Label Review Manual

Chapter 14: Identification Numbers



I. Introduction

The EPA Registration Number and the Establishment Number are required on all pesticide products. 40 CFR 156.10(a)(1)(iv)-(v). The purpose of an Identification Number is to provide a unique product number for regular registrations, distributor registrations, Special Local Needs registrations, and Experimental Use Permits.

II. EPA registration number

A. Purpose and Form of the Registration Number

The EPA Registration Number indicates which company holds the registration for the pesticide product, and in which sequence the product was submitted to EPA by the company. For example, the first product submission by a particular company will receive EPA file symbol -R which upon registration will become product number one; the second will be two; and so on. The registration number must be preceded by either the phrase, "EPA Registration No.", or "EPA Reg. No." 40 CFR 156.10(e). This phrase will be followed by a company number then a dash (-), and then the product number. Instructions for obtaining a company number are available at http://www.epa.gov/pesticides/bluebook/chapter14.html

B. Assignment of Registration Number

Before a pesticide product is registered under *FIFRA Section 3*, it is assigned an EPA File Symbol which is comprised of the company number followed by a series of letters representing the potential product number. Product numbers are assigned sequentially to each company. The letters are used to indicate that the product is not registered. The letters come from the word "REGULATION". Each letter represents a number starting with "1 (one)", and ending in "0 (zero)". Accordingly, R=1, E=2, G=3, U=4, L=5, A=6, T=7, I=8, O=9, and N=0.

R	E	G	U	L	Α	т	I	o	N
1	2	3	4	5	6	7	8	9	0

Therefore, if 6767-EGN were registered, it would become EPA Registration Number 6767-230. "6767" is the number identifying the company holding the registration and "230" is the number identifying that specific product.

C. Location of the Registration Number

The Registration Number must be stated on the label. Although no specific location is required, the preferred location is on the front panel near the registrant's name and address. The registration number must be set in type and style similar to and running parallel to other print on the section of the label where the registration number is located. 40 CFR 156.10 (e).

III. Distributor numbers

FIFRA and the regulations permit distribution or sale of a registered product under a distributor's name and address. 40 CFR 152.132. This is called "supplemental distribution." Although distributor labels are not submitted to EPA for review or stamped accepted, questions that concern them may arise from internal or external customers. The distributor label must be the same as that for federally registered product (basic registration) except for: product name, name and address of distributor, distributor number, establishment number (final Establishment at which the product was produced), and any claims (uses, for example) that are deleted from the label. 40 CFR 152.132(d). No new claims may be added. Distributors may not make amendments to a product's master label. Only the basic registrant can amend the EPA-approved registered label.

Subject to the exceptions above, this regulation was intended to ensure that labeling statements made for a distributor product are *identical* to those made for the EPA-reviewed and approved basic product labeling. The Agency will however, generally permit minor formatting differences, such as different label colors and backgrounds, type styles or label sizes, provided the text, prominence and location of labeling statements on the distributor label are identical to that of the basic product and that the distributor label meets all applicable regulatory requirements.

Both a registrant's name and a distributor's name can appear on the label, but it has to be VERY clear who is doing what. (see *Chapter 15*, *Company Name and Address*).

Distributor products must bear the EPA Registration Number of the basic product, followed by a dash [-], and then followed by the distributor's company number. 40 CFR 152.132(d)(3). For example, Company A has a registered product, Kill It Dead Herbicide, EPA Registration No. 262-598. Company A enters into a supplemental distribution agreement with Company B as a distributor. The Agency receives the necessary documentation substantiating this supplemental distributor arrangement and then assigns to Company B the Number 10007. The herbicide marketed by Company B (under their product name, Make It Brown Herbicide) must bear the EPA Registration No. 262-598-10007. An EPA Registration Number consisting of three sets of numbers partitioned by dashes can readily be identified as a distributor product. As discussed above, only Company A could amend the EPA-approved registered label.

IV. EPA Establishment Number

The Establishment Number is assigned by EPA Regional Offices (domestic establishments) and the *Office of Enforcement and Compliance Assurance (OECA)* (foreign establishments). See 40 CFR 167. A facility that produces pesticides must have a company number assigned by the Office of Pesticide Programs before an EPA Establishment Number is assigned. The Establishment Number is not reviewed by the Product Management teams. The PM teams only responsibility is to ensure that the number is formatted correctly.

A. Purpose and Location of Establishment Number

The Establishment Number indicates the final establishment at which the product was produced. 40 CFR 156.10(f); see also 40 CFR 167.3. This number must be preceded by the phrase, "EPA Est.," and may appear anywhere on the pesticide product label or the immediate container but it must appear on the outer container or wrapper of the product if the establishment registration number cannot be clearly read through the outer container or wrapper. 40 CFR 156.10(f). It often is grouped together with the EPA Registration Number but is not required to be. [Note: The Establishment Number may be changed by non-notification. (See PR Notice 98-10.) The final establishment where the product will be produced might not be known when the draft label is submitted, or the registrant may intend to place the Establishment Number directly on the container rather than the label, so the Establishment Number might not appear on the draft label submitted for review.

B. State Designation

As a matter of Agency practice, letters such as MO, AZ, or PA appear after the producer's company number in establishment numbers. These letters represent the state in which the product was produced.

Example 1: an establishment number may be written as EPA Est. (Company No.)-MO-1, which would indicate that the product was produced in the first establishment registered by that company in Missouri.

Example 2: If corporation XYZ's company number is 98989, and the last phase of pesticide production takes place at producing Establishment Number 002 in Hawaii, then the Establishment Number for this product would read EPA Est. 98989-HI-002.

C. Multiple Establishment Numbers

Some registrants may produce an identical product in more than one establishment. The Agency permits the use of multiple establishment numbers on products on a case-by-case basis provided that the registrants meet existing labeling requirements and follow the format for multiple establishment numbers.

Note: A company number must be in place first, then the establishment number may be set up to reflect both the state in which the establishment is registered and also, which number it is in the state itself.

If a producer lists multiple establishment numbers, the establishment number for the actual production site of a particular product must be very obviously marked or highlighted, for example, with an arrow, a notch, a bullet, etc. For instance, a master label may list three establishments in two states, all of which produce the same product. The same label can be used at all three establishments by marking the site where individually labeled products are actually produced.

Products may also be produced in sequential steps at multiple establishments. Use of the word "last" implies that a product traveled through sequential establishments during its production. Only the establishment number of the last establishment at which a product is produced is required to be on the label. 40 CFR 156.10(f). If the product is changed as it moves from site to site, the required label would change at each site so that the establishment number of the final establishment up to that point is indicated on the product label at each site.

D. Foreign Establishment Numbers

Foreign producers of pesticides or devices must also have company and establishment numbers. Instructions for obtaining these numbers are included along with general guidance on company and establishment numbers provided in chapter 14 of the Agency's registration manual at http://www.epa.gov/pesticides/bluebook/chapter14.html

V. Special Local Need (SLN) registration number

The Special Local Need registration number (SLN number) is also known as a FIFRA Section 24(c) Registration Number. 40 CFR 162.153(e). These registrations are issued by the states to meet special local needs. See 40 CFR Part 162. The number is written as "EPA SLN No." followed by the two letter state designation, then the last two digits of the year of issuance, and finally a four digit number which is the consecutive number of registrations that the registering state has issued in that particular year.

For example: If the company ABC applied for a section 24(c) registration in the State of North Carolina and it was the 34th SLN registration accepted by North Carolina in the year 1995, then the 24(c) registration number would be EPA SLN No. NC950034.

The EPA 24(c) registration number is assigned by the state and entered on the Application for Notification of State Registration of a Pesticide To Meet a Special Local Need (EPA form 8570-25).

VI. Experimental Use Permit number

A person may apply for an Experimental Use Permit (EUP) under *Section 5 of FIFRA* to develop data on either a new product or a new use site for a future FIFRA Section 3 registration. EUP applications (*EPA form 8570-17*) are assigned file symbols, which are written as Company Number-EUP-File Symbol. The file symbol is translated to an EUP registration number once the EUP has been issued by the Agency and/or an associated temporary tolerance has been established.

Note: The application for a permit may be denied. See Section II.B for information on the translation of file symbols to registration numbers (See 40 CFR 172.6 (a)(2))

For example: Company MNO, whose company number is 98979, applies for an EUP to collect data on the crop kale and no tolerance is yet established for kale. It is given a file symbol RLE until the EUP has been issued and the temporary tolerance has been established, if applicable. If this EUP application is issued, the file symbol 98979-EUP-RLE will become EUP Number 98979-EUP-152, indicating this is the 152nd permit for which this company has applied.