



***A GUIDE
FOR REQUESTING SECTION
24(c) SPECIAL LOCAL NEED
REGISTRATIONS IN
WASHINGTON
STATE***

***REGISTRATION SERVICES PROGRAM
PESTICIDE MANAGEMENT DIVISION
WASHINGTON STATE DEPARTMENT OF AGRICULTURE***

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A GUIDE FOR REQUESTING SPECIAL LOCAL NEED (SLN) PESTICIDE REGISTRATIONS IN WASHINGTON STATE

The Washington State Department of Agriculture (WSDA) is the designated lead agency for the regulation of pesticides in the state of Washington. WSDA has the authority under section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to register an additional use of a federally registered pesticide product, or a new end use product for use in “special local need” situations. These registrations, reviewed and issued by WSDA, become federal registrations under Section 3 of FIFRA, but can only be distributed and used within the state of Washington. EPA is responsible for overseeing the general program and has 90 days to perform a limited review of these registrations. Within the review period the EPA can require modifications to the SLN registration or in some cases deny the SLN registration.

According to federal definition, a Special Local Need (SLN) is “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 product is not sufficiently available.” The need to control a nationwide pest or a pest problem in a large region of the US does not fall under the definition of a special local need. Candidates for SLN registrations may include (but are not limited to) a new method or timing of application, a changed rate, new crop, new site, new pest, a less hazardous formulation, choice of products or an application to a particular soil type. In contrast to Section 18 emergency exemptions, SLN registrations can be issued to prevent or delay pesticide resistance to certain pesticides by various pest organisms.

In most situations it is the pesticide registrant that applies to WSDA for an SLN registration. The following instructions are intended to help applicants ensure that all the necessary information is submitted to WSDA. A complete request will expedite WSDA’s review, and help the whole process to proceed smoothly. Please submit your request in the same order and format as outlined in the instructions. For a quick overview of the requirements, refer to the WSDA SLN application checklist (Part V). No fee is required to request an SLN registration in Washington, except that "stand-alone" SLN registrations require a pesticide registration fee (\$390 / 2 years).

I. INSTRUCTIONS FOR REQUESTING NEW SLN REGISTRATIONS

A. COVER LETTER

Submit a cover letter that discusses, in detail, the events which brought about the “special local need” request. The discussion must include:

1. A description of the pest problem.
2. 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. States generally may not consider a price differential between products as justification to grant an SLN registration.

Washington State University (WSU) maintains a database of all pesticide products currently registered in the state of Washington (and Oregon). The Pesticide Information Center On-Line (PICOL) at WSU Tri-Cities can provide a list of currently registered insecticides, herbicides, fungicides, rodenticides, etc.,

on almost any pest for any given crop in the Pacific Northwest. For further information contact CharLee Parker (WSU) at (509) 372-7489 or refer to the WSU web site (<http://wsprs.wsu.edu/>).

WSDA depends heavily on the technical expertise of WSU researchers, extension specialists and other unaffiliated experts. A discussion of the currently registered alternatives and why they will not work or are not sufficiently available may be incorporated into their letter of support (refer to Part I, Section B).

3. Whether the pest problem is nationwide or localized (indicate if the proposed use has been requested or granted in other states).
4. The estimated annual value of the SLN registration to users in Washington should be included. The estimated annual value should include the expected cost savings and/or yield increase, and should be rounded to the nearest thousand dollars.

B. LETTERS OF SUPPORT

Submit one (1) copy of letters of support for the SLN registration from the following:

- A.** A WSU 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.

C. FEDERAL SLN APPLICATION

Submit a signed and dated federal SLN application form [EPA form 8570-25 (1-94)] (<http://www.epa.gov/opprd001/forms/8570-25.pdf>), except when the request is for a supplemental distributor SLN registration (refer to Part I, Section K).

D. SUPPORTING DATA

An SLN registration must be accompanied by supporting data. Submit one (1) copy of field data, published articles, and other documents which support the request.

(1) Residue data

- a. If this request is for use on a food or feed crop, a federal tolerance or exemption from the requirement of a tolerance must exist. Cite the specific section in the Code of Federal Regulations (CFR) where the tolerance or exemption from tolerance can be found.
- b. 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?
- c. 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:
 - i. Increased application rate.

- ii. Increased number of applications.
 - iii. Decreased interval between applications.
 - iv. Decreased pre-harvest interval.
 - v. Certain changes in use pattern (i.e. a change from soil application to foliar application).
 - vi. Certain changes in formulation (i.e. addition of a sticker or extender to the formulation, or conversion to a slow-release formulation). Any SLN request involving a change in formulation that is submitted without supporting residue data must be accompanied with a detailed explanation of why residues would not be increased with the change.
- d. Residue data submitted in support of an SLN registration must be in conformance with applicable requirements in EPA's Residue Chemistry Test Guidelines OPPTS 860.1000 Background and 860.1500 Crop Field Tests (<http://www.epa.gov/opptsfrs/home/guidelin.htm>). Note that the latter publication contains a section specifically devoted to SLN registrations.
- e. Residue data should always be generated under Good Laboratory Practices (GLP) as established under 40 CFR 160.* 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.

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, provide the appropriate reference number, such as the Master Record Identification (MRID) number.

*Although EPA guidance on SLN registrations indicates that "non-GLP data are not automatically rejected" EPA has clarified this by indicating that applicants should

"conduct, thus submit, GLP studies always. Scientific credibility or assurance is a plus for GLP studies. However, there are cases where EPA would review and accept non-GLP data on a case-by-case basis. (i.e., refereed journal articles, academic publications, etc.). In most cases these are submitted as supplemental information to substantiate basic GLP information which may have already been reviewed by EPA. In other words, for a specific chemical, there may already be a significant body of information and EPA or the state feel assured on study results."

EPA also indicated that if the state is considering non-GLP residue data as a basis for issuing an SLN a conference with EPA's Registration and Science Divisions should be arranged prior to issuance. Applicants should be aware that such an EPA review prior to issuance will take a considerable amount of time and will substantially delay completion of the state review process.

(2) Efficacy data

The SLN registration request must be supported by efficacy data (comparative data when other registered pesticides are available for use). Efficacy data must be accompanied by the study protocol and the procedures used to carry it out. Whenever possible, field trials should cover a minimum of two growing seasons and be performed in Washington.

Efficacy data generated in areas outside Washington 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 Washington.

(3) Phytotoxicity data

Discuss the potential for the proposed use to cause phytotoxicity to the crop and submit any applicable data (foliar uses only).

(4) Effects on beneficial insects

A pollinator protection statement is required for insecticides and fungicides that are toxic to bees, when applied to a crop or site that is attractive to bees. WSDA may require that registrants submit toxicity data for beneficial and/or pollinating insects (foliar uses only).

(5) Effects on aquatic organisms

Discuss any potential adverse effects to aquatic organisms. The WSDA Aquatic Risk Assessment form (<http://agr.wa.gov/PestFert/Pesticides/docs/AquatRiskAssess4129.pdf>) **must** be submitted with every request (except for indoor or seed treatment uses). WSDA may require that registrants submit additional aquatic toxicity data (aquatic uses only).

E. REGISTRATION STATUS

The request must also address the following questions:

- (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 registration for the proposed use 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.
- (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) Has the registration for **other** uses of the product previously been denied, disapproved, suspended or canceled by the EPA? If the answer is yes, provide a detailed discussion of the action (also refer to Part I, Section F).
- (5) 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.
- (6) Is the pesticide currently undergoing reregistration? If so, is the proposed use being supported?

F. UNREASONABLE ADVERSE EFFECTS DETERMINATION

1. If any of the conditions in (a) through (c) below apply, WSDA must determine that the use will not cause unreasonable adverse effects on people or the environment:
 - a. The product has a composition not similar to any federally registered product.
 - b. The use pattern is not similar to any federally registered uses of the same product or product with a similar composition (a not similar use pattern would include a change from non-food use to food use, outdoor use to indoor use, ground application to aerial application, terrestrial use to aquatic use and non-domestic use to domestic use).
 - c. Registrations for **other** uses of the same product (or products with similar composition) have been denied, disapproved, suspended, or canceled by the EPA.
2. If any of the conditions described in (a) through (c) above apply to this application, a detailed discussion of the potential risks from the proposed use must be submitted. As appropriate, the discussion must address the potential risk to human health, endangered or threatened species, beneficial organisms, groundwater and the environment. Items which may need to be addressed include, but are not limited to:
 - a. Proximity to aquatic systems.
 - b. Proximity to endangered species habitats.
 - c. Proximity to residences.
 - d. Potential for off-target movement.
 - e. Soil type considerations (i.e. potential to leach, potential for carryover, etc).
 - f. Proposals to mitigate risk (i.e. protective clothing, setback restrictions, soil type restrictions, etc.).
3. WSDA will review potential risks and proposals to mitigate risks. When appropriate, WSDA will consult with other state agencies (e.g. Ecology, Fish & Wildlife, Health) and/or federal agencies (e.g. EPA, NOAA Fisheries, USFWS) to determine if proposed risk mitigation measures are adequate.

G. SLN LABEL REQUIREMENTS (Refer to Part IV for example)

- (1) Criteria for registration (RCW 15.58.100) – WSDA will register the label or labeling for a pesticide product if it is determined that the labeling and other material required to be submitted comply with the requirements of RCW 15.58 (i.e. the product will perform its intended function without unreasonable adverse effects on the environment).
- (2) Submit one copy of the current federally registered product labeling. If a federal label does not exist, then submit proof that each active ingredient comes from a federally registered product and each inert ingredient is presently found in a federally registered product.
- (3) Submit 2 copies of the proposed SLN label [refer to WAC 16-228-1400(4)] which must include:

- a. A restricted use pesticide (RUP) designation statement (when applicable):
- i. A federal RUP designation statement is required for all federal RUPs. Wording, size and format of the RUP statement must be identical to the RUP statement on the federal label. The RUP statement must be located at the top of the first page of the SLN label.
 - ii. A state RUP designation statement is required for all state RUPs that do not have a federal RUP statement. The following active ingredients and/or uses are designated as state RUPs (refer to WAC 16-228-1231 and 1235):
 - aquatic pesticides (most uses),
 - clopyralid (certain uses),
 - certain active ingredients and their isomers (atrazine, bromacil, DCPA, disulfoton, diuron, hexazinone, metolachlor, metribuzin, picloram, prometon, simazine, tebuthiuron) to protect groundwater (most uses),
 - phenoxy hormone-type herbicides and dicamba when distributed in eastern Washington (most uses),
 - strychnine and its salts (all uses).

The required state RUP designation statement for a state RUP (aquatic, clopyralid, groundwater, strychnine) is as follows:

“PRODUCT NAME (active ingredient) is a state restricted use pesticide and is to be distributed only by licensed pesticide dealers. Only certified applicators or persons under the direct supervision of a certified applicator may use or apply PRODUCT NAME (active ingredient).”

The required state RUP designation statement for a state RUP (phenoxy) is as follows:

“PRODUCT NAME (active ingredient) is a state restricted use pesticide when distributed in counties located east of the crest of the Cascade Mountains, and is to be distributed only by licensed pesticide dealers. Only certified applicators or persons under the direct supervision of a certified applicator may use or apply PRODUCT NAME (active ingredient) when distributed in counties located east of the crest of the Cascade Mountains.”

- b. The statement:

“FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF WASHINGTON”

- c. The trade name of the product.
- d. The EPA registration numbers of the product:

“EPA Reg. No.” & “EPA SLN No.: WA-*

*(Note: The applicant will be contacted and an actual SLN registration number will be assigned and filled in by WSDA prior to issuing the SLN registration.)

e. The statement:

“It is a violation of federal law to use this product in a manner inconsistent with its labeling.”

f. The statement:

“This labeling must be in the possession of the user at the time of application.”

g. The applicable directions/restrictions statement:

i. For agricultural use SLN labels the statement:

“Follow all applicable directions, restrictions, Worker Protection Standard requirements, and precautions on the EPA registered label.”

ii. For non-agricultural use SLN labels the statement:

“Follow all applicable directions, restrictions, and precautions on the EPA registered label.”

h. Directions for use to meet the special local need (this should include the crop/site, pest(s), application rate and concentration, method of application, frequency and timing of application, pre-harvest interval and any other restrictions or precautions **beyond those found on the federal label**). The following environmental restriction statements are required (when applicable):

i. Beneficial Insects - A pollinator protection statement (PPS) is required for insecticides and fungicides that are toxic to bees, when applied to a crop or site that is attractive to bees. The PPS must include a description of the hazard, followed by a statement consistent with WSDA requirements for the active ingredient and the crop or site. Refer to “Pollinator Protection Requirements for Section 18 Emergency Exemptions and Section 24(c) Special Local Need Registrations in Washington State” for guidance on PPS (<http://agr.wa.gov/PestFert/Pesticides/docs/PollinatorSLNSect18.pdf>).

ii. Herbicides - A statement referring to WSDA herbicide rules is required for herbicides used in areas that are subject to those rules (e.g. phenoxy, desiccant, and sulfonyleurea herbicides in portions of Eastern Washington). A form to request WSDA laws and rules is available on the internet (<http://agr.wa.gov/PestFert/docs/Form4311.pdf>). Consult with WSDA for specific wording referring to WSDA herbicide rules.

iii. Aquatic toxicity - An aquatic toxicity statement is required for pesticides that have a label statement (on the federal label) indicating product toxicity to fish or aquatic invertebrates.

The required statement for aquatic toxicity is as follows:

Repeat the aquatic advisory statement from the Section 3 label. (For example: ***“This pesticide is toxic to fish.”*** or ***“This pesticide is extremely toxic to fish and wildlife.”***)

This statement must be followed by: ***“(Product Name) should not be used under this SLN label where impact on listed threatened or endangered species is likely. You may refer to the WSDA Endangered Species Program web site at <http://agr.wa.gov/PestFert/NatResources/EndangSpecies.aspx>, or contact the Washington Department of Fish & Wildlife, National Marine Fisheries Service (NOAA Fisheries) or US Fish & Wildlife Service for information regarding aquatic species listed as threatened or endangered. Consult the federal label for additional restrictions and precautions to protect aquatic organisms.”***

Any buffers required by the Section 3 label or the RED/IREL should be included in this section.

In addition, the following statement is required for 54 active ingredients impacted by a U.S. District Court final order, unless EPA has made a “no effect” determination or a “not likely to adversely affect” determination:

“Certain uses of (active ingredient) may be restricted by a U.S. District Court final order. You may refer to the WSDA Endangered Species Program web site at <http://agr.wa.gov/PestFert/natresources/Buffers.aspx> for information regarding pesticides that are impacted by the final order.”

- i. If the pesticide is subject to EPA PR Notice 87-1 regarding chemigation (http://www.epa.gov/PR_Notices/), then the SLN label must contain a statement either prohibiting or giving specific directions for use through an irrigation system.

- i. If chemigation is to be prohibited on the SLN label, the following statement is required:

“For use under this SLN label do not apply this product through any type of irrigation system.”

- ii. If chemigation is to be allowed on the SLN label and the federal label allows chemigation, the following statement is required:

“This product may be applied through irrigation systems. Refer to the EPA registered label for chemigation directions.”

In addition, the SLN label must include the WSDA Chemigation Guidance statement (see below). The statement on application off-site is not required if chemigation is limited to microirrigation systems (such as drip irrigation) only.

- iii. If chemigation is to be allowed on the SLN label and the federal label does not allow chemigation, the SLN label must have complete directions for chemigation as specified in EPA PR Notice 87-1. The SLN label may not allow chemigation through the following types of irrigation systems unless specifically authorized in writing by a WSDA Chemigation Specialist: big gun, flood (basin), furrow, or border. In addition, the SLN label must include the WSDA Chemigation Guidance statement. The statement on application off-site is not required if chemigation is limited to microirrigation systems (such as drip irrigation) only.

“WSDA Chemigation Guidance:

- *Application off-site is prohibited. The chemigation application must be continuously observed whenever sensitive areas as defined in WAC 16-202-1002(44) (including but not limited to schools, parks, dwellings, occupied buildings or structures, public roadways, and waters of the state) are at risk of being exposed to drift, runoff, or overspray. In order to minimize the potential for application off-site, WSDA recommends that the product only be applied through low pressure irrigation systems (defined as 2 to 35 pounds/square inch measured at the nozzle) with a nozzle release height no higher than 3 feet above the target crop, and that end guns be disabled throughout the application.*
 - *An inspection port or a direct access point is required, and it must be positioned immediately upstream of the irrigation mainline check valve and be of sufficient size to allow visual and manual inspection of the check valve and low pressure drain. The inspection port or access point must have a minimum diameter of four inches, unless an alternative access system is approved by WSDA (WAC 16-202-1012[1]).*
 - *The chemigation application tank cannot be placed within 20 feet of the wellhead or other sensitive areas. Mixing or loading activities cannot occur within 20 feet of the wellhead or other sensitive areas (WAC 16-202-1008[1]).*
 - *WSDA Chemigation Rules (WAC 16-202-1001 through WAC 16-202-1024), and information on USEPA Authorized Alternative Chemigation Safety Equipment, Distribution Uniformity and other chemigation topics are available on the WSDA website (<http://agr.wa.gov/PestFert/ChemFert/default.aspx>).*”
- j. A container disposal statement (when applicable):
- i. Plastic containers - **“WSDA Container Disposal Guidance: Pesticide containers must be properly cleaned prior to disposal. The best time to clean empty pesticide containers is during mixing and loading, because residue can be difficult to remove after it dries. Triple rinse (or pressure rinse) the pesticide container, empty all pesticide rinse**

water into the spray tank, and apply to a labeled crop or site. Recycling cleaned containers is the best method of container disposal. Information regarding the recycling of empty and cleaned plastic pesticide containers in Washington is available on the WSDA Waste Pesticide Program web site at <http://agr.wa.gov/PestFert/Pesticides/WastePesticide.aspx>. Cleaned containers may also be disposed of in a sanitary landfill, if permitted by the county. Burning is not a legal method of container disposal in Washington.”

- ii. Paper containers - *“WSDA Container Disposal Guidance: Completely empty the contents of the pesticide container into application equipment, and apply to a labeled crop or site. The empty container may be disposed of in a sanitary landfill. Burning is not a legal method of container disposal in Washington.”*

- k. The following expiration date statement is required for all SLN labels:

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

(All SLN labels expire on the fifth year after issuance, unless WSDA determines that a shorter period is appropriate.)

The purpose of the expiration date is to allow for periodic review of the SLN label to insure that precautions 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 SLN label consistent with current WSDA requirements. The expiration date may be extended for five years, unless WSDA determines that a shorter period is appropriate (refer to Part II, Section A for guidance on submitting a revised SLN label to WSDA).

- l. The name and address of the SLN registrant.
- m. For label restrictions related to alfalfa, clover and certain small vegetable crops grown for seed refer to Part I, Section H.
- n. A label revision date (such as **Rev. 01/01/2001**).

H. CROPS GROWN FOR SEED

Alfalfa, clover and certain small seeded vegetable seed crops grown to produce seed specifically for crop reproduction purposes are considered “nonfood and nonfeed sites” for purposes of pesticide registration in the state of Washington. The “nonfood and nonfeed” designation eliminates the requirement for tolerances and allows pesticides without a tolerance to be registered on the designated seed crops. EPA has accepted this designation based upon growers’ and processors’ strict adherence to Washington rules found in WAC 16-228-1270, “Use of pesticides on small seeded vegetable seed crops and seed alfalfa” (<http://apps.leg.wa.gov/WAC/default.aspx?cite=16-228>).

The following statements must be included on the SLN label under the heading **“Restrictions / Precautions”**:

“1. All (crop) seed screenings shall be disposed of in such a way that they cannot be distributed or used for human food or animal feed. The seed conditioner shall keep records of screening disposal for three years from the date of disposal and shall furnish the records to the director immediately upon request. Conditioner disposal records shall consist of documentation of on-farm disposal, disposal at a controlled dumpsite, incinerator, composter or other equivalent disposal site and shall include the lot numbers, amount of material disposed of, the grower(s), and the date of disposal.

2. No portion of the (crop) seed plant, including but not limited to green chop, hay, pellets, meal, whole seed, cracked seed, roots, bulbs, leaves and seed screenings may be used or distributed for food or feed purposes.

3. (Crop) seed shall bear a tag or container label which forbids use of the seed for human consumption or animal feed.

4. (Crop) seed may not be distributed for human consumption or animal feed.”

Applicants that wish to apply for an SLN registration under the nonfood/nonfeed designation must obtain a copy of WSDA seed crop rules and consult with WSDA.

I. WAIVER OF LIABILITY STATEMENTS ON SLN LABELS

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 of liability language on SLN labels. Additional information on this issue is available on the EPA web site (<http://www.epa.gov/pesticides/regulating/labels/pdf/warranty.pdf>). The following is an example of waiver of liability language that is acceptable to EPA:

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

“(Registrant) intends that this Section 24(c) label be distributed only 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 that all such use is at the user’s and/or grower’s risk, to the extent consistent with applicable law.”

“This Special Conditions and Disclaimer statement is required by (Registrant) and is not required or enforced by the USEPA or the WSDA.”

When a waiver of liability statement is included on the SLN label it must be placed on the last page. A sentence referring the user to the waiver of liability statement may be placed on the first page of the SLN label (associated with the required statements e., f., and g.).

“Read and understand the (Registrant’s) Special Conditions and Disclaimer for use before using (Product) on (Crop).”

Waiver of liability certificates are not part of the SLN label. These certificates are agreements made between the Registrant and/or Grower Association and the users.

J. CONFIDENTIAL STATEMENT OF FORMULA

Indicate if a confidential statement of formula (CSF), listing the active and inert ingredients contained in the product, is on file with WSDA. If a CSF is not on file with WSDA, the applicant must submit a CSF with the SLN registration request as required by RCW 15.58.060 of the Washington Pesticide Control Act.

K. SLN’s FOR SUPPLEMENTAL DISTRIBUTOR PRODUCTS

EPA requires that SLN registrations be based on a primary Section 3 registration (these registrations have a two part EPA Registration No., such as 123-456). 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 123-456-789. WSDA will issue a supplemental distributor SLN registration when the following conditions are met:

- (1) An identical SLN registration has been issued by WSDA 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 WSDA with the supplemental distributor SLN request, and
- (3) A cover letter, a copy of the federal label, and 2 copies of the draft supplemental distributor SLN label have been submitted to WSDA.

A federal SLN application form is not required for supplemental distributor SLN registrations and the SLN label is not submitted to EPA. Supplemental distributor SLN labels are assigned the same SLN registration number as the primary SLN labels, but differ by having a letter (such as b, c, d) following the SLN number.

Any action taken on or changes made to the primary SLN also affects the distributor SLN (i.e. If the primary registrant decides to voluntarily cancel their SLN registration, the supplemental distributor SLN is automatically cancelled). 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.

L. “ME-TOO” SLN REGISTRATIONS

WSDA allows SLN registrations of products that are identical in formulation to existing SLN registrations (“Me-Too” SLN registrations) when the following conditions are met:

- (1) The “Me-Too” SLN registrant must submit a cover letter, a completed EPA SLN application form, a copy of the federal label, and 2 copies of the draft SLN label. They do not need to submit any non-proprietary data (i.e. WSU or IR-4 data) that is already on file with WSDA.
- (2) The “Me-Too” SLN registrant must have a letter of authorization from the original registrant to cite any proprietary data (or must submit their own data).
- (3) The “Me-Too” SLN registrant must submit letters of support (refer to Section B), and verification that a special local need still exists. Some applications may require additional information.
- (4) Label wording of the “Me-Too” SLN must be essentially identical to the wording of the SLN label the “Me-Too” is based on, except for changes required by WSDA or EPA.

In certain situations, WSDA may not issue a “Me-Too” SLN registration, such as when the use has been added to a Section 3 label with the same active ingredient and formulation or a new Section 3 pesticide has been registered that will adequately control the pest problem.

M. SLN LABELS FOR MULTIPLE STATES

Many pest problems of crops grown in Washington also occur in other PNW states, and WSDA works closely with Oregon and Idaho on pesticide registration issues. However, each state has specific labeling requirements for SLN registrations. Therefore, WSDA policy is that the SLN label needs to be for Washington only, unless the registration is for a “stand-alone” pesticide (not federally registered).

N. THIRD-PARTY SLN REGISTRATIONS

Third-party SLN registrations are issued to a company other than the registrant when the registrant of the product is not willing to apply for an SLN registration. However, third-party SLN registrations will not be issued without a letter of authorization from the registrant of the product. In such instances, the third-party registrant becomes the registrant of the SLN registration and is responsible for maintenance fees, any data to support the SLN registration, the addition of required label language for worker protection standard, endangered species etc., and all other obligations of a registrant under FIFRA.

II. 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 WSDA. The request must include a detailed discussion of the label changes, 2 copies of the SLN label with the proposed revisions, and any necessary data or other documents to support the requested changes. Once the SLN labels are approved, WSDA will notify the EPA of the changes and submit a revised label for their records.

It is important that registrants do not distribute revised SLN labels until they have been approved by WSDA. SLN labels that have been revised without approval by WSDA

violate the Washington Pesticide Control Act, RCW 15.58, and may be considered “misbranded” under FIFRA.

WSDA has the authority under RCW 15.58 to revise SLN labels when necessary to ensure that human health and the environment are adequately protected. WSDA will notify the registrant of proposed revisions, and will discuss proposed revisions upon request.

B. TRANSFERRING SLN REGISTRATIONS

When SLN registrations are transferred from one company to a second company and both products are being distributed in Washington, then the SLN registration for the new product is considered to be a new SLN registration. A new SLN application must be submitted to WSDA for review and it must include a cover letter, a completed EPA SLN application form, a copy of the federal label, 2 copies of the draft SLN label, and a copy of EPA’s letter approving transfer of the SLN registration.

If the old product SLN registration will be canceled in Washington and will no longer be distributed, then the new product is considered to be a revised SLN registration. In this case, a letter of request, a copy of the federal label, 2 copies of the revised SLN label, and a copy of EPA’s letter approving transfer of the SLN registration is to be submitted to WSDA for review and approval. Refer to Part II, Section A for guidance on submitting a revised SLN label to WSDA.

Exceptions to the above will be addressed by WSDA on a case-by-case basis. Some applications may require additional information.

C. WITHDRAWING OR CANCELING EXISTING SLN REGISTRATIONS

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

If WSDA determines that a pesticide or its labeling does not comply with the provisions of RCW 15.58 or the rules adopted thereunder, WSDA may cancel the registration after a hearing in accordance with the provisions of RCW 34.05 (Administrative Procedure Act).

III. WSDA CONTACT INFORMATION

Submit requests for new SLN registrations (including “Me-Too” SLN registrations and third-party SLN registrations) to:

Erik W. Johansen / Special Pesticide Registration Program Coordinator
Washington State Department of Agriculture
Pesticide Management Division
1111 Washington Street SE, 2nd Floor
PO Box 42560
Olympia, WA 98504-2560

Submit requests for new supplemental distributor SLN registrations, and requests for revising, transferring, withdrawing, or canceling existing SLN registrations to the WSDA Pesticide Registration Specialist assigned to the registrant:

Steve Foss, 360-902-2049, sfoss@agr.wa.gov

Erik Johansen, 360-902-2078, ejohansen@agr.wa.gov

Mike Norman, 360-902-1851, mnorman@agr.wa.gov

Wendy Sue Wheeler, 360-902-1972, wswheeler@agr.wa.gov

If you have administrative questions regarding the submission of an SLN registration request, please contact Joy Harkness (WSDA Help Desk) at (360) 902-2030 or e-mail jharkness@agr.wa.gov.

IV. WSDA SLN LABEL FORMAT

FEDERAL / STATE RESTRICTED USE PESTICIDE STATEMENT (WHEN APPLICABLE)

FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF WASHINGTON



PRODUCT NAME



EPA REG. NO. 123-456

EPA SLN NO. WA-XXXXXX

- It is a violation of federal law to use this product in a manner inconsistent with its labeling.
- This labeling must be in the possession of the user at the time of application.
- Follow all applicable directions, restrictions, Worker Protection Standard requirements, and precautions on the EPA registered label.

Directions for Use

- Crop or Site / Pest(s).
- Application rate and concentration.
- Method / Frequency / Timing of application.

Restrictions / Precautions

- Pre-harvest interval.
- Aquatic toxicity, endangered species, pollinator protection, seed crop, etc.
- For use under this SLN label do not apply this product through any type of irrigation system.

WSDA Container Disposal Guidance (When applicable)

This label for (Product name) expires and must not be distributed or used in accordance with this SLN registration after December 31, 20XX.



24c Registrant:

Chemical Company, Inc.
20039 97th Avenue
Middletown, ST 00000

Rev. 01/01/2001

V. WSDA SLN APPLICATION CHECKLIST

IS THE APPLICATION COMPLETE? – The following items must be included (when applicable):

1. Cover letter - all SLN registrations.
2. Draft SLN label (2 copies) - all SLN registrations.
3. Current federal label (1 copy) - all SLN registrations.
4. Completed EPA SLN application form - all SLN registrations except supplemental distributor SLN registrations.
5. Letter of support from a WSU 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 - 40 CFR 180. _____
8. Efficacy data - required for all uses.**
9. Phytotoxicity data - required if foliar use.**
10. Effects on beneficial insects – data may be required if foliar use.**
11. Aquatic risk assessment form - required except for indoor and seed treatment uses.**
**Not required for supplemental distributor SLN registrations.
12. Confidential Statement of Formula - required if CSF is not already on file with WSDA.
13. Letter of authorization from the primary registrant - required for supplemental distributor SLN registrations or third-party SLN registrations, or for “Me-Too” SLN registrations that cite proprietary data.
14. 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 have been denied, disapproved, suspended, or canceled?
3. Is the product is under special review at the EPA?
4. Is the pesticide undergoing Reregistration?
5. Is the product not similar to any federally registered product?
6. Is the use pattern not similar to any federally registered uses?

IS THE SLN LABEL FORMAT CONSISTENT WITH WSDA REQUIREMENTS?

Refer to the SLN guidance document and WAC 16-228-1400(4):

1. Federal / State RUP statement (when applicable).
2. “FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF WASHINGTON”
3. Product Brand Name. _____
4. EPA Reg. No. _____
5. EPA SLN No. WA-xxxxxx (assigned by WSDA)
6. “It is a violation of federal law to use this product in a manner inconsistent with its labeling.”
7. “This labeling must be in the possession of the user at the time of application.”
8. “Follow all applicable directions, restrictions, Worker Protection Standard requirements, and precautions on the EPA registered label.” (Agricultural) OR “Follow all applicable directions, restrictions, and precautions on the EPA registered label.” (Non-agricultural)
9. Directions for use: Crop or site to be treated _____,
Pest(s) to be controlled _____,
Application rate _____,
Concentration _____,
Method of application _____,
Frequency and timing of application _____,
Restricted entry interval (REI) _____,
Pre-harvest interval (PHI) _____.
10. Restrictions / Precautions (e.g. pollinator protection, herbicide drift, aquatic toxicity, chemigation, endangered species, seed crop, etc.) applicable to the use.
11. WSDA container disposal guidance.
12. Expiration date statement.
13. Name and address of the SLN registrant.
14. Label identification code (such as the revision date).
15. If SLN label has a waiver of liability statement, it must be consistent with EPA and WSDA requirements.