**Pesticide Registration Manual:** 

# **Chapter 16 - Transfer of Product Registrations and Data Rights**

### Introduction

This chapter discusses specific information to be submitted to EPA for the transfer of product registration and/or data rights from one person or company to another, as outlined in 40 CFR 152.135 (registration transfers) and 40 CFR 152.98 (data rights transfers).

Applications for new products that are still pending registration (not registered) may also be transferred, as well as Special Local Need registrations (SLNs), Experimental Use Permits (EUPs), and Tolerance Petitions.

## **Transfer of Product Registrations**

Upon receipt and approval by EPA of the documents described in 40 CFR 152.135(b), the registration is transferred to the new registrant. At that point, the new registrant is responsible for all actions concerning that registration and is liable as the registrant under FIFRA and the regulations. The new registrant is then permitted to distribute and sell the registered pesticide without having to apply for a new registration.

### **Requirements for Approval of Registration Transfers**

Persons seeking approval of the transfer of a product registration are required to submit a document (a Transfer Agreement) signed by the authorized representative of the registrant of the product to be transferred (the transferor) and by the person to whom the product registration is to be transferred (the transferee), containing the following information (See 40 CFR 152.135(b)):

- the name, address, phone number, EPA-assigned <u>company number</u>(4 pp, 118 K, PDF), and state of incorporation (if any) of the transferor;
- the name, address, phone number, EPA-assigned company number, and state of incorporation of the transferee (Note: If the transferee does not have an EPA-assigned company number, one should be requested before a transfer request is submitted);
- the product name(s) and EPA registration number(s), or the EPA File Symbol for pending products, of the products to be transferred;
- a statement that the transferor transfers irrevocably to the transferee all right, title, and interest in the EPA registration(s) listed by product name and EPA Registration Number in the document;

- a statement that the transferred registration(s) will not serve as collateral or otherwise secure any loan or other payment arrangement or executory promise, and that the registration(s) will not revert to the transferor unless a new transfer agreement is submitted to and approved by the Agency;
- a description of the general nature of the underlying transaction, e.g., sale, merger, spin-off, or bankruptcy transfer (no financial information need be disclosed);
- a statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and
- an acknowledgment by the transferee that his rights and duties concerning the registration under FIFRA and its implementing regulations will be deemed by EPA to be the same as those of the transferor at the time the transfer is approved.

### Transferor Submission of a Notarized Affirmation Statement

In addition to the Transfer Agreement, the transferor must submit to the Agency, as required by 40 CFR 152.135(c), a notarized statement affirming that:

- the person signing the transfer agreement is authorized by the registrant to bind the transferor:
- no court order prohibits the transfer, and that any required court approvals have been obtained; and
- the transfer is authorized under all relevant federal, state and local laws and all relevant corporate charters, bylaws, partnerships, or other agreement.

**Important Note**: For the protection of all parties, it is highly recommended that the notarized Affirmation Statement be signed by an authorized person or company official other than the one signing the transfer agreement.

If the required documents are submitted, and no information available to the Agency indicates that the information is incorrect, the Agency will approve the transfer without requiring that the transferee obtain a new registration(s) and notify the transferor and the transferee of its approval.

The transfer will be effective on the date of Agency approval. Thereafter, the transferee will be regarded as the registrant for all purposes under FIFRA. The Agency cannot "postdate" or "backdate" a transfer, therefore the time it takes the Agency to process the transfer needs to be considered.

**Important Note**: When product registrations are transferred from one registrant to another, all restrictions, data requirements, conditions of registration, including timeframes for the submittal of data or other information, suspensions or any other requirements existing on the

registration are transferred with the registration. The new registrant (transferee) is responsible for adhering to or complying with all such restrictions, data requirements, conditions of registration, timeframes, suspensions, or any other requirements that have been imposed on the acquired product registration.

Rights to exclusive use of data or compensation under FIFRA section 3(c)(1)(D) are separate from the registration itself and may be retained by the transferor, or may be transferred independently in accordance with the provisions of 40 CFR 152.98. If the registrant as the original data submitter wishes to transfer data rights at the same time as the registration is transferred, a single transfer document containing the information required by this section for both the registration and the data may be submitted.

#### Timeframe for the Submittal of Data or Other Information

The new registrant is responsible for the submittal of all required data according to the schedules already established by the Agency as a result of a Data Call-In under FIFRA section 3(c)(2)(B), or a condition of the registration under FIFRA section 3(c)(7), for the acquired product registrations. Failure to comply with these timeframes may result in the issuance of a Notice of Intent to Suspend the registration of the affected product under FIFRA section 3(c)(2)(B), or a Notice of Intent to Cancel the registration of the affected product under FIFRA section 6(e).

### **Requests for Time Extensions**

Requests for the extension of time to submit required data or other information from the new registrant, merely because it acquired the registration after the FIFRA section 3(c)(2)(B) data call-in was issued, or after the conditions of registration under FIFRA section 3(c)(7) were imposed, will not be granted. If new registrants have other valid reasons for delays in the testing that were clearly outside of their control, then such a request for time extensions will be considered based on established procedures. If a registrant expects delays, and believes a time extension is necessary, the Agency should be informed as soon as possible and well before the due date.

Transfers that occur while a FIFRA section 3(c)(2)(B) data call-in is being issued or during the 90-day response time to the data call-in are subject to the same conditions expressed above.

### **Canceled Products and Unpaid Fees**

The owner of a registration is responsible for payment of any new or previously unpaid fees for product maintenance and regulatory actions, including new applications, reregistrations, amendments, or tolerances.

**Important Note**: Neither registrations nor data can be transferred while fees, including maintenance fees, are listed as unpaid. Also, canceled or withdrawn products cannot be transferred.

## **Transfer of Data and Data Rights**

The transfer of data and data rights is described in 40 CFR 152.98.

Transfer of data protection rights (including rights to exclusive use of data and/or data compensation) under <u>FIFRA section 3(c)(1)(F)</u>) is separate from the product registration itself and does not automatically transfer to the new registrant. These data and the respective ownership rights may be retained by the transferor or may be transferred independently in accordance with 40 CFR 152.98. If a registrant, as the original data submitter, wishes to transfer data rights at the same time as it transfers the registration, it may submit a single transfer document containing the information required by both 40 CFR 152.98 and 40 CFR 152.135.

## **Required Documentation for Processing Transfer of Data Rights**

A person who possesses rights to exclusive use or compensation under  $\underline{FIFRA}$   $\underline{3(c)(1)(F)}$  may transfer such rights to another person by submitting a transfer document to EPA that contains the following information (See 40 CFR 152.98(a))

- The name, address, and state of incorporation (if any) of the original data submitter (the transferor).
- The name, address, and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee). (Note: Inclusion of phone number and email address of both the transferor and transferee is highly recommended).

- Identification of each item of data being transferred including:
  - the name of the study or item of data;
- whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;
  - the name of the party or laboratory that conducted the study;
  - the date the study was submitted to the Agency;
  - the EPA document number assigned to the item of data (the Master Record Identification Number [MRID] or Accession Number), if known, if not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data;
  - a statement that the transferor transfers irrevocably to the transferee all rights, titles and interest in the items of data named;
  - a statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and
  - the names, signatures, and titles of the transferor and transferee, and the date signed.

Note Regarding Exclusive Use: Exclusive use of data does not generally extend beyond 10 years from the date of registration of the pesticide. For more information see <u>FIFRA section</u> 3(c)(1)(F) and <u>Chapter 10</u>.

**Note**: A transfer of data will not automatically be reflected on the Data Submitters List. If you wish for additions or changes to the Data Submitters List, please submit a separate request to:

#### **Document Processing Desk (DSL)**

Office of Pesticide Programs (7504P) U. S. Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Avenue, N.W. Washington, DC 20460-0001

## Notarized Transferor Affirmation Statement for Transferring Data Rights

In addition to the Transfer Agreement, the transferor must submit to the Agency, as required by 40 CFR 152.98(b), a notarized statement affirming that:

- the person signing this transfer agreement is authorized by the original data submitter to bind the data submitter;
- no court order prohibits the transfer and any required court approvals have been obtained; and
- this transfer is authorized under federal, state and local laws and relevant corporate charters, bylaws or partnership agreements.

**Important Note**: There are subtle differences in the language of the Affirmation Statement requirements outlined in 40 CFR 152.135 and 40 CFR 152.98. For transfers that include both registrations and data, one notarized Affirmation Statement may be submitted as long as it contains all of the information required by both subsections.

The Agency will acknowledge the transfer of the data by notifying both transferor and transferee, and will state the effective date of the transfer. Thereafter, the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under <u>FIFRA section 3(c)(1)(F)</u> unless a new transfer agreement is submitted to the Agency

**Important Note:** It is the transferee's responsibility to ensure that copies of all data, and any underlying raw data, are received from the transferor. The Agency does not provide such copies of data to the new registrant. The Agency requires registrants to maintain copies of all studies and the relevant raw data for the life of the registration (see 40 CFR Part 169).

**Important Note**: Registration and/or Data transfers can only be executed between existing EPA company numbers (i.e. from EPA one company number to another EPA company number). If the transferee does not have an EPA-issued company number then, one must be requested before the transfer process can begin. To request for an EPA company number please see: Pesticide Registration Manual: How to Obtain a Company Number and Register an Official Address. Note: if a company number is being transferred then, a new company number is not needed (see section "Transfer of Company Ownership").

### **Transfer of Company Ownership**

The transfer of a company ownership, including all registrations and data must also follow the requirements for transferring registrations outlined in both 40 CFR 152.135 and 40 CFR 152.98. In the section of the Transfer Agreement that refers to registrations substitute "Company Ownership."

**Company Number (Ownership) Transfers**: If the transferring parties wish to transfer an existing EPA company number (Company Transfer) the following must be true:

- The transferor is (or will be effective on the date of transfer) no longer engaged in production, sale, or distribution of pesticides and is transferring all pesticide products and data to the transferee;
- The transferee will, in effect, assume the transferor's EPA company number; or
- The transferred EPA company number will become a separate division or D/B/A of the transferee's existing EPA company number.

Example: Joe's Pesticide Company (EPA company # 1234) decides to get out of the agricultural pesticide business and sell all of its agricultural pesticide registrations and data to Lou's Pesticide Company (EPA company # 5678). Since Lou's Pesticide Company already has EPA company # 5678, the parties may transfer EPA company number 1234 to Lou's Pesticide Company/Agricultural Division. From that point, EPA company number 1234\* will be known by the name Lou's Pesticide Company/Agricultural Division (EPA company # 1234).

Another Example: The new company number could also be named Lou's Pesticide Company, D/B/A/ Joe's Agricultural Pesticides. These are just two examples.

**Important Note**: The owner of a company number must keep the Agency informed of its current name, address, and contact or authorized agent (<u>40 CFR 152.122</u>) as described in the Agency's guidance on company numbers.

## **Submitting Transfer Requests and Contacts for More Information**

To submit your transfer request or if you require additional information concerning the transfer of product registrations or data rights, please send all requests and inquiries to <a href="mailto:companyownershipchanges@epa.gov">companyownershipchanges@epa.gov</a>. ATTN: Louis Vaughn

### **Transfer Deficiencies**

If a transfer submission is found deficient, a Notice of *Transfer Deficiency* will be issued by EPA, requesting additional information or corrections. It is the Agency's policy that if the requested information is not received within 60 days of the date of the Notice of *Transfer Deficiency*, the transfer will be considered to be inactive and abandoned by the transferor and no further action will be taken on the request.

## **Sample Transfer Documents**

There is no required form for the Transfer Agreement or for the Transferor Affirmation Statement. However, as a convenience, a sample file is available: Registration and Data Transfer Agreement (rtf). Company Transfer Agreement (rtf)

## **References Cited in Chapter 16**

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

Code of Federal Regulation, Title 40

• Part 152 - Pesticide registration and classification procedures

<u>Federal Insecticide, Fungicide, and Rodenticide Act</u>, as amended by the <u>Food Quality Protection Act</u> of August 3, 1996

- Section 3 Registration of pesticides
- Section 6 Administrative review; suspension