

Requirements to Obtain a Special Local Need (SLN) Pesticide Registration in the State of Idaho.

INTRODUCTION

The Idaho State Department of Agriculture (ISDA), 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 defined 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).

Special local Need registrations will only be granted if Idaho growers have a legitimate need for the product and should not be used as a marketing tool, or as a method of circumventing EPA requirements.

Under FIFRA section 24(c), each State is authorized to register a new end use product for any use, or an additional use of a federally registered pesticide product, if the following conditions exist, 40 CFR 162.152 (a):

- (1) There is a special local need for the use within the State;
- (2) The use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 et seq.), if the use is a food or feed use;
- (3) Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the Administrator, or voluntarily cancelled by the registrant subsequent to issuance by the Administrator of a notice of intent to cancel that registration, because of health or environmental concerns about an ingredient contained in the pesticide product, unless such denial, disapproval, suspension or cancellation has been superseded by subsequent action of the Administrator; and
- (4) The registration is in accord with the purposes of FIFRA.

Examples of types of SLN registration requests considered include: the addition of a crop or site; addition of a new pest; incorporation of an alternate application method, such as chemigation or dip (for bulbs etc.); change in the timing of application; encouragement of the use of reduced risk pesticides or pesticides which facilitate resistance management; or the modification of the application rate.

Three specific criteria that need to be met before an SLN request will be considered in Idaho are:

- (1) There is no pesticide product registered by the EPA for such use.
- (2) There is no EPA- registered product which, under the conditions of use within the State, would be as safe and/or as efficacious for such use within the terms and conditions of EPA registration.
- (3) An appropriate EPA- registered pesticide product is not available.

When the State grants an SLN registration, the U.S. EPA is informed and provided with a letter of notification and a copy of the accepted label. 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, an SLN that has not been disapproved is considered federally registered, but is authorized for distribution and use only within that State, 40 CFR 162.152 (c). EPA may disapprove the registration at any time if it is believed that the use constitutes an imminent hazard, or may result in excessive residue levels, 40 CFR 162.154 (b). However, usually the registrant and the State exercise the option to withdraw the registration prior to EPA disapproving the registration.

All provisions as stated in 40 CFR 162.152 must be met:

Sec. 162.152. State Registration Authority.

(b) Types of registrations

(1) Amendments to federal registrations.

- (i) Subject to the provisions of paragraphs (a) and (b)(1)(ii) through (iv) of this section, States may register any new use of a federally registered pesticide product.
- (ii) A State may register any use of a federally registered product for which registration of other uses of the product was denied, disapproved, suspended or cancelled by the Administrator in reaching such a determination only after the State consults with appropriate EPA personnel.
- (iii) Except as provided in paragraph (a)(3) of this section, a State may register any use of a federally registered product for which registration of some or all uses has been voluntarily cancelled by the registrant, provided that a State may register such a use only after the State has consulted with appropriate EPA personnel.
- (iv) A State may not register an amendment to a federally registered manufacturing-use product.

(2) ***New products.***

- (i) Subject to the provisions of paragraph (a) and subparagraphs (b)(2) (ii) and (iii) of this section, a State may issue registrations to meet special local needs for the following types of new end-use products:
 - (A) A product which is identical in composition to a federally registered product, but which has differences in packaging, or in the identity of the formulator.
 - (B) A product which contains the same active and inert ingredients as a federally registered product, but in different percentages.
 - (C) Subject to the requirements of paragraph (b)(2)(ii) of this section, a product containing a new combination of active, or active and inert, ingredients.
- (ii) A State may register a new product only if each of the active ingredients in the new product is present because of the use of one or more federally registered products and if each of the inert ingredients in the new product is contained in a federally registered product.
- (iii) A State may not register a new manufacturing-use product.
- (iv) A State may register any use of a new product containing an ingredient described in paragraph (a)(3) of this section, if the new product registration is for a formulation or a use not included in the denial, disapproval, suspension, or cancellation, or if the federally registered use was voluntarily cancelled without a prior notice of intent to cancel by the Administrator. However, a formulation or use of such a new product which was not considered by the Administrator during such proceedings, or which was not the subject of a notice of intent to cancel, may be registered by a State only after the State consults with appropriate EPA personnel regarding the registration application.

COVER LETTER AND SUPPORTING DOCUMENTATION

Submit a cover letter that discusses, in detail, the events that brought about the “special local need” request. The registrant must justify the use of the pesticide and indicate what precautionary measures have been implemented to adequately protect humans and the environment. 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) and, (3) a list of the available pesticides (or active ingredients) currently registered for the use in question, and the reasons why they will not adequately control the pest problem and/or they are not sufficiently available. In addition, the questions below need to be answered:

- a. Is the product currently federally registered? If the answer is no, is the product identical in composition to a federally registered product or does it

contain the same active ingredient(s) and inert ingredient(s), but in different percentages, as that of a federally registered product?

- b. Has the proposed use or other uses previously been denied, disapproved, suspended or canceled by the EPA? If the answer is yes, include a detailed discussion of the action taken by the EPA.
- c. Has the registration for the proposed use been voluntarily canceled? If the answer is yes, explain the reason(s) for the voluntary cancellation.
- d. Is the product under special review at the EPA? If the answer is yes, provide a detailed discussion of the concern that triggered the special review and its current status.
- e. Is the pesticide currently undergoing re-registration? If so, is the proposed use being supported?

LETTERS OF SUPPORT

Submit letters of support for the SLN registration from the following:

- a. A University of Idaho researcher, extension specialist or other unaffiliated expert who is capable of verifying the special local need, and has worked with (or is familiar with) the proposed use and the registered alternatives.
- b. 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.

FEDERAL SLN APPLICATION

Submit a signed, completed and dated federal SLN application form, except when the request is for an SLN registration under a supplemental distributor label. The form is available on ISDA's website:

www.agri.idaho.gov/AGRI/Categories/Pesticides/registration/Section24cmain.php. Upon granting the SLN, ISDA will complete the rest of the form, sign it, retain a copy for the ISDA files, and send a copy to the registrant and to EPA.

ISDA PESTICIDE REGISTRATION FORM

Section 22-3402(1), Idaho Code states: "REGISTRATION – LABELS – INFORMATION REQUIRED - FEES. (1) any pesticide which is distributed within this state shall be registered with the department, and such registration shall be renewed annually." Prior to approving an SLN registration, the product must be registered as a pesticide in Idaho. An ISDA Pesticide Registration Form may be downloaded from the ISDA website:

www.agri.idaho.gov/AGRI/Categories/Pesticides/Documents/Pesticide%20Registration/frmPestReg2013.pdf). Please provide the information required on this form. ISDA will assign the SLN number.

APPLYING FOR AN SLN REGISTRATION FOR A NON-FEDERALLY REGISTERED PRODUCT.

According to the U.S. EPA, Office of Pesticide Programs, Label Review Manual, Chapter 17, "Although most 24(c) registrations amend federally registered products with supplemental labels, the state may also register a new end-use product (not federally registered) as a 24(c) registration. The ingredients (including inerts) of the new end-use product must be contained in one or more federally registered Section 3 Products. (CFR 162.152 (b)(ii))." In the state of Idaho, if the active ingredient and/or inerts are not federally registered, and if certain criteria are met, the Section 18 process may be an option.

PROPOSED SLN LABEL

In addition to the information which usually appears on the SLN label (registrant and product's name, rate, restricted use designation statement (if applicable), crop/site etc.), ISDA has supplementary requirements.

The following information is required to be placed on the label. In some situations, additional information will be required on the label. You will be notified during the label review what additional information is required.

- (1) Ingredients Statement
- (2) Indication if the product is a Restricted Use Pesticide
- (3) Signal Word
- (4) Environmental Hazards (entire statement)
- (5) **Pertinent** Directions for Use, including Agricultural Use Requirements (WPS)
- (6) **Pertinent** General Information

The SLN label must also state:

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

"Follow all applicable directions, restrictions, and precautions on this Supplemental 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."

The EPAN SLN No. must appear on the front panel of the label, either beside or below the EPA Reg. No.

Surface Water Protection Statement

If a pesticide is classified as a “Restricted Use Pesticide” because of its toxicity to fish and/or aquatic organisms, and will be used in one or more counties where listed threatened or endangered aquatic species occur, the registrant may be required to include a “Surface Water Protection Statement” on the label. A NW Region Species List can be found at the NOAA Fisheries, National Marine Fisheries Service Web site, <http://www.nwr.noaa.gov/>

In certain cases, regardless of classification status, the statement below will be required:

“Do not apply this product to fields when soil moisture is nearing, at, or exceeding field capacity, and/or when a rain event likely to produce runoff from the treated field is forecasted by NOAA/NWS (National Weather Service), and will occur within 48 hours.”

Chemigation

If the pesticide is subject to EPA PR Notice 87-1 regarding chemigation, then the SLN label must contain a statement either prohibiting or giving specific directions for use through irrigation equipment. If chemigation is to be prohibited, include the statement:

“Do not apply this product through any type of irrigation system.”

If chemigation will be allowed, the SLN label must provide chemigation instructions and data supporting efficacy with this type of application.

Expiration Date

A three-year (3) expiration date is indicated on all revised, amended, transferred or issued SLN labels. For example, an SLN issued between January 1 and December 31, 2016 would contain the following statement:

“This label is valid until _____, 2019 or until otherwise amended, withdrawn, canceled, or suspended.”

The purpose of the expiration date is to allow review of the SLN label after it has been in use to insure that precautions, PPE, and restrictions are still adequate, and to determine if the SLN registration is still required (i.e. the use may have been added to the Section 3 label). Thirty (30) days prior to the expiration date, the registrant should submit a revised label to ISDA requesting an extension of the expiration date for another three (3) years, together with any additional data that has become available to the registrant since the SLN label was first approved by ISDA.

DATA

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

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 the 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 food or feed 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.

The data should be generated under Good Laboratory Practices (GLP) as established under Part 160 CFR. A signed statement must accompany the data (1) indicating the study was performed under GLP, or (2) describing in detail all differences between the practices used in the study and those required under GLP with an explanation as to why this will not invalidate the data, or (3) indicating the requester did not conduct the study and does not know whether the study was conducted in accordance with GLP.

The residue data must be accompanied by the field and laboratory protocols and the procedures used to carry them out. If the data is also on file at the EPA, include the appropriate references (e.g. MRID number).

Efficacy data

The SLN registration request must be supported by efficacy data (comparative data when other registered pesticides are available for use) of the material used at different rates. Whenever possible, field trials should cover a minimum of two growing seasons and be performed in Idaho. Data generated in areas outside Idaho may be used if it can be shown that the conditions under which the trials were conducted were similar to conditions

in Idaho. Efficacy data must be accompanied by the study protocol and the procedures used to carry it out. The rate and time of year the pesticide was applied, must be appropriate for the SLN request. For example, consider the scenario where the SLN label provides growers the option of a fall and/or spring application. Studies must be submitted that consider application in the Fall and Spring as well as the effects of multiple applications.

Phytotoxicity data

Discuss the potential for the proposed use to cause phytotoxicity to the crop and submit any applicable data. Horticultural growth data is often warranted, for perennial and some annual crops. An example, a potential registrant wants an SLN for the use of an herbicide and the site is defined as, "recently established non-bearing apple orchards". In this situation, the youngest trees are approximately one inch in diameter. All the studies submitted but one, were conducted on mature apple trees. Should the SLN be granted? No, for the protection of the growers, the State needs growth data to indicate if the herbicide causes stunting, or some other negative effect.

EFFECTS ON BENEFICIAL INSECTS OR USEFULNESS WITH IN AN IPM PROGRAM

Discuss any potential adverse or positive effects to beneficial and/or pollinating insects. Discuss if this is a reduced risk pesticide, how this product can be used to promote resistance management, or used within an integrated pest management program. Discuss how to time applications based on the plant phenology, life cycle of the pest, or the results of pest monitoring data.

ADVERSE EFFECTS

As part of the Section 24(c) process, ISDA is required to assess if the Unreasonable Adverse Effects Determination Provision, as stated in 40 CFR 162.153 (c), is being met:

(1) 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 and proposals to mitigate the risk. Areas that may need to be addressed include, but are not limited to:

- a. Aquatic systems.
- b. Endangered species habitats.
- c. Residences.

- d. Drift or other off-target movement.
- e. Soil type considerations (i.e. potential to leach, potential for carryover, etc.).

ISDA will review potential risks and proposals to mitigate risks. When appropriate, ISDA will consult with other agencies (e.g. NOAA Fisheries, IDF&G, USFWS) to determine if proposed risk mitigation measures are adequate.

WAIVER OF LIABILITY STATEMENTS (This section is subject to frequent change)

Waiver of liability statements are used to limit product liability and are only applicable for crops grown on very limited acreage (e.g. some seed crops). EPA is opposed to enforcing limitations of user's rights, and will only allow certain waiver language. The following language is currently acceptable to EPA (subject to change):

“(Registrant’s) Special Conditions and Disclaimer for use of (Product) on (Crop)”

“(Registrant) intends that this Section 24(c) label be distributed by the Grower Association only to end users and/or growers who agree in writing to the terms and conditions required by the **Grower Association** including a waiver and release from all liability and indemnification by the user and/or grower of (Registrant), **Grower Association**, and others for failure to perform and crop damage from the use of (Product) on (Crop). If such terms and conditions are unacceptable, return (Product) at once unopened.”

“This product, when used on (Crop), may lead to crop injury, loss, or damage. (Registrant) recommends that the user and/or grower test this product in order to determine its suitability for such intended use. The **(Grower Association)** and (Registrant) make this product available to the user and/or grower solely to the extent the benefit and utility, in the sole opinion of the user and/or grower, outweigh the extent of potential injury associated with the use of this product. The decision to use or not to use this (Pesticide) must be made by each individual (Product) user and/or grower on the basis of possible crop injury from (Product), the severity of (Pest) infestation, the cost of alternative (Pest) controls, and other factors. (Registrant) intends that, because of the risk of failure to perform or crop damage, such use is at the user's and/or grower's risk.”

CONFIDENTIAL STATEMENT OF FORMULA

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

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 is 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.

Supplemental distributor products have an EPA Registration No. formatted in a three- part series such as, XXX-XX-XXX. EPA does not allow supplemental distributors of the Section 3 product (also called a sub-registrant) to be the SLN registrant.

If a distributor of a Section 3 product also wants to distribute an SLN label, an SLN registration must be issued to the registrant of the Section 3 product. A written letter of approval, signed by the primary (Section 3) registrant agreeing to the supplemental distributor SLN label, must be submitted to ISDA, along with the supplemental distributor's SLN request.

If the SLN package proves satisfactory, ISDA will issue an SLN registration to the primary registrant, and approve the labels of both the primary registrant and the distributor. The labels should essentially appear similar, and have the same SLN No. The distributor's SLN label should indicate on the back page (bottom) that the 24(c) registrant is [company name and address of primary registrant], and the distributor is, [company name and address of distributor]. The primary registrant needs to complete EPA form 8570-25 [Rev. 1-94].

The primary registrant's label and EPA form 8570-25 will be forwarded to EPA, and the distributor label will be forwarded at the same time to EPA as a matter of courtesy. When the primary registrant's SLN registration is canceled or withdrawn, the distributor' SLN label automatically becomes invalid.

“ME-TOO” REGISTRATIONS

ISDA does not grant one company an SLN request simply because another company has an SLN. Each potential registrant must build its own SLN package. If data compensation is an issue, registrants should make formal arrangement with each other prior to the ISDA being contacted.

CHANGES TO EXISTING SLN REGISTRATIONS

AMENDING OR REVISING SLN REGISTRATIONS

In order to amend or revise an SLN label in any manner, registrants must first submit a request to the ISDA. The request must include a detailed discussion of the label changes, three (3) copies of the (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 notification indicating the changes have been accepted. Significantly revised SLNs may be assigned a new SLN number.

TRANSFERRING SLN REGISTRATIONS

When a registration is transferred from one company to another company, it is considered a new registration, will be assigned a new SLN number by ISDA, and will be required to meet all of the requirements listed in this document. The new proposed registrant must complete a federal SLN application form (EPA form 8570-25 [Rev. 1-94]). 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”.

WITHDRAWING OR CANCELING EXISTING SLN REGISTRATIONS

ISDA must receive a written request from the registrant to voluntarily withdraw or cancel an SLN registration. ISDA will notify EPA of the change in registration status. Because this cancellation may have an impact on grower/user groups, ISDA requests a brief explanation of the reason(s) for cancellation.

CONTACT INFORMATION

Submit the completed SLN Registration request package to:

Idaho State Department of Agriculture
Attention: Ben Miller
P.O. Box 7723
Boise, Idaho 83707

If you have questions about the SLN process, please call (208) 332-8593. You may also send your inquiries by e-mail to ben.miller@agri.idaho.gov.



United States Environmental Protection Agency
Office of Pesticide Programs
Registration Division (TS-767)
Washington, DC 20460

**Application for/Notification of State Registration
of a Pesticide To Meet a Special Local Need**
(Pursuant to Section 24(C) of the Federal Insecticide,
Fungicide, and Rodenticide Act, as Amended)

For State Use Only
Registration No. Assigned

Date Registration Issued

1. Name and Address of Applicant for Registration	2. Product Is (Check one)	
	EPA-Registered <input type="checkbox"/>	EPA Registration Number
	New (not EPA-registered) <input type="checkbox"/> Attach EPA Form 8570-4, Certified Statement of Formula, for new products.	EPA Company Number
3. Active Ingredient(s) in Product		

4. Product Name	5. If this is a food/feed use, a tolerance or other residue clearance is required. Cite appropriate regulations in 40 CFR Part 180, 21 CFR Part 193, and/or 21 CFR Part 561.
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6. Type of Registration (Give details in Item 12 or on a separate page, properly identified and attached to this form): a. To permit use of a new product. b. To amend EPA registrations for one or more of the following purposes: (1) To permit use on additional crops or animals. (2) To permit use at additional sites. (3) To permit use against additional pests. (4) To permit use of additional application techniques or equipment. (5) To permit use at different application rates. (6) Other (specify below)	7. Nature of Special Local Need (Check one)	
	a. <input type="checkbox"/> There is no pesticide product registered by EPA for such use.	
	b. <input type="checkbox"/> There is no EPA-registered pesticide product which, under the conditions of use within the State, would be as safe and/or as efficacious for such use within the terms and conditions of EPA registration.	
	c. <input type="checkbox"/> An appropriate EPA-registered pesticide product is not available.	
	8. If this registration is an amendment to an EPA-registered product, is it for a "changed use pattern" as defined in 40 CFR 162.3(k)? <input type="checkbox"/> Yes (discuss in item 12 below) <input type="checkbox"/> No	
	9. Has an EPA Registration or Experimental Use Permit for Use of this chemical ever been: (Check applicable box(es)) <input type="checkbox"/> Sought <input type="checkbox"/> Issued <input type="checkbox"/> Denied <input type="checkbox"/> Canceled <input type="checkbox"/> Suspended Previous Permit Action: <input type="checkbox"/> Registration <input type="checkbox"/> Experimental Use Permit <input type="checkbox"/> No Previous Permit Action	

10. Has a FIFRA Section 24(C) registration for this use of the product ever, by another State been (Check applicable box(es)) <input type="checkbox"/> Sought <input type="checkbox"/> Issued <input type="checkbox"/> Denied <input type="checkbox"/> Revoked If any of the above are checked, list States in item 12 below. <input type="checkbox"/> No FIFRA Section 24(C) Action	11. Endangered Species Act: (Give details in Item 12 or on a separate page, properly identified and attached to this form) Identify the counties where this pesticide will be used. If Statewide, indicate "all." Provide a list of Federally protected endangered/threatened species which occur in the areas of proposed use.
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<p align="center">Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>		12. Comments
Signature of Applicant or Authorized Representative		
Title		
Telephone Number	Date	

Determination by State Agency
This registration is for a Special Local Need and is being issued in accordance with section 24(c) of FIFRA, as amended. To the best of our knowledge, the information above is correct, except as noted in "Comments" below or in attachments.

Name, Title, and Address of State Agency Official	Comments (by State Agency Only)	Received by EPA
Title		
Telephone Number	Date	