

A Guide for Pesticide Registrants



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Chapter 1: Introduction to Pesticide Registration

Overview

The purpose of this document is to provide guidance to the State Chemist Section's (SCS) stakeholders on applying for pesticide registration, and amendments. Guidance includes information on:

- Determining if a product requires registration
- Types of product registrations
- Submitting an application for registration of a new product or amendment of a currently registered product
- The internal registration process at the SCS
- Maintaining a product registration
- Other related information such as enforcement, and product cancellation/termination

Authority to Regulate

There are both federal and state laws that govern the import, manufacture, production, mixing, distribution, consignment, and use of pesticide products.

The *federal* authority to regulate pesticides is found in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Code of Federal Regulations Title 40 ([40 CFR 150 - 189](#)). The U.S. Environmental Protection Agency (USEPA) is responsible for regulating pesticides at the federal level.

A *State's* authority to regulate pesticides is found in FIFRA, Section 24(a) and reads "A state may regulate the sale or use of any Federally-registered pesticide or device in the state, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act." SCS is given further authority in the Agriculture Article of the Annotated Code of Maryland: Agriculture Article, Title 5, Subtitle 1.

Does My Product/Device Require Maryland Registration?

What is a Pesticide?

The Agriculture Article, Title 5, Subtitle 1 and Title 5, Subtitle 2, defines a pesticide as any of the following:

- (t) Pesticide. -- "Pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, fungi, weeds, or other forms of plant or animal life or viruses, except viruses on or in living humans or

other animals, which the Secretary declares to be a pest; and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

- (1) Pesticide. -- "Pesticide" means any substance or mixture of substances intended for:
- (1) Preventing, destroying, repelling, or mitigating any pest;
 - (2) Use as a plant regulator, defoliant, or desiccant; or
 - (3) Use as a spray adjuvant such as a wetting agent or adhesive.

A product requires registration in Maryland if:

- (1) The U.S. Environmental Protection Agency (U.S. EPA) Office of Pesticide Programs requires registration of the product, and the product is imported, manufactured, produced, mixed, or consigned as part of a commercial enterprise.
- (2) Maryland law requires registration of the product even if U.S. EPA does not (e.g., spray adjuvants, structural pest control devices, FIFRA 25(b) products).

Types of Products

Certain products require both federal and state registration while others require only state registration. The following information will help determine which products require registration in Maryland:

Products that require U.S. EPA and SCS registration

Technical grade active ingredient (TGAI) and manufacturing use products (MUPs):
Defined as any federally registered product that is distributed or sold for manufacturing, formulation, reformulation, or repackaging into other pesticide products must be registered.

Maryland requires the registration of TGAI products and MUPs that are:
Manufactured in Maryland or
Used in Maryland to manufacture or formulate an end-use product.

If the raw material is registered at U.S. EPA as a pesticide, then it must be registered in Maryland before being delivered, consigned, or sold into Maryland for use in the formulation of any pesticide (MUP or End Use) within the state.

Spray adjuvants require registration with SCS.

End-use products: products sold, used, or distributed in Maryland (e.g., disinfectants, sanitizers, agricultural chemicals, certain pheromones, home, and garden products, etc.) for pesticidal purposes that are not TGAI or MUPs.

Additional products that require Maryland registration

Additional/alternate brand names: pesticide products sold under alternate/product brand names in Maryland require separate registrations.

Note: Applicants must notify U.S. EPA of all alternate brand names through their notification process (see U.S. EPA form 8570-1). •

Supplemental distributor products: products distributed or sold under another company's name and address (also known as supplemental registrations or subregistrants; must have the same formulation, label, and packaging as the basic manufacturer).

Note: Supplemental distributors must submit to U.S. EPA a statement (U.S. EPA form 8570-5) signed by both the registrant and the distributor acknowledging their agreement.

Spray adjuvants (often referred to as “adjuvants”): products that are intended to be used with other pesticides to aid the application or enhance the effect of that pesticide (e.g., wetting agents, pH modifiers, stickers, spreaders, etc.).

Structural pest control devices: any device or method used to mitigate any wood destroying pest.

FIFRA 25(b) products: FIFRA section 25(b) products must be registered.

Products that do not require SCS or U.S. EPA registration as pesticides:

1. **Fertilizers and soil amendments:** Products intended solely for use as fertilizers and soil conditioners are also regulated by SCS.
2. **Devices:** physical or mechanical means to trap, destroy, or mitigate a pest which do not include a pesticidal substance may not need registration. This is solely dependent upon the label and reviewed on a case-by-case basis.

Note: Other requirements *do* apply to pest control devices. U.S. EPA *requires* companies that manufacturer pest control devices to obtain U.S. EPA establishment numbers for their products –for more information go to <http://www.epa.gov/pesticides/factsheets/devices>.
3. **Human/Animal Drugs:** products intended to control viruses, bacteria, microorganisms or pests regulated by another agency, on or in living man or other animals (e.g., internal parasite control, athlete's foot products, hand sanitizers, etc.).

Note: These products are regulated by a number of different agencies (FDA, Maryland Board of Pharmacy, etc.). Products that are not considered pesticides and are specifically exempted in 40 CFR Parts 152.8, 152.10, and 152.20.

Types of Registrations

Product registrations and exemptions from registration in Maryland fall into the following types:

Full registration – is one that has fulfilled all Maryland registration requirements (known federally as a FIFRA section 3 registration). **Note:** The majority of products are registered under this section.

Experimental Use Permit (known federally as a FIFRA section 5 registration). An Experimental Use Permit is a permit issued by U.S. EPA that allows a person/company to test an unregistered pesticide product or an unregistered use of a currently registered product, to develop the data necessary to register the product under Section 3 of FIFRA. This type of permitting is handled by MDA's Pesticide Regulation Section.

FIFRA section 18 - Emergency Exemption from registration. FIFRA section 18 authorizes use of an unregistered pesticide in a state for a limited time if U.S. EPA determines that emergency conditions exist. This type of exemption is handled by MDA's Pesticide Regulation Section.

FIFRA section 24(c) - Special Local Need (SLN) registration. FIFRA section 24(c) allows states to register new products or an additional use of an existing product to address a pest situation that is existing or imminent, and that a Section 3 product cannot currently mitigate.

FIFRA section 25(b) – Exemption from federal registration.

Chapter 2: How to Obtain a New Product Registration

Registration

The following submission requirements apply to:

New products not currently registered with SCS.

Products currently registered with SCS but are intended to be sold under additional/alternate brand names in Maryland.

Supplemental distributor (sub-registrant) products not currently registered with SCS.

Quick Guide

To apply for a *new product* registration, the following are required:

Cover letter (strongly recommended).

Maryland Application for Pesticide New Product Registration.

Copies of labels are to be e-mailed to labels.statechemist@maryland.gov.

Data to support registration is to be e-mailed to labels.statechemist@maryland.gov when requested.

US EPA documentation if requested is to be e-mailed to labels.statechemist@maryland.gov.

Labels, efficacy data, SDS, and CSF for 25(b) products are to be e-mailed to labels.statechemist@maryland.gov. Include the EPA number in the information line, if applicable.

\$110 application fee.

Designated agent letter (when applicable).

The mailing address is on the application.

Detailed Information

Cover letter

Each submission should be accompanied by a detailed cover letter. SCS suggests the following information be included:

The registrant's (company) name, address, and contact information (e.g., telephone number, e-mail address).

The product name.

The EPA registration number or if it is a 25(b) FIFRA Exempt product.

The reason for submission of the package (e.g., request for new end-use product registration, supplemental distribution, etc.).

For supplemental distributors –

Note if the basic registrant's product is currently registered with SCS, whether or not additional items (e.g., CSF or supporting data) will or have been sent separately by a third party.

Note: if requesting to submit the product concurrently with submission of an application to U.S. EPA for federal registration, include a justification for the concurrent submission (all products require federal registration prior to submission at SCS).

Maryland Application for Pesticide Registration

To apply for registration of a pesticide product in Maryland, a Maryland Application for Pesticide New Product Registration must be filled out and submitted to SCS.

General information on submitting an application:

The application must be signed and dated by the registrant or a designated agent.

The registrant's company name and address must be consistent with the company's information on file with U.S. EPA.

Data to support registration

All products proposed for registration in Maryland must be supported by scientific data. All data required by 40 CFR, Part 158 or 161 for federal registration, regardless of submission to U.S. EPA, must be supplied to SCS when requested. In addition, any study not identified in federal regulations, but required by U.S. EPA to support registration of the pesticide product, may also be requested by SCS. For example, federal regulations require that all registrants generate product performance data, but U.S. EPA does not generally require this data be submitted to support registration of non-public health products. SCS requires that the enforcement analytical method (EAM), which fulfills EPA's Data Requirement 830.1800, be sent to labels.statechemist@maryland.gov. Include the EPA number in the information line.

In addition, SCS may require supplemental data to support the registration or amendment of a pesticide product (e.g., hazards to bees, indoor exposure, health effects data, etc.).

U.S. EPA documentation

This does not apply to adjuvants or other products that do not require federal registration!

See Chapter 1 for information on products that do not require federal registration.

U.S. EPA stamped-accepted label, market label and accompanying letter of acceptance

Applicants must submit a copy of the stamped-accepted label, the most current the market label, and accompanying letter of acceptance.

Additional correspondence to/from U.S. EPA

Once a product label is stamped-accepted by the U.S. EPA, any documents relevant to that label (i.e., federal amendments, notifications, etc.) may be requested and shall be submitted to SCS. In addition, any written (e-mail or hard copy) correspondence between the registrant and U.S. EPA pertinent to the current stamped-accepted label or cover letter may be requested.

Additional/alternate brand name form

Registrants are required to notify U.S. EPA using form 8570-1, when distributing a product under an additional/alternate brand name. A copy of this completed form must be submitted to SCS. U.S. EPA's return response to the company is required.

Supplemental distributor form

If the applicant is a supplemental distributor, U.S. EPA's Notice of Supplemental Distribution of a Registered Pesticide Product form (8570-5) must be signed and dated by both the basic registrant and the supplemental distributor and submitted to SCS. This form is required whether or not the basic registrant is registered in Maryland.

Application fees

All new products and renewals are \$110 per product/brand name. The registration period is from 01/01 to 12/31 of each calendar year.

All registration/application fees are processing fees, are non-refundable, and do not guarantee registration of the product.

Make check or money order payable to "Maryland Department of Agriculture." Payment cannot be made by credit card at this time.

Kelly Services may be used for new product registration.

Designated agents/representative letter

A "designated agent" is a designated member of a firm, an independent consultant, or similar representative authorized to make business decisions on behalf of the registrant. Designated agents must submit a designated agent letter to SCS with their submission.

Chapter 3 – New Pesticide Product Registrations – General Review Procedures

Processing the Application

All application submissions are received by the Maryland Department of Agriculture (MDA) lockbox system setup with our current bank, Wells Fargo. On average it takes 3-30 business days before they are received by the SCS staff. Once received from the lockbox, application packages are sent to the Department's Fiscal Services. From Fiscal Services, the application packet is forwarded to the program.

Upon receipt, the registration staff enter preliminary information into SCS's Database. At this point, the following occurs:

- (1) Payment information is entered into the database to record the payment received from the registrant. This information links the check information to the respective registrant.
- (2) Registrant number, company number, check number, date received, and the amount of the check is entered onto the application form.
- (3) After the above occurs, the application is forwarded to the appropriate person for review.

Evaluation Process

Each company that registers new pesticide products in Maryland is reviewed by the appropriate SCS personnel. Unlike U.S. EPA, SCS does not register products according to active ingredient and/or use type. Special submissions (e.g., new active ingredient, major new use, FIFRA section 24c Special Local Needs, FIFRA section 18 Emergency Exemptions) may be assigned to other SCS staff or given to the Pesticide Regulation Section, but the assigned reviewer remains the registrant's point of contact

Once received, the submission will be checked for all required documents. If a higher level of review is required, additional data or information may be requested.

Products that contain active ingredients found in currently registered products

Time frames for requests to register products containing active ingredients found in currently registered products vary based on the number of submissions received, and the complexity of the submission.

Products that contain new active ingredients

SCS considers an active ingredient to be "new" if it is not found in a currently registered product in Maryland. Application submissions to register products containing new active ingredients may be subject to more extensive data requirements that take more time to evaluate than products with currently registered active ingredients. Multiple scientific evaluations may be required.

Amendments

Products frequently undergo changes to the label, either at the initiative of the registrant or as required by U.S. EPA or other regulatory authorities. Label revisions must be submitted to the department before they can be sold in Maryland.

Additional/Alternate Brand Name Products

Additional/alternate brand name products sold in Maryland require separate registrations.

Chapter 4: How to Maintain a Product Registration

General

There are two ways to renew and terminate pesticide products. There are third parties, and a renewal portal. The program has a renewal portal that will be discussed below. Renewals are required under the Agricultural Article, Title 5, Subtitle 1, Section 105. The terminal process is also in the section. Late renewals are subject to a late fee as outlined in Section 105.

Renewal

Portal

The renewal portal is found at the following URL:

<https://egov.maryland.gov/mda/chemist>. The renewal portal opens on November 1 of each year, two months before the expiration date of the pesticide products. Prior to October 31st, an email blast to all registrants is sent out as a reminder to expect the renewal postcards in the mail. These postcards are mailed out the first week of November. The postcard will contain information needed to log into the portal to renew. This information is the RNO (Registrant Number), and a PIN Number that is unique to the registrant.

Once logged in as the registrant, the portal brings up all the companies (manufacturers) that are under the registrant. Each company can be brought up and products selected for addition to the shopping cart. Once all the products are in the shopping cart, follow the instructions on the webpage to check out. There are three options for payment: e-check, credit card, or invoice. The invoice can be printed out and mailed into the lockbox address with payment.

Once product payment is made, the products will be renewed for the following registration year. The invoice and other renewal type may take approximately 2-20 business days to renew.

Terminal Process

The terminal process is a process that gives registrants the necessary time to remove a product from the shelves of a brick-and-mortar store, and to cease distribution online. The terminal process can be initiated by clicking on a product name after logging into the portal. This opens up the product window. At the bottom right of the page is a button that says Terminate Product. Click the button and a pop-up box appears asking if you are sure you want to terminate. If you want to start the terminal process, then click ok, and add the product to the cart. When you check out and payment is received, then the terminal process starts for the upcoming registration year. This first year is known as T1 or first year terminal. The product will show on your certificate with the terminal year on the line. The following year when you renew it will automatically move to second

year terminal or T2. Once the terminal period is over, the status of the product will be cancelled. It will stay in cancelled status for a calendar year before it moves to retired. This gives the registrant the opportunity to put the product into active status. If a product is retired, and the registrant wants to register it, it will have to be done as a new product and go through the new product registration process.

Chapter 5: Pesticide Areas of Interest

Pesticide Regulation Section, Maryland Department of Agriculture

The Pesticide Regulation Section administers Maryland's Pesticide Applicator's Law, approves training courses in the handling, storage, and use of pesticides, conducts examinations to determine that pesticide applicators are competent to follow prescribed pest control practices, enforces federal laws on the sale and use of pesticides, and investigates pesticide accidents or incidents and consumer complaints on pesticide misuse. The program also handles the FIFRA Section 18, Emergency Exemption.

To find out more, call Pesticide Regulation at (410) 841-5710.

URL: https://mda.maryland.gov/plants-pests/Pages/pesticide_regulation.aspx

Contact: Rob Hoffstetter, Program Manager, rob.hofstetter@maryland.gov
Kelly Love, Inspector Manager, Kelly.love@maryland.gov

CIPAC (Collaborative International Pesticides Analytical Council)

The abbreviation CIPAC stands for Collaborative International Pesticides Analytical Council. It is an international, no-profit, and non-governmental organization devoted to:

- Promote the international agreement on methods for the analysis of pesticides and physico-chemical test methods for formulations.
- Promote inter-laboratory programs for the evaluation of test methods.

The methods are proposed by companies and are collaboratively studied by laboratories all over the world. After evaluation of the collaborative study and adoption of the method, the methods are published in the CIPAC Handbooks. These are a collection of studied methods. CIPAC is a source of “gold standard” methods for pesticide formulations.

URL: <https://cipac.org/>

AAPCO (Association of American Pesticide Control Officials)

The Association of American Pesticide Control Officials (AAPCO) members represent the officials charged by law with the execution of the state, territorial, provincial, and federal laws in the United States, including all its territories (hereafter referred to as states), and in Canada regulating the production, labeling, distribution, sale, use, and disposal of pesticides. AAPCO's mission is to represent states in the development, implementation, and communication of sound public policies and programs related to the sale, use, transport and disposal of pesticides.

URL: <https://aapco.org/>

AOACI (Association of Official Analytical Collaborations)

AOACI stands for the Association of Official Analytical Collaborations and brings together government, industry, and academia to establish standard methods of analysis that ensure the safety and integrity of foods and other products that impact public health around the world. As a leader of analytical excellence, AOACI advances food safety, food integrity, and public health, by bringing together members, organizations, and experts dedicated to developing and validating standards, methods, and technologies of global relevance.

AOAC was established in 1884 as the Association of Official Agricultural Chemist. Later the Association of Official Analytical Chemist name was adopted to better reflect additional safety areas. The OMA (Official Methods of Analysis) program is the association's premier methods program. Approved methods undergo rigorous, systematic scientific scrutiny to ensure they are highly credible and defensible, and can be used with confidence by industry, regulatory agencies, research organizations, testing laboratories, and academic institutions. The OMA methods are considered to be "gold standard" methods.

URL: <https://www.aoac.org/>

Kelly Registration Services

Kelly has assisted pesticide companies and state agencies in the registering of pesticide products. Kelly has developed a software system that streamlines the registration process for pesticide products. Renewals and new pesticide products can be registered through the Kelly system. It also provides a way to search if a pesticide product is registered in a state. For Maryland, search options include company name, product name, pest, pesticide type, active ingredient, restricted use, company ID, product EPA ID, application site, formulation type, and searching by multiple criteria.

URL: <http://www.kellysolutions.com/MD/pesticideindex.htm>

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