred to another company, supplemental distributorships do not transfer with the section 3 registration. Registrants must notify all supplemental distributors of the transferred product of the transfer agreement.
- If the new basic registrant wishes to continue any supplemental distributorship or add new ones, the basic registrant must fill out a new "Notice of Supplemental Distribution of a Registered Product" Form 8570-5.

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Requirements for Approval of Supplemental Distribution

The following conditions must be met before EPA will permit supplemental distribution of a federally registered pesticide product:

- The registrant of the federally registered product for which a second party wishes to obtain supplemental registration must have submitted to the Agency a statement (EPA Form 8570-5, Notice of Supplemental Registration of Distributor) in triplicate signed by both the registrant of the basic registered product and the second party ("the distributor"). Refer to 40 CFR 152.132(a) The basic registrant is the **only one** who can submit EPA Form 8570-5 as explained in 40 CFR 152.132(a) and in the EPA Form 8570-5 instructions. The application, which includes the 8570-5 form and a cover letter must include the following information:
 - the cover letter must have the name and address of the registrant of the basic registered product;
 - the 8570-5 form must have the basic registered product and the registration number of the federally registered product; and
 - the name and address of the distributor, the distributor's company number, and the name of the distributor product. If EPA has not already assigned the distributor a company number, one will be assigned upon written request, and must be assigned before 8570-5 is completed and submitted. Refer to Chapter 14, or below, for obtaining a company number; and to Chapter 21 for the address and distribution code when submitting.

Applications that are incomplete or that contain errors will be returned with a checklist explaining the reason for rejection or disapproval.

- The distributor product is produced, packaged, and labeled in a registered establishment operated by the same producer (or under contract with basic producer according to 40 CFR 152.30) who produces, packages, and labels the basic registered product (40 CFR 152.132(b)).
- The distributor product may not be repackaged. It must remain in the basic registrant's or producer's original, unopened container. Refer to <u>Chapter 14</u>, which explains how to obtain an establishment registration.
- The labeling associated with the distributor product must be the same as that of the basic registered product, with the following exceptions:

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- the product name of the distributor's product may be different from that of the registrant's, but it may not be misleading (40 CFR 152.132(d)(1);
- the name and address of the distributor's company may appear instead of the registrant's name and address (a phrase such as "Distributed by..." must be used) (40 CFR 152.132(d)(2)), and 40 CFR 156.10(c));
- the EPA registration number of the basic registered product must be followed by a hyphen, followed by the distributor's company number (e.g., if the registration number of the registrant's product is EPA Reg. No. 999999-88888, and the distributor's company number is 777777, then the distributor's number appearing on the label should be EPA Reg. No. 999999-88888-777777) (40 CFR 152.132(d)(3));
- the establishment number on the label must be that of the final establishment at which the basic registered product was produced, which includes packaging and/or repackaging for sale (40 CFR 152.132(d)(4)); and
- any specific claims on the registrant's label, such as the sites of application or pests to be controlled, may be omitted from the distributor's product label provided that no changes are necessary in any of the precautionary or other labeling of the basic registered product (40 CFR 152.132(d)(5)).

Important Note: The distributor, also known as a "subregistrant," may not make additions to the registrant's basic product label (i.e., add claims, additional sites, or pests).

Cancellation of a Distributor Product

When a registrant enters into a relationship with a supplement distributor, for each product involved, the registrant must submit to the Agency a statement (8570-5 form) signed by both registrant and supplemental distributor that lists the names and addresses of the distributor, the distributor's company number, any additional brand names to be used, and the registration number of the basic product (40 CFR 152.132(a)). Providing a complete Form 8570-5 fulfills this requirement. Since the basic registrant is the **only one** who can submit EPA Form 8570-5 as explained in 40 CFR 152.132(a) and in the EPA Form 8570-5 instructions. A cover letter from the basic registrant including their address and reason for the application will aid in the Agency's approval process. Just as the registrant's product ("the basic registration") may have alternate brand names, a Supplemental (Distributor) Product can have multiple names associated with a product.

If a basic registrant voluntarily cancels its basic product registration, <u>40 CFR</u> <u>152.132(e)</u> states all distributor products distributed or sold under that registration number are also canceled and that the registrant is responsible for notifying all distributors of the terms and conditions of cancellation.

In addition to instances when a basic registration is voluntarily canceled, and therefore all distributor products are canceled, the registrant may wish to notify the Agency that a supplemental distributor relationship has ended. In this situation the basic registration remains but the distributor product(s) is/are canceled. There are also times when the basic registrant and/or distributor wants to remove a brand name from a distributor product while keeping both the basic and distributor registrations active. The Agency requests that these types of notifications be provided by letter. To assure efficient processing, when notifying the Agency of the end of a supplemental distributor relationship, the following should be included in the subject line and body of the request letter:

"Notification of Termination of Supplemental Distributor Agreement," then add the PRODUCT NUMBER including the distributor company number for which the relationship has ended. This will terminate all distributor products associated with the cited registrant's product and distributor company number.

When notifying the Agency of changes to the brand name of a supplemental distributor product, the following should be included in the subject line and body of the request letter:

"Notification of [Removal and/or Change] of Distributor Product Name," then add the PRODUCT NAME you would like removed or changed.

Please note, when a basic registrant terminates a supplemental registration, EPA interprets 40 CFR 152.130(c) to generally permit a supplemental distributor 18 months to sell and distribute existing stocks after the basic registrant terminates the supplemental registration. In this context, the supplemental registrant's existing stocks are only those affected pesticide products that have been released for shipment as of the effective date of termination of the subject supplemental registration. Sale or distribution of any quantities of the affected distributor product produced after the effective date of termination would be considered illegal under FIFRA.

It is important to note that while EPA regulations and policy may permit such distribution or sale of existing stocks for 18 months following termination of the supplemental distribution, the contractual arrangement between the basic registrant and the supplemental distributor may contain terms that further limit or preclude sale and distribution by the supplemental distributor (although such contractual arrangements would be enforceable through the courts, and not by EPA). The registrant and supplemental distributor are equally liable for any violations that occur during the 18 months during which the existing supplemental product can be sold, unless a contractual arrangement between the two limits the existing stocks period. The ability for the supplemental distributor to sell and distribute is linked to the liability of the basic registrant.

If the supplemental distributor is legally selling and distributing, the basic registrant is still liable for any violations. The basic registrant would not, however, be liable for any violations stemming from distributor product that is produced after the termination of the relationship.

After the relationship between basic registrant and supplemental distributor is officially and totally terminated (either by the passing of 18 months after the basic registrant notified the Agency of the end of the relationship or by a contract that finally ends the relationship earlier by disallowing existing stocks), the basic registrant is no longer liable for any violations that occur based on the distributor's product.

Concerning a Supplemental Registration of a Distributor Product

The registrant of the basic registered product should submit the completed application (cover letter and 8570-5 form) and any subsequent requests or notifications via the Pesticide Submission Portal (PSP): https://cdx.epa.gov/epa_home.asp or to Shirley@epa.gov).

For more information on electronic submissions of pesticide applications go here.

Please note, these items should not be directed/sent to the registering division or product manager.

Where to Request a Company Number

To obtain an EPA assigned company number go here.

Where to Request an Establishment Registration

Information on how and where to register an establishment (pesticide product producing facility) may be found on the <u>Pesticide Establishment Registration and Reporting</u> Web page and Chapter 14.

Contacts for More Information

For further information, please contact <u>Shirley Burgess</u> (burgess.shirley@epa.gov) or by calling 703-308-8628.

References Cited in Chapter 9

Refer to Chapter 19 for information on the sources of these documents.

Code of Federal Regulation, Title 40

- Part 152 Pesticide registration and classification procedures
- Part 156 Labeling requirements for pesticides and devices

EPA Form 8570-5 - Notice of Supplemental Registration of Distributors