

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).

SLN 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an ingredient contained in the pesticide product, unless such denial, disapproval, suspension or cancellation has been superseded by subsequent action of the Administrator; and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 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 which need to be met before an SLN request will be considered in Idaho are:

1. There is no pesticide product registered by 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. However, if there are environmental, pesticide residue/tolerance, or worker safety concerns, the state will elect to consult with EPA in evaluating a SLN request.

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 that has not been disapproved is considered federally registered, but is authorized for distribution and use only with that State, 40 CFR 162.152(c). EPA may disapprove the registration at any time it is believed that the use constitutes an imminent hazard, or may result in excessive residue levels, 40 CFR 162.154(b).

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 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:

1. 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?
2. Has the proposed use or other uses previously been denied, disapproved, suspended or canceled by EPA? If the answer is yes, include a detailed discussion of the action taken by the EPA.

3. Has the registration for the proposed use been voluntarily canceled? If the answer is yes, explain the reason(s) for the voluntary cancellation.
4. Is the product under special review at the EPA? If the answer is yes, provide a detailed discussion of the concern that instigated the special review and its current status.
5. 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:

1. 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 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 the growers/applicators will suffice.

Federal SLN Application:

Submit a signed, completed and dated federal SLN application form, except when the request for a SLN registration under a supplemental distributor label. The form is available from the US EPA website (www.epa.gov) and searching for EPA Form 8570-25. Upon granting the SLN, ISDA will complete the required information on the form, retain a copy for the ISDA files, and send a copy to the registrant and to the EPA

ISDA Pesticide Registration:

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. If the product is currently registered in Idaho as a pesticide product, an additional registration for 24(c) is not necessary. The ISDA Agricultural Resources Division Webpage for Pesticide Product Licensing has information for registering pesticide products in Idaho.

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 ingredients 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 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) if applicable.
6. Pertinent General Information.

The SLN label must also include the statements:

"This label and the federal label for this product must be accessible to the user at the time of the 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 EPA 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 use 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 Northwest 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 five-year (5) expiration date is indicated on all revised, amended transferred or issued SLN labels. For example, an SLN issued between January 1 and December 31, 2020 would contain the statement:

"This label is valid until December 31, 2025 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 five (5) years (or less, if applicable), with any additional data that has become available to the registrant since the SLN label was first approved by ISDA.

Data:

A SLN registration must be accompanied by supporting documentation. Submit field data, published articles, written statements by qualified experts (see "Letters of Support" in this document) 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, or 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:

1. Increased application rate.
2. Increased number of applications.
3. Decreased interval between applications.
4. Decreased pre-harvest interval.
5. 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 data indicating or describing:

1. The study was performed under GLP, or
2. (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. 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 reference (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 conditions under which the trials were conducted were similar to conditions in the growing areas of Idaho. Efficacy data must be accompanied by the

study protocol and 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. The SLN will not be granted in this case 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 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:

- Aquatic systems.
- Endangered species habitats.
- Residences.
- Drift or other types of off-target movement.
- 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:

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 or specialty 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 (please note that the language is subject to change or modification. Contact ISDA for guidance on statements):

"(Registrant's) Special Conditions and Disclaimer for use of (Product) on (Crop/Site)"

"(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 other for failure to perform and crop damage from the use of (Product) on (Crop/Site). 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 product 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."

Note that ISDA endeavors to approve labels that are easily understood by most pesticide applicators that may use the products. Use of excessively wordy or confusing liability statements from registrants may be subject to modification before ISDA approves the insertion of statements into the respective 24(c) labels.

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 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.

Supplemental distributor products have an EPA Registration Number formatted in a three-part series (e.g. 123-45-678). 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, and 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 Number. 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 the EPA Form 8570-25.

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 cancelled or withdrawn, the distributor's 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 their own SLN package. If data compensation is an issue, registrants should make formal arrangement with each other prior to 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 ISDA. The request must include a detailed discussion of the label changes, three copies of the (propose 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 SLN's 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 and will be assigned a new SLN by ISDA. The new registrant will be required to meet all of the requirements listed in this document. The new proposed registrant must complete a federal SLN application for (EZPA Form 8570-25). The original SLN number associated with the original company may be cancelled immediately by the original company, or may be cancelled after the material has cleared the channels of trade/distribution.

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 request a brief explanation of the reason(s) for the cancellation.

Contact Information:

Submit SLN Registration request packets to:

Idaho State Department of Agriculture
Attention: Pesticide Product Registration (24(c) Registration)
PO Box 7249
Boise, ID 83707

To submit SLN packets by email, send to:

_ProductRegistration@isda.idaho.gov (Please note the underscore before Product Registration)

If you have questions concerning the SLN process, please contact ISDA at (208) 332-8609. You may also send inquires by email to the email address listed above.