HOW TO APPLY FOR A SECTION 24(c) SPECIAL LOCAL NEED (SLN) REGISTRATION IN THE STATE OF MONTANA

PESTICIDE REGISTRATION, LICENSING & TRAINING PROGRAM SECTION

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Contact Information

Submit Section 24(c) registrations to:

- Licensing, Registration and Training Program Manager
  Phone: (406) 444-3676
  Email: pestreg@mt.gov

- Pesticide Registration Specialist
  Phone: (406) 444-5471
  Email: pestreg@mt.gov

Montana Department of Agriculture
Agriculture Sciences Bureau
PO Box 200201
302 N. Roberts
Helena, MT 59620

Submission of documents by email (pdf format) is strongly encouraged.

I. MDA SECTION 24(c) APPLICATION CHECKLIST

DOES THE SECTION 24(c) APPLICATION CONTAIN THE REQUIRED INFORMATION?

1. Cover letter – all SLN registrations.
2. Draft SLN label – all SLN registrations.
3. Current federal label – all SLN registrations.
4. Completed EPA SLN application form – all SLN registrations except supplemental distributor SLN registrations.
5. Letter of support from a MDA researcher, extension specialist or other unaffiliated expert verifying the special local need.
6. Letter of support from commodity organization and/or individual growers.
7. Residue data – required if food or feed use. Tolerance (or exemption) – 40 CFR 180.
8. Efficacy data – should be submitted for all uses, required for public health uses.
9. Phytotoxicity data – may be required if herbicide or plant growth regulator.
10. Confidential Statement of Formula – required if CSF is not already on file with MDA.
11. Letter of authorization from primary registrant – required for supplemental distributor SLN registration.
12. EPA transfer letter – required if SLN registration was transferred to a new registrant.

WHAT IS THE PRODUCT REGISTRATION STATUS?

1. Is the product currently registered with EPA?
2. Has registration for the proposed use or other uses of product been denied, disapproved, suspended, or canceled?
3. Is the product under special review at the EPA?
4. Is the pesticide undergoing re-registration?
5. Is the product not unlike any federally registered product?
6. Is the use pattern not unlike any federally registered uses?

II. MDA SECTION 24(c) LABEL GUIDANCE

1. A statement clearly indicating that the label is an SLN label, followed by the statement:

   "FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF MONTANA"

2. Trade name of the product
3. The EPA registration numbers of the product:

   EPA Reg. No. and EPA SLN No. MT-XXXXXX

4. The signal word (if the pesticide is category 1)
5. Ingredients Statement
6. Indication if the product is a Restricted Use Pesticide
7. The following expiration date statement:

   "This label for (Product name) expires and must not be distributed or used in accordance with this SLN registration after December 31, (Fifth year)"

8. The statements:

   "The label and the federal label for this product must be in possession of the user at the time of pesticide application."

   "Follow all applicable directions, restrictions, and precautions on the SLN label and the main EPA registered label. It is a violation of federal law to use this product in a manner inconsistent with its labeling."

9. Directions for use:

   - Crop/site, pest(s),
   - Application rate and concentration
   - Application methods, frequency and timing
   - Restricted entry interval and pre-harvest interval
   - Maximum annual application rate
   - Any other restrictions or precautions that are applicable to the intended use.
   - Include the Agricultural Use Requirements (WPS)

10. Name and address of the SLN registrant

III. REQUIREMENTS TO OBTAIN A SPECIAL LOCAL NEED (SLN) PESTICIDE REGISTRATION IN THE STATE OF MONTANA

A. INTRODUCTION

The Montana Department of Agriculture (MDA), as defined in 40 CFR 162.151(j) is the designated lead agency responsible for registering pesticides to meet special local needs under section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as Amended.

A special local need (SLN) is defines as, "an existing or imminent pest problem within a State for which the State lead agency, based upon satisfactory supporting information has determined that an appropriate federally registered pesticide is not sufficiently available", 40 CFR 162.151(i).

The Montana Pesticides Act 8-8-201 (8)(a) requires that all 24(c) applications be reviewed by three agencies; the Department of Agriculture, the Department of Public Health and Human Services, and the Department of Fish, Wildlife and Parks.

When the State grants a SLN registration, the EPA is informed and provided with a letter of notification and a copy of the accepted label. If there are environmental, pesticide residue/tolerance, or worker safety concerns, the state may elect to consult with EPA in evaluating a SLN request. Once EPA receives notification from the State that a SLN has been granted, the State receives a letter acknowledging receipt of the State's action, but not a letter of acceptance from EPA.

After receiving notification from the State, EPA has 90 days in which to conduct a review of the SLN for required pertinent information. The EPA may request modifications of the label or conditions of registration from the State, request data, disapprove the registration or request for the state to withdraw the registration. After 90 days, a SLN which has not been disapproved is considered federally registered, but is only authorized for distribution and use within that State, 40 CFR 162.154(b).

Types of SLN registration requests considered at MDA include: the addition of a crop, site or pest; alternate application method; change in timing of application; encouragement of the use of reduced risk pesticides or pesticides which facilitate resistance management; or modification of the application rate.

The pesticide registrant applies to MDA for a SLN registration through the following instructions that are intended to ensure that all necessary information is submitted to MDA. A complete application will expedite MDA's review. Submit the application in the same order and format as outlined in the instructions.

IV. APPLYING FOR A NEW SLN REGISTRATION

A. COVER LETTER

Submit a cover letter that discusses, in detail, the event which brought about the "special local need" request. The discussion must provide:

1. A description of the pest problem.
2. An indication whether the pest problem is nationwide or localized (indicate if the proposed use has been requested or granted in other states).
3. A list of the available pesticides (or active ingredients) currently registered for use in question and the reasons why they will not adequately control the pest problem and/or if they are not sufficiently available.
4. If the pesticide is to be used near or in an environmentally sensitive area justify the use of the pesticide and indicate any precautionary measures to be implemented.
5. If the registration of the proposed use has been previously denied, disapproved, suspended or canceled by EPA include a detailed discussion of the action taken by the EPA.
6. If the registration for the proposed use has been voluntarily canceled explain the reason(s) for the cancellation.
7. If the product is under special review by EPA provide a detailed discussion of the concern that triggered the review and its status.
8. Indicate if the pesticide is currently undergoing re-registration and is the proposed use is being supported.

B. LETTERS OF SUPPORT

Submit a letter of support for the SLN registration from each of the following:

1. A MSU researcher, extension specialist or other unaffiliated expert who can verify the special local need, and has worked with (or is familiar with) the proposed use and the registered alternatives.
2. An individual representing the commodity group, commission or association for the crop/site. In the absence of a commodity or user organization, individual letters of support from growers/applicators will suffice.

C. FEDERAL SLN APPLICATION

Submit a signed and dated federal SLN application form (EPA form 8570-25), except when the request if for a SLN registration under a supplemental distributor label.

D. PROPOSED SLN LABEL

Submit a copy of the proposed SLN label which must include:

1. A statement clearly indicating that the label is an SLN label, followed by the statement:
   - "FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF MONTANA"

2. Trade name of the product
3. The EPA registration numbers of the product: EPA Reg. No. and EPA SLN No. MT-XXXXXX
4. The signal word (if the pesticide is category 1)
5. Ingredients Statement
6. Indication if the product is a Restricted Use Pesticide
7. The following expiration date statement:
    - This label for (Product name) expires and must not be distributed or used in accordance with this SLN registration after December 31, (Fifth year)
8. The statements:
    - The label and the federal label for this product must be in possession of the user at the time of pesticide application.
    - Follow all applicable directions, restrictions, and precautions on the SLN label and the main EPA registered label. It is a violation of federal law to use this product in a manner inconsistent with its labeling.
9. Directions for use to meet the special local need that includes crop/site, pest(s), application rate and concentration, method(s) of application, frequency and timing of application, restricted entry interval, pre-harvest interval, maximum annual application rate and any other restrictions or precautions that are applicable to the intended use. Include the Agricultural Use Requirements (WPS).

E. SECTION 3 LABEL

Submit a copy of the current EPA-approved FIFRA Section 3 labeling.

F. DATA

A SLN registration must be accompanied by supporting documentation. Submit copies of field data, published articles, written statements by qualified experts (see "Letters of Support" above) and other documents which support the request.

1. RESIDUE DATA:

    According to Section 24(c)(3) of FIFRA, "In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act, that permits the residues of the pesticide on the food or feed." Please cite the tolerance or exemption from tolerance and reference the specific Code of Federal Regulation (CFR) where the tolerance information can be found.

    Describe the practice(s) involved in producing the crop. Is the crop marketed fresh? Processed? Both? What happens to the crop residue/by products? Is any portion of it fed to livestock?

    Data showing that the proposed use will not result in crop residues exceeding the established tolerances must be submitted if the proposal involves any of the following:

a. Increased application rate

b. Increased number of applications

c. Decreased interval between applications

d. Decreased pre-harvest interval

e. Change from soil application to foliar application

2. EFFICACY DATA:

   The SLN registration request must be supported by efficacy data of the material used at different rates. Whenever possible, field trials should cover a minimum of two growing seasons and be performed in Montana. Data generated in areas outside Montana may be used if it can be shown that the conditions under which the trials were conducted were similar to conditions in the growing areas of Montana.

3. PHYTOTOXICITY DATA

   Discuss the potential for the proposed use to cause phytotoxicity to the crop and submit any applicable data.

G. ADVERSE EFFECTS

As part of the Section 24(c) process, the Department is required to assess if the unreasonable adverse effects determination provision as stated in 40 CFR 162.153(c) is being met.

Prior to issuing a registration in the following cases, the State shall determine that use of the product for which registration is sought will not cause unreasonable adverse effects on man or the environment, when used in accordance with labeling directions or widespread and commonly recognized practices.

Registrants must address the potential risk to human health, endangered or threatened species, beneficial organisms, groundwater and the environment. Areas which may need to be addressed include, but are not limited to:

1. Proximity to aquatic systems
2. Proximity to endangered species habitats
3. Proximity to residences
4. Potential for off-target movement
5. Soil type considerations (i.e. potential to leach, carryover, etc.)

MDA will review potential risks and proposals to mitigate risks. When appropriate, MDA will consult with other agencies (FWS, DPHHS) to determine if proposed risk mitigation measures are adequate.

H. CONFIDENTIAL STATEMENT OF FORMULA

In Montana, a confidential statement of formula is only required if the product is not currently registered under Section 3.

IV. SLN's FOR SUPPLEMENTAL DISTRIBUTOR PRODUCTS

Section 3(e) of FIFRA allows pesticide registrants to distribute or sell a registered pesticide product under a different name instead of or in addition to their own. Such distribution and sale are termed "supplemental distribution" and the product is termed a "distributor product." EPA requires the pesticide registrant to submit a supplemental statement (EPA Form 8570-5) when the registrant has entered into an agreement with a second company that will distribute the registrant's product under the second company's name and product name.

EPA requires that SLN registrations be based on a primary Section 3 registration (these registrations have a two-part EPA Registration No., such as XXX-XXX). Supplemental distributor products are pesticides sub-registered under the primary EPA registration number. Supplemental distributor registration numbers are the same as the primary EPA Registration No. except there is a third part to the registration number, such as XXX-XXX-XXX. MDA will issue a supplemental distributor SLN registration when the following conditions are met:

1. An identical SLN registration has been issued by MDA under the primary Section 3 registration,
2. A letter of authorization from the primary SLN registrant (authorizing the supplemental distributor SLN registration) has been submitted to MDA with the supplemental distributor SLN request, and
3. A cover letter, a copy of the federal label, and a copy of the draft supplemental distributor SLN label have been submitted to MDA.

A federal SLN application form is not required for supplemental distributor SLN registrations and the SLN label is not submitted to EPA. When the primary registrant's SLN registration is canceled or withdrawn, the distributor' SLN label automatically becomes invalid. Any action taken on or changes made to the primary SLN also affects the distributor SLN. It is the responsibility of the supplemental distributor to communicate with the primary registrant, and to stay current with planned changes to the primary SLN registration.

V. CHANGES TO EXISTING SLN REGISTRATIONS

A. REVISING SLN REGISTRATIONS

In order to revise an SLN label in any manner, registrants must first submit a request to the MDA. The request must include a detailed discussion of the label changes, copy of proposed revised label, and any necessary data or other documents to support the requested changes. Revised or amended labels may not be distributed until the registrant receives written or email notification indicating the changes have been accepted. Significantly revised SLNs may be assigned a new SLN number. If the SLN label is approved, MDA will notify the EPA of the changes and submit a revised label for their records.

B. TRANSFERRING SLN REGISTRATIONS

When SLN registration is transferred from one company to another company, it is considered a new registration and will be assigned a new SLN number by MDA. The new proposed registrant must submit a cover letter, a completed EPA SLN application form (EPA form 8570-25), a copy of the federal Section 3 label, a copy of the proposed SLN label, and a copy of EPA's letter approving transfer of the SLN registration. The original SLN No. associated with the original company may be canceled immediately by the original company, or may be canceled after the material has cleared the "channels of trade".

C. WITHDRAWING OR CANCELLING EXISTING SLN REGISTRATIONS

MDA must receive a letter or email from the registrant to withdraw or cancel an SLN registration, and MDA will notify EPA of the change in registration status. Since cancellation of an SLN registration may have an impact on grower/user groups, the MDA requests a brief explanation of the reason(s) for cancellation.