

ODA Pesticide Registration Guidance: FIFRA Section 24(c) Special Local Need (SLN) Registrations

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1. Overview

This guidance document summarizes how to apply for a new FIFRA Section 24(c) Special Local Need (SLN) registration in Oregon, the type of supporting information that must be included in an application, and the circumstances under which the Oregon Department of Agriculture (ODA) may or may not issue a new SLN registration. It also summarizes the processes of extending the expiration date of a registered SLN, revising a registered SLN label, and cancelling an SLN registration. Finally, this guidance includes resources for applicants to ensure that their applications are complete and that their labels include all necessary information.

This document provides guidance only. It does not modify any requirements under Section 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, its implementing regulations at 40 CFR 162, the Oregon Pesticide Control Act, or any Oregon Administrative Rule. ODA may deviate from this guidance where warranted.

2. What is an SLN?

Generally, before a pesticide product may be sold and distributed in the United States, it must first be registered by the United States Environmental Protection Agency (EPA) under Section 3 of FIFRA. Before that federally registered product may be sold and distributed in Oregon, it must be registered with the ODA under the Oregon Pesticide Control Act. ODA reviews the product labeling to ensure that it contains only the uses for which EPA has registered that product, along with all the EPA-required directions, restrictions, and precautions. The labeling affixed to a product container can be called the "Section 3 labeling."

Under Section 24(c) of FIFRA, as amended, the Oregon Department of Agriculture (ODA) may register an additional use of a federally registered end use pesticide¹ to meet a "special local need." This is referred to as a Special Local Need (SLN) registration. As defined in 40 CFR 162.151:

¹ This guidance focuses on SLN registrations which add an additional use to a federally registered product. ODA does have limited authority to register a new end use product as an SLN (see 40 CFR 162.152(b)(2)). ODA has not received an SLN request like this in years. If you are interested in applying for an SLN for a new end use product, contact the ODA Pesticides Program. ODA may NOT use Section 24(c) of FIFRA to register a new manufacturing-use product (40 CFR 162.152(b)(2)(iii)), or a new end-use product that contains an active or inert ingredient not found in any federally registered product (40 CFR 162.152(b)(2)(iii)).

"Special local need means an existing or imminent pest problem within a State for which the State lead agency [i.e., the ODA], based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available."

As further explained in this document, ODA has the authority to review an application for an SLN registration to determine whether a special local need exists.² While SLNs are registered by ODA, and use under the SLN label may begin as soon as the SLN is registered by ODA, EPA has 90 days to review every SLN label ODA registers.³ In their 90-day review, EPA can request modifications to the label and has the authority to disapprove SLN registrations.⁴ After 90 days, the SLN is considered a federal registration, albeit one issued by ODA and limited to distribution and use in Oregon.⁵

The definition of special local need has several components. In the past, ODA has issued SLNs to:

- Permit use on an additional site: The SLN label "adds" use on a crop not currently on the main container labeling. If the SLN is for use on a food or feed crop, then the use must be covered by an EPA-established tolerance or exemption from tolerance requirements.⁶
- Permit use of an additional application method: For example, if a product's main container labeling permits use on a certain crop, but only by ground application, ODA could register an SLN to permit aerial application to that crop, provided all other conditions of SLN registration are met. If the proposed use is a food or feed crop, the applicant must submit data to ODA that show that the modified use pattern will not result in residue levels that exceed the EPA-established tolerance.⁷
- Increase application rate
- Change application timing
- Change the number or frequency of applications

² 40 CFR 162.153(b).

³ 40 CFR 162.154(c).

⁴ Ibid.

⁵ 40 CFR 162.152(c)(1).

⁶ ODA may only grant an SLN for a food or feed use if "the use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (<u>21 U.S.C. 346</u> et seq.)" (40 CFR 162.152(a)(2)).

⁷ Ibid.

There are several situations in which ODA may not issue an SLN registration, and/or EPA may disapprove of an SLN registration, including:

- The definition of special local need is not met.⁸ For example, if there are multiple registered products available to control the pest of concern on the crop of interest, and the proposed use is not more effective against the pest than the registered options, then ODA would likely be unable to register the proposed SLN.
- The proposed SLN is for use on a food or feed crop, and the use is not covered by an EPA-established tolerance or exemption from tolerance requirements.⁹
- The proposed SLN is for a use that has been previously denied, disapproved, suspended or cancelled by EPA.¹⁰
- The proposed SLN is for a use that has been voluntarily cancelled by the registrant after receiving from EPA a notice to intent to cancel that use because of health or environmental concerns associated with an ingredient in the product.¹¹
- The proposed SLN is not "in accord with the purposes of FIFRA." 12

ODA may not issue an SLN registration for a manufacturing-use pesticide (i.e., a pesticide exclusively labeled for use in formulating other pesticide products).¹³

Finally, ODA may not issue an SLN that establishes a new "use pattern," because that new use pattern would require additional data be submitted to EPA that EPA would be unable to review in their 90-day review period. For example, if an herbicide is exclusively registered in the United States for terrestrial use, ODA could not register an SLN for an aquatic use. For assistance in determining whether a site or crop would be a new "use pattern," consult EPA's Pesticide Use Site Index (https://www.epa.gov/pesticide-registration/pesticide-use-site-index) and 40 CFR 158, Data Requirements for Pesticides.

For more examples of which uses could or could not be registered under FIFRA Section 24(c), see https://www.epa.gov/pesticide-registration/guidance-fifra-24c-registrations.

^{8 40} CFR 162.152(a)(1).

^{9 40} CFR 162.152(a)(2).

¹⁰ 40 CFR 162.152(a)(3).

¹¹ Ibid.

¹² 40 CFR 162.152(a)(4).

¹³ 40 CFR 162.152(b)(1)(iv) and 40 CFR 162.152(b)(2)(iii).

3. Applying for a New SLN Registration

3.1: Application Materials

The <u>registrant¹⁴</u> of the pesticide product is responsible for submitting a <u>complete</u> application to ODA for review and consideration.

A complete application includes:

- 1. Applicant cover letter.
- 2. ODA Pesticide Product Registration (PPR) application form, including application fee.
- 3. Draft proposed SLN label.
- 4. EPA Form 8570-25.
- 5. Letters of support.
 - a. One from a representative of the growers (e.g., a commodity commission)
 - b. One from a researcher not affiliated with the pesticide registrant who can speak to the special local need. Typically, this letter is written by an Oregon State University (OSU) Extension agent.
- 6. Efficacy and crop safety data.
- 7. Residue data (food and feed uses only).

3.1.1: Applicant Cover Letter

The SLN applicant must include a cover letter summarizing the application package, the proposed SLN registration, and the special local need this registration is proposed to address. In addition, the applicant must address the following in their cover letter:

- Are similar SLNs active in other states? If so, which states, and what are the SLN registration numbers? Please note that this information must also be entered on EPA Form 8570-25.
- Are similar SLN applications pending in other states? If so, which states?
- In an ideal world, approximately when in the calendar year would use under the proposed SLN label begin?

¹⁴ The majority of SLN applications are submitted by the registrant of the FIFRA Section 3 registration (i.e., the name of the company on the main container labeling). In certain circumstances, ODA may issue an SLN registration to a "third party" (e.g., a commodity group). There are requirements that the prospective third party SLN registrant must meet, and they would assume certain responsibilities for the registration. If a third party is interested in pursuing an SLN registration, contact the ODA Pesticides Program.

3.1.2: ODA PPR Form and Payment

Before ODA may begin review of an SLN application, the applicant must submit a completed PPR form and nonrefundable application fee. The PPR form will state the application fee. The application fee is per proposed SLN registration. The completed form and payment must be submitted to ODA by mail or fax per the instructions on the form. ODA is not able to accept PPR forms by email because they contain payment information.

Even if your company has an active Pesticide Product Registration (PPR) license, do NOT submit an SLN application through MyLicense. MyLicense may only be used for Section 3 and 25(b) registrations only. If you apply for an SLN through MyLicense, your annual renewal and certificate printing could be delayed.

3.1.3: Draft Proposed SLN Label

The applicant must submit the proposed SLN label for ODA's review. ODA will review this proposed label against the Section 3 label for the product and the rest of the SLN application materials (including the efficacy, crop safety, and residue data, if applicable). For information on what information must be on the SLN label, and how the label must be written, consult the appendices of this guidance.

3.1.4: FPA Form 8570-25

The applicant must complete all sections of EPA Form 8570-25, Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need, except for the sections labeled "For State Use Only" or "Determination by State Agency." Blank forms are available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms.

3.1.5: Letters of Support

The letters of support are crucial in explaining how the proposed registration meets the definition of special local need at 40 CFR 162.151.

At a minimum, the applicant must submit two (2) letters of support to ODA:

- I. One letter from a representative of the growers (e.g., the commodity commission).
- II. One letter from a researcher not affiliated with the pesticide registrant who can speak to the special local need (e.g., an OSU Extension agent).

Please ensure that whoever writes a letter of support includes their contact information in their letter, including an email address. This allows ODA to keep them in the loop on the status of the application, and to send a copy of the approved label once the SLN is registered, if applicable.

Collectively, the letters of support should address the following:

- <u>Pest problem:</u> What is/are the pest (or pests) of interest? What damage do they cause to the crop/site? What are the consequences if left uncontrolled? Is this a newly introduced pest in Oregon? If not, is this a regional or nationwide pest?
- <u>Current registered alternatives:</u> What are growers currently using to control this pest, and why are the current options not meeting grower needs?
 - For a list of products currently registered in OR to control that crop and pest, you may use Washington State University's (WSU's) Pesticide Information Center OnLine (PICOL; https://picol.cahnrs.wsu.edu/). When using PICOL, be sure to select the state as "Oregon" and not "Oregon and Washington."
 - o If ODA has already granted one or more SLNs for control of this same pest on this same crop or site, ODA will need to know how this proposed SLN compares to the registered SLNs. For example, what is/are the benefit(s) of this proposed SLN compared to the registered SLN(s)? Could the SLN be applied at a different crop stage? Would the SLN target a different life stage of the pest?
 - o If there is confirmed or suspected resistance to active ingredient(s)/mode(s) of action currently used to control that pest, that information should be included in the letter of support. Resistance arguments need to be specific. The general argument of "this would be another active ingredient, which is valuable for resistance management" is not sufficient justification by itself for ODA to grant an SLN registration. If the applicant claims that the proposed SLN is needed to address a current pest resistance problem, that claim must be supported by data.
- <u>Data summary:</u> If the letter writer was involved in generating the supporting efficacy, crop safety, and/or residue data, they may summarize their findings in their support letter.

3.1.6: Efficacy and Crop Safety Data

To grant an SLN, ODA needs <u>two years</u> of field data, preferably collected in the Pacific Northwest, that demonstrate the proposed SLN is effective against the target pest and does not cause unacceptable phytotoxicity to the crop or site of interest.

The data should compare the proposed use to an untreated control and to the pesticides that growers/applicators are currently using to control that pest. The data do not need to compare the proposed SLN to every single registered option; if multiple options are available, comparing the product to the one or two options growers primarily rely on is sufficient. Finally, the data must be analyzed for statistical significance.

To be protective of growers, the data should be collected in the Pacific Northwest. If the supporting data were collected outside of the Pacific Northwest, ODA will need a written explanation of why the differences in climate and cultural considerations between the Pacific Northwest and the state in which the data were collected are not expected to result in poor pest control or unacceptable crop damage. This information can be incorporated into the letter of support from a researcher not affiliated with the registrant.

3.1.7: Residue Data (Food/Feed Uses Only)

If the proposed SLN is for use on a food or feed crop, the applicant must submit data to ODA that support that the proposed use will not result in residue levels that exceed the EPA-established tolerance. The residue data must describe how the pesticide was applied (e.g., application rate, number of applications, reapplication interval, preharvest interval, etc.). The applicant does not necessarily need to submit the raw data to ODA. For example, if EPA has published a Summary of Analytical Chemistry and Residue Data in response to the tolerance petition, the applicant may submit that. Many of those summaries are available in regulations.gov in the docket for the tolerance petition.

3.2: Submitting the Application

The ODA PPR form and application payment can NOT be submitted by email. They must be submitted by mail or fax, per the instructions on the PPR form.

All other materials may be submitted by email to Matthew Bucy at matthew.bucy@oda.oregon.gov. If the applicant prefers to submit all or some of the application materials by mail, please notify Matthew so that he knows to expect this. If mailing these materials, mail to:

ATTN: Special Local Needs Registrations ODA Pesticides Program 635 Capitol St. NE Salem, OR 97301-2532

All application materials should be submitted on the same date to avoid delays in processing.

3.3: Application Review Process

Once ODA receives an SLN application, ODA will screen the application to ensure that it includes all the required materials. If materials are missing, ODA will notify the applicant of what is missing. Once ODA receives a complete application, ODA will contact the applicant to confirm receipt of a complete SLN application and provide an expected date by which the initial review will be completed. ODA currently strives to review new SLN applications within 60 days of receiving a complete application.

ODA will then review the application and proposed label to confirm that, among other things:

- The definition of special local need is met and supported by the efficacy and crop safety data.
- The SLN label includes all necessary information, and is written clearly, concisely, and in accordance with ODA guidance.
- The proposed use directions are supported by the efficacy, crop safety, and residue data, if applicable.
- For food and feed uses, that a tolerance or tolerance exemption has been established by EPA and that the proposed use will not result in residue levels that exceed the EPA-established tolerance.
- For use on seed crops subject to the Special Crop Use Restrictions (see Section 4.5), that the use may be considered a non-food/non-food use per Oregon Administrative Rule (OAR) 603-057-0535.
- If a Registration Review Interim Decision (ID) has been published by EPA for the active ingredient(s) in the product, that the ID-required risk mitigation measures do not preclude registration of the proposed SLN.
- EPA does not have any risk concerns that would preclude ODA from registering the SLN.

During the course of ODA's review, ODA may determine that additional information is required to evaluate the proposed SLN, and may reach out to the applicant, the support letter authors, OSU Extension, pesticide regulatory agencies in other states, or EPA's Office of Pesticide Programs, as needed. Specifically, ODA may need to consult with EPA if:

- The proposed SLN is for use of a product for which registration of other uses of the product have been denied, disapproved, suspended, or cancelled by EPA.¹⁵
- The proposed use has previously been voluntarily cancelled by the registrant.¹⁶

¹⁵ 40 CFR 162.152(b)(1)(ii)

¹⁶ 40 CFR 162.152(b)(1)(iii).

Once ODA has finished its review, if ODA has determined that it can register the proposed SLN, ODA will email an annotated label to the applicant which describes the label changes that must be implemented before ODA can register that label.

If ODA has determined that, based on the information currently available to ODA, the proposed SLN cannot be registered, ODA will send a letter to the applicant communicating this. This letter will describe why the proposed SLN cannot be registered, corrective actions the applicant could take (if applicable), and the next steps available to the applicant.

3.4: Registration Process

An SLN label may not be used or distributed until it is approved by ODA. Once the applicant submits to ODA a label that has made all required revisions, ODA will add the SLN Registration Number to the label, finish the EPA Form 8570-25, and email the label and form to EPA's 24(c) Mailbox alongside an ODA cover letter explaining the special local need. Once ODA completes these steps, the SLN is registered in Oregon. That same day, ODA will forward these materials to the applicant (now the SLN registrant) and post the label for viewing in ODA's Search Registered Pesticide Products (https://oda.direct/PesticideProductSearch). Use and distribution of the SLN label may then begin.

Once EPA receives the ODA-registered SLN label, EPA has 90 days to review it. In their 90-day review, EPA may require revisions to the label and has authority to disapprove it. If EPA requires any revisions to the label, ODA will contact the SLN registrant to implement the changes. Once ODA approves the updated label, ODA will distribute the updated label using the same process described in Section 3.3.

3.5: EPA Review Process

EPA has the authority to disapprove of any SLN registered by ODA. Generally, if EPA intends to disapprove an SLN, they will notify ODA in writing of their intent to disapprove and their reasoning.¹⁷ This notice will provide ODA at least 10 days to respond and will provide ODA the opportunity to consult with EPA.¹⁸ EPA will make a final decision on disapproval, and provide written notification regarding disapproval, within 90 days of the effective date of the SLN registration.¹⁹

¹⁷ 40 CFR 162.154(a)(2).

¹⁸ Ibid.

¹⁹ 40 CFR 162.154(c).

EPA may disapprove of an SLN for one or more of the following reasons:

- The SLN authorizes use on a food or feed crop, and the use is NOT covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act.²⁰
- EPA has determined that use of the pesticide under the SLN registration would constitute an imminent hazard.²¹
- There is not a special local need, as defined at 40 CFR 162.151.²²
- Registration for this same use has previously been denied, disapproved, suspended or cancelled by EPA, unless such actions have been superseded by subsequent EPA actions.²³
- Registration for this same use has been previously voluntarily cancelled by the registrant subsequent to EPA issuing a notice of intent to cancel the registration because of health or environmental concerns, unless this has been superseded by a subsequent EPA action.²⁴
- The registration is not in accord with the purposes of FIFRA.²⁵
- The SLN may pose unreasonable adverse effects on man or the environment by the registered use.²⁶

In addition to their 90-day review, EPA has the authority to disapprove of an SLN at any time if the use would "constitute an imminent hazard" or result in residue levels on a food or feed crop that exceed or are not covered by a tolerance, exemption, or other clearance under FFDCA.²⁷

An SLN that is issued by ODA, and that is not disapproved by EPA, shall be considered a federal registration, albeit one that only authorizes distribution and use within Oregon.²⁸ It is subject to all provisions of FIFRA that apply to federally registered products, including EPA's Registration Review program.²⁹

²⁰ 40 CFR 162.152(a)(2).

²¹ 7 U.S.C. 136(v)(c)(3).

²² 40 CFR 162.152(a)(1).

²³ 40 CFR 162.152(a)(3).

²⁴ Ibid.

²⁵ 40 CFR 162.152(a)(4).

²⁶ 40 CFR 162.154(a)(1)(i).

²⁷ 40 CFR 162.154(b)(1).

²⁸ 40 CFR 162.152(c)(1).

²⁹ 40 CFR 162.152(c)(1).

4. Special Procedures

4.1: Distributor SLN Labels

ODA may only issue an SLN to the federal registrant.³⁰ If a distributor registrant³¹ is interested in an SLN label, the federal registrant must apply to ODA for an SLN. If ODA is able to register the SLN, ODA would approve a label for the primary registrant and a label for the distributor registrant. The SLN Registration Numbers would be the same, and the labels would only differ in their registrant name, EPA Registration Number, product name (if applicable), and trademark statements (if applicable).³²

When applying for the SLN, in addition to the materials listed in "3.1: Application Materials," the distributor registrant must also submit an ODA PPR and payment for their SLN label. When applying for the SLN, it is acceptable to submit a draft label only for the federal registrant's product. If ODA is able to register the SLN, ODA will send the annotated copy to both the federal registrant and the distributor. ODA will notify the distributor that they must submit a label that matches the federal registrant's revised label, except for the allowable differences described in the preceding paragraph.

4.2: Non-bearing Uses

ODA may only register an SLN for use on a food or feed crop if EPA has established a tolerance that would cover the residues of the pesticide on that crop or has exempted the active ingredient from tolerance requirements. However, ODA could possibly issue an SLN for use on a non-bearing crop if the label restricted harvest of the crop for 365 days after the last application under the SLN labeling (e.g., "Do not harvest [crop name] for at least 365 days after the last date this product was applied under this SLN labeling"). If an applicant is interested in an SLN for use on a non-bearing crop, they should contact the ODA Pesticides Program before submitting their application to confirm such a restriction is appropriate for the crop of interest.

³⁰ This issue is discussed at length in EPA's Guidance on FIFRA 24(c) Registrations (https://www.epa.gov/pesticide-registration/guidance-fifra-24c-registrations)

³¹ "Distributor registrant" and "distributor" in this context refer to supplemental distribution of a registered pesticide. Not, for example, a pesticide dealer.

³² 40 CFR 152.132.

4.3: Changes in Registrant Name or Registrant

In Oregon, pesticide products that are "readily distinguishable" from one another must be registered separately.³³ Products may be readily distinguishable from one another if, among other circumstances:

- The products bear different registrant names, even if the rest of the labeling is identical.³⁴
- The products bear different EPA Registration Numbers, even if the rest of the labeling is identical.³⁵

When a registrant changes their name on their pesticide labels, they must apply for new product registrations for the products labeled with the "new" company name. Similarly, if a registrant had any SLNs registered to authorize use of a product labeled with the "old" company name, they must apply for a new SLN for the product labeled with the "new" company name. Generally, the registrant will not need to submit any crop safety, efficacy, or residue data, or letters in support of such an application, so long as those materials are on file with the existing SLN for the "old" company name and the only difference between the text of the old label and the new label will be the company name.

For a new SLN that is needed only due to a change in the name of the registrant, the applicant will generally only need to submit to ODA:

- EPA Form 8570-25
- ODA PPR form and payment
- Draft SLN label

If the name of your company has changed, and you have SLNs for products bearing the old company name, contact the ODA Pesticides Program to discuss obtaining new SLNs for products bearing the new company name.

If you have obtained the federal registration for a product for which the previous registrant had SLNs in Oregon, you will need to apply for new SLNs for the product bearing your company name. In addition to the materials needed when the *name* of the registrant changes, ODA may need a letter permitting use of the data on file with ODA if such data are owned by the former registrant. Contact the ODA Pesticides Program to determine if this is the case for the SLNs of interest.

³³ Oregon Administrative Rule (OAR) 603-057-0001.

³⁴ Ibid.

³⁵ Ibid.

4.4: SLNs for Crops for Export Only

While most SLNs are intended for use on crops that will be sold in the United States, ODA may register an SLN which authorizes use of a product on a crop that will be exported (i.e., ALL of the crop treated under the SLN will be exported outside of the United States). In the past, ODA has registered SLNs specifically to meet an import requirement of another country. Generally, ODA has not required efficacy or crop safety data to support these uses. Rather, ODA has required documentation of the special local need. This information would need to address at least the following questions:

- What is the specific import requirement this SLN would meet?
- Which markets have this requirement?
- Is this a new or amended export requirement?
- If this is not a new export requirement, which pesticides were growers previously using to meet this export requirement? Why are those pesticides no longer suitable? For example, are those pesticides no longer registered in Oregon?

The applicant may need to submit residue data, depending on the specifics of the application and the claimed special local need. If you are interested in applying for an SLN for use on a crop for export only, contact the ODA Pesticides Program to discuss the special local need and the information ODA will need to review the application.

4.5: Crops Grown for Seed - Special Crop Use Restrictions

ODA may only register an SLN for use on a food or feed crop if EPA has established a tolerance that would cover the residues of the pesticide on that crop or has exempted the active ingredient from tolerance requirements. However, per Oregon Administrative Rule (OAR) 603-057-0535 Pesticide Use on Crops Grown for Seed Production, use on certain crops grown for seed may be considered a non-food/non-feed use provided certain restrictions are followed. These restrictions are communicated on the SLN label under the heading "Special Crop Use Restrictions."

For the purposes of SLN registration, the following crops, when grown exclusively for seed, are generally eligible to be considered non-food/non-feed uses when subject to the restrictions of OAR 603-057-0535:³⁶

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³⁶ OAR 603-057-0535(1).

Alfalfa	Clover	Mizuna
Alliums (except garlic)	Collards	Mustard (including Chinese)
Arugula	Cucumber	Parsley
Beet (garden and sugar)	Dill	Parsnip
Birdsfoot Trefoil	Drug & Medicinal Crops	Radish (except daikon)
Broccoli (including Chinese)	Endive	Rapeseed (industrial oil only)
		[as defined in OAR 603-052-
		0860(c)(d))]
Brussels Sprouts	Escarole	Rutabaga
Burdock	Herbs (Culinary)	Spinach
Cabbage (including Chinese)	Herbs (Dietary Supplement)	Squash, Summer
Carrot	Kale (including Chinese)	Squash, Winter (except
		Pumpkin)
Cauliflower	Kohlrabi	Swiss Chard
Celery	Lettuce	Turnip
Cilantro/Coriander	Meadowfoam	Vetch

Not every crop is able to be considered non-food/non-feed per OAR 603-057-0535, even when grown for seed. The following crops must always be considered food/feed uses, even when grown for seed, and therefore ODA could only issue an SLN for use on any of these crops if a tolerance or exemption from tolerance requirements has been established by EPA:³⁷

- Cereal grains, including barley, buckwheat, corn, millet, oats, rye, sorghum, triticale, and wheat.
- Legume vegetables (succulent and dried), including all peas, beans, chickpeas, and lentils,
- Canola (as defined in OAR 603-052-0860(a)),
- Garlic,
- Potatoes,
- Pumpkins,
- Sunflower.

Additionally, per EPA's September 30, 2000, draft policy "Additional Guidance on the Crop - 'Grasses Grown for Seed," EPA considers uses on grasses grown for seed to be a food/feed use. Therefore, if a tolerance has not been established that would cover use of a pesticide on grasses grown for seed, ODA could not issue an SLN for use of that pesticide on grasses grown

³⁷ OAR 603-057-0535(2).

for seed. The only possible exception is if use were limited to establishment year only. If an applicant is interested in pursuing an SLN for use on grasses grown for seed in the establishment year only, the applicant should contact the ODA Pesticides Program.

If the applicant is uncertain whether a proposed SLN for use on a crop grown for seed may be considered a non-food/non-feed use under OAR 603-057-0535, the applicant should contact the ODA Pesticides Program before submitting their application.

5.Registered SLN - Expiration Date Extension Process

Whenever ODA registers an SLN, the approved label will state that the label is valid until a specific date unless otherwise amended, withdrawn, cancelled, or suspended. Generally, ODA assigns SLNs an expiration date of December 31st 5 years after the year of issuance. For example, a new SLN registered in 2026 will generally be labeled with the expiration date December 31, 2031.

There may be circumstances where ODA requires that the label expire sooner than five years after the year of issuance. For example, if EPA has published a Proposed Interim Registration Review Decision (PID) in which EPA has proposed that the use authorized by the SLN be cancelled due to risk concerns, ODA would generally only extend the expiration date until EPA anticipates completing their Interim Registration Review Decision (ID; i.e., their decision as to whether the use will actually be cancelled).

Generally, so long as the SLN continues to meet the claimed special local need and all other conditions of registration continue to be met, the expiration date may be extended.

Unless specifically requested, ODA does not require additional letters of support to extend an SLN registration. However, registrants are welcome to submit letters in support of extending the expiration date.

To extend the expiration date of an SLN, the SLN registrant must email a draft updated SLN label as a PDF to Matthew Bucy at matthew.bucy@oda.oregon.gov. If any other revisions have been made to the label, the applicant must identify those in their email. Depending on the revisions requested (e.g., raising the application rate), ODA may require supporting data or other supporting materials.

ODA will review the proposed label and evaluate whether the special local need claimed at initial registration still exists. If ODA is able to extend the expiration date, ODA will email the SLN registrant an annotated label detailing any revisions that must be made. Once an approvable label is ready, ODA will register the label and notify the registrant and stakeholders using the same process described in Section 3.4. The revised SLN label with the extended expiration date may NOT be used and distributed until ODA approves it.

Unless told otherwise by ODA, applicants should not submit expiration date extension requests sooner than September 1st the year their label expires.

6. Registered SLN – Label Revision Requests

Once an SLN is registered, the registrant may request the label be revised at any time. Similarly, if ODA identifies that a registered label must be revised, ODA may contact the registrant at any time notifying them that they must update their label.

If ODA has determined that an SLN label must be revised (e.g., a statement on the label must be clarified), ODA will email the registrant a description of the changes necessary (either as a list or as a redlined label) and a summary of any additional information needed. The registrant must then update their label and email the updated label as a PDF to ODA for review. The edited label is not effective until it is approved by ODA; ODA will notify the registrant and stakeholders when the updated label is approved using the same procedure described in Section 3.4. The revised label may not be used or distributed until ODA approves it.

If the registrant has determined that edits are needed to one of their SLN labels, they may email a clean edited label as a PDF, a description of the changes made (e.g., a redlined label or cover letter), and an explanation of why the changes were necessary. ODA will review the proposed revisions. If further revisions are required, or the proposed revisions are not acceptable, ODA will notify the registrant. If a revised label is acceptable, ODA will register it and notify the registrant and stakeholders of this using the same procedure described in Section 3.4. The revised label may not be used or distributed until ODA approves it.

<u>NOTE:</u> Changes to the application directions (e.g., increasing the application rate, adding an application method, etc.) require supporting data.

For food and feed uses, if the revisions include an increased application rate, increased number of applications, or decreased pre-harvest interval (PHI), ODA will need to consult the data used to establish the tolerance to confirm that the revised application directions are supported by

these data. If the tolerance has not changed since the SLN was first issued, then ODA will refer to the residue data on file, and additional data will likely not be needed. If the EPA-established tolerance has been modified since the SLN was issued, or the registrant has additional residue data to support the request, then those data must be submitted to ODA. If you are interested in revising the application directions or restrictions on an SLN label, prior to submitting the revised label for review, contact the ODA Pesticides Program to discuss whether ODA will need additional data to review the label.

7. Registered SLN - Cancellation Process

To voluntarily cancel ("VOLCAN") an SLN, the registrant must submit a letter to ODA requesting that the SLN be voluntarily cancelled. The registrant's letter must:

- 1. State the reason for cancellation.
- 2. State whether they want to waive the 180-day public comment period in the Federal Register. An SLN registrant may only waive the 180-day public comment period; they may not waive all rights to a comment period. Submitting a letter that requests to waive all rights to a comment period will delay processing of the cancellation request.

This letter may be emailed as a PDF to Matthew Bucy at matthew.bucy@oda.oregon.gov.

It is insufficient for an SLN registrant to simply mark their SLN for cancellation on their annual Oregon Pesticide Product Registration (PPR) renewal. ODA cannot cancel the SLN without a formal letter containing the information identified above. If an SLN registrant marks an SLN for cancellation on their annual renewal without submitting a cancellation letter to ODA containing the information identified above, their annual PPR renewal will be delayed.

Once ODA receives the registrant's letter requesting the SLN be cancelled, ODA will submit that letter alongside an ODA cancellation letter to EPA. Once ODA submits both letters to EPA, that SLN is cancelled in Oregon. ODA will notify the registrant the same day that ODA sends both letters to EPA. Once the SLN is cancelled in Oregon, the SLN label may no longer be used or distributed. After receiving both letters from ODA, EPA will publish in the Federal Register a Notice regarding the cancellation of the federal registration for the SLN.

It is important to remember that SLNs are registered for <u>use</u> and distribution. Every SLN label prominently states "For Distribution and Use Only in the State of Oregon" or "For Distribution and Use Only in [specific counties] in Oregon." A product may not be used under a cancelled SLN label, even if the SLN was cancelled before the cancellation date on the SLN label (every label will state "This label is valid until [date] or until...cancelled..."). Before cancelling an SLN,

it is imperative that the registrant check with their field staff to confirm that growers who had been using their product under the SLN label do not have existing stocks of that product they intended to apply under the SLN label.

The day that an SLN is cancelled in Oregon, use under that SLN labeling must stop.

8. Resources

- 40 CFR 162, Subpart D: Regulations Pertaining to State Registration of Pesticides To Meet Special Local Needs: https://www.ecfr.gov/current/title-40/part-162.
- 2. 40 CFR 180.41, Crop group tables: https://www.ecfr.gov/current/title-40/part-180/section-180.41.
- 3. EPA Form 8570-25, Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need: https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms.
- 4. EPA's Guidance on FIFRA 24(c) Registrations: https://www.epa.gov/pesticide-registration/guidance-fifra-24c-registrations.
- 5. EPA Pesticide Use Sites and Major Use Patterns: https://www.epa.gov/pesticide-registration/pesticide-use-sites-and-major-use-patterns.
- 6. Oregon Administrative Rule (OAR) 603-057-0535 Pesticide Use on Crops Grown for Seed Production:
 - https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=158978.

9. Frequently Asked Questions

9.1 I am a pesticide registrant. I see that another registrant has an SLN for use of a specific active ingredient on a specific crop. I have a registered product containing that same active ingredient. Can I get an identical SLN to authorize the same use of my product?

Part of the definition of "special local need" at 40 CFR 162.151 is that a federally registered pesticide product is not available. Once ODA has registered an SLN, it has made a federally registered product available, therefore addressing the special local need.

ODA does not grant "me too" SLNs. If an applicant were to apply for an SLN with the argument that the requested use is available on another product label, that would not be sufficient justification for ODA to grant that SLN. The applicant would need to make an argument as to what special local need their SLN, if registered, would address.

9.2 I am interested in applying for an SLN for use of a product on multiple crops. Can I include all the crops on one SLN label, or will I need to apply for multiple SLNs?

If the crops are similar, then ODA would allow the applicant to apply for one SLN label for use on all those crops. "Similar" in this context means the crops are all in the same crop group or subgroup³⁸ or are all crops grown for seed subject to the Special Crop Use Restrictions and OAR 603-057-0535. ODA would not allow food uses and non-food uses to appear on the same SLN label.

9.3 How do I cite another registrant's data?

If an applicant is interested in citing data from another registrant that is already on file with ODA, ODA would need a signed letter from the registrant that owns those data giving the applicant permission to use them in support of their SLN application. An example of when this would be needed could be if Company A has purchased Company B's product and Company B had an SLN registered in Oregon. Company A would need to apply for a new SLN to authorize use of the product bearing their company name. If data owned by Company B are already on file with ODA, then, before ODA could issue an SLN to Company A, Company A would need to get a letter from Company B permitting use of Company B's data.

9.4 We are waiting for EPA to establish a tolerance for use of our product on a crop. Can we get an SLN for use on that crop while we wait?

No. ODA may only issue an SLN for a food or feed use if "the use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act."³⁹ If a tolerance has not been established, the applicant's only avenues to an SLN registration are an SLN limited to the non-bearing crop (if applicable), the crop grown for seed subject to the Special Crop Use Restrictions required by 603-057-0535 (if eligible), or to establishment year only (if the crop is grasses grown for seed).

³⁸ See 40 CFR 180.41.

^{39 40} CFR 162.152(a)(2).

9.5 Do I need to include the Agricultural Use Requirements box and other Worker Protection Standard (WPS) information on the SLN label?

Generally, no. Any SLN for use subject to the WPS will have a statement on the label referring the applicator to the main container labeling for WPS requirements. However, if the use on the SLN label has a unique restricted entry interval (REI) compared to the uses on the main container labeling, then the REI should be stated on the SLN label, but not the rest of the WPS information.

9.6 Do I need to include the Environmental Hazards from the main container labeling on the SLN label?

Generally, no. ODA previously required that the Environmental Hazards section from the main container labeling be duplicated on the SLN label. ODA no longer requires this. The Environmental Hazards does not include crop-specific information. The statements apply to all labeled uses of the product. The SLN label already requires the applicator to follow all directions, restrictions, and precautions on the main container labeling, which would include the Environmental Hazards. ODA reserves the right to require the Environmental Hazards on a case-by-case basis if it seems an appropriate risk mitigation measure.

9.7 As part of the SLN application, do I need to submit a copy of the main container labeling and the EPA-stamped labeling upon which the container labeling is based?

Not as part of the SLN application, no. The main container labeling and associated EPA-stamped label are required as part of an application to register a Section 3 product for sale and distribution in Oregon. These materials would already be on file with ODA as part of the Section 3 registration.

9.8 Do I have to express application rates per year, or can I express them per season or per crop cycle?

The SLN label must at least specify a maximum annual application rate and maximum number of applications per year. If the applicant would like to also express a rate per season, per crop cycle, etc., then the SLN label must state how many seasons, crop cycles, etc. there are per calendar year.

9.9 Instead of collecting two years of efficacy and crop safety data, can I collect one year of data from multiple different fields?

No. ODA requires two years of field data to ensure that the product will be effective against the target pest without causing unacceptable crop damage. If data are only submitted from one year of trials, that year could have been atypical (e.g., hotter than average) in a way that presents an incomplete picture of the product's efficacy and crop safety.

Appendices

Appendix A: SLN Label Template

<u>Disclaimer</u>: This SLN Label Template is a guidance document which identifies the information that generally must appear on an Oregon SLN label and **the order in which that information must be presented**. ODA may allow or require an SLN label be formatted differently or have different content than that described in this guidance. Some of the label elements in this template may not be applicable to every product (e.g., there would be no Restricted Use Pesticide box for a general-use product). All label text must adhere to font size requirements under FIFRA.

How to use this template:

- Each label element is followed by an explanatory endnote.
- Text that is highlighted is text that would be replaced/filled in when writing an SLN label.
- Text that is not highlighted, but is in brackets, is text that may or may not be required depending on the desired use and/or the specific product.

[RESTRICTED USE PESTICIDE¹] [RUP Statement]

FIFRA Section 24(c) Special Local Need (SLN) Label²

For Distribution and Use Only in the State of Oregon³

[Mode of Action Box]4

Product Name⁵

EPA Reg. No. XXXXXXX-XXXXXX⁶ EPA SLN No. OR-

For Control/Suppression of Pest(s) on Crop(s)8

This label is valid until December 31, XXXX or until otherwise amended, withdrawn, cancelled, or suspended⁹

Active Ingredient¹⁰

active ingredient name.....XX%

Other Ingredients.....XX%

TOTAL 100%

Contains XX lb. active ingredient name per gallon

KEEP OUT OF REACH OF CHILDREN¹¹ SIGNAL WORD¹²

[Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle (If you do not understand the label, find someone to explain it to you in detail)]¹³

Directions for Use

- [Restricted Use Pesticide]¹⁴
- It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
- This SLN label and the label affixed to the main container of Product Name must be in the possession of the user at the time of pesticide application.¹⁶
- Follow all applicable directions, restrictions, [Worker Protection Standard requirements], and precautions on this SLN label and the label affixed to the main container of Product Name.¹⁷

SLN-specific use directions¹⁸

Special Crop Use Restrictions¹⁹

[if needed, select the appropriate version from Appendix C]

[Registrant warranty]²⁰

Section 24(c) Registrant:²¹

- The label must refer to itself as a "Special Local Need Label," not a "Supplemental Label."
- Include "(SLN)" so that this abbreviation may be used throughout the label.
- ³ For Distribution and Use Only in the State of Oregon: Must be "Distribution and Use," not "Sale and Use" or "Sale and Distribution." This label element is required by 40 CFR 162.153(e)(3)(i). If use and distribution of the SLN is to be limited to specific counties, revise "in the State of Oregon" to "in the Counties of county names" in the State of Oregon" or "in county name" County in the State of Oregon.
- ⁴ Mode of Action (MOA) Box: If the MOA box is present on the Section 3 label, it must be present in the upper right quadrant of page 1 of the SLN label. Commonly, registrants place the MOA box above and to the right of the product name. Alternatively, the MOA box may be placed above and to the right of "FIFRA Section 24(c) Special Local Need (SLN) Label." Do not include the rest of the resistance management information from the Section 3 label on the SLN label.
- ⁵ **Product Name:** Use the full product name registered in Oregon and use the same product name consistently throughout the label. This label element is required by 40 CFR 162.153(e)(3)(iii).
- ⁶ **EPA Reg. No.:** This label element is required by 40 CFR 162.153(e)(3)(v).
- ⁷ **EPA SLN No.**: If you are applying for a new SLN, ODA will assign the SLN number prior to registration. When submitting a draft label for a new SLN, please leave the SLN number blank. For registered SLNs, do not change the SLN No. when revising the label or extending the expiration date. This label element is required by 40 CFR 162.153(e)(3)(vi).
- ⁸ **Pest and crop statement:** Select the term (e.g., "control" or "suppression") that the efficacy data support. You may use different terms for different pests (e.g., "For control of X and suppression of Y…"). Where applicable, use the crop name(s) found in <u>40 CFR 180.1</u> or <u>40 CFR 180.41</u>.
- ⁹ Expiration date statement: For new SLNs with two years of satisfactory efficacy and crop safety data, ODA will generally allow an expiration date 5 years into the future. For example, the label of a new SLN registered in 2026 would generally have an expiration date of December 31, 2031, provided that the efficacy and crop safety data submitted with the application were acceptable. When extending expiration dates, ODA generally allows the expiration date to be extended by five years. There are circumstances where ODA may only permit a shorter extension and/or require additional supporting information to extend the date the full five

¹ **Restricted Use Pesticide (RUP) box:** Include if the product is a federally Restricted Use Pesticide (RUP).

² FIFRA Section 24(c) Special Local Need Label:

years (e.g., if EPA has proposed cancellation of this use as part of Registration Review and the Registration Review Interim Decision is anticipated to be issued in less than 5 years).

- ¹⁰ **Ingredients Statement:** The full Ingredients Statement must appear on the SLN label, including statements such as "Contains 4 lb. of active ingredient per gallon."
- ¹¹ **Keep Out of Reach of Children (KOROC):** If EPA allowed an alternative statement on the Section 3 label, then use that on the SLN label.
- ¹² **Signal Word:** This must match the Section 3 label.
- ¹³ **Spanish statement:** If this statement is not present on the Section 3 label, then it is optional on the SLN label. If this statement is present on the Section 3 label, then both the Spanish statement and its English translation must be present on the SLN label.
- ¹⁴ **Directions for Use (DFU) RUP Statement**: If the product is a federally Restricted Use Pesticide, then this statement is required per 40 CFR 156.10(i)(2)(i).
- ¹⁵ **DFU Statement #1 (Misuse statement):** This statement must appear immediately beneath "Restricted Use Pesticide" (if required) or immediately beneath the heading "Directions for Use" (if the product is not a federally restricted use pesticide). This statement and its location are required by 40 CFR 156.10(i)(2)(ii).
- ¹⁶ **DFU Statement #2:** Must use the term "the label affixed to the main container of Product Name."
- ¹⁷ **DFU Statement #3:** If the use is subject to Worker Protection Standard (WPS) requirements, include a reference to the WPS requirements on this SLN label and the label affixed to the main container of the product. Do not include the Agricultural Use Requirements box on the SLN label. Unless the use authorized by the SLN label has a unique restricted entry interval (REI) or unique personal protective equipment (PPE), do not repeat that information on the SLN label. This label element is required by 40 CFR 162.153(e)(3)(vii).
- ¹⁸ **SLN-specific use directions:** See Appendix B Directions for Use Checklist for requirements and guidance.
- ¹⁹ **Special Crop Use Restrictions:** Only include this section if the SLN is for use on a crop (or crops) grown for seed and the use would be considered a non-feed/non-food use under Oregon Administrative Rule (OAR) 603-057-0535 Pesticide Use on Crops Grown for Seed. See Appendix C for the text of this element.
- ²⁰ **Registrant warranty:** ODA and EPA do not require this label element, but many registrants opt to include it. Common section titles include "Special Conditions and Risk of Use" or "Conditions of Sale and Limitation of Warranty and Liability." If included on the SLN label, the registrant warranty section must:
 - Be the second-to-last section on the SLN label, placed immediately above the Section 24(c) registrant mailing address.

- Include the following as the final statement: "These/this section title are required by registrant name and not specified by the U.S. EPA or the State of Oregon."
- Align with EPA's Pesticide Labels: Guidance on Warranty Statements.

²¹ **Registrant mailing address:** Only required on the last page of the label. This label element is required by 40 CFR 162.153(e)(3)(iv). The section title may be Section 24(c) Registrant or 24(c) Registrant.

Appendix B: Directions for Use Checklist

Site and pest information

The SLN label must state "For [Control/Suppression] of Pest(s) on Crop(s)." See Appendix A SLN Label Template for more information.

Directions for Use Completeness

The SLN Directions for Use must explicitly state the following:

- Maximum single application rate (rate "per acre per application").
- o Maximum annual application rate (rate "per acre per year").
- o Maximum number of applications per year.
- o Minimum re-application interval (if multiple applications are permitted).
- o Pre-harvest interval (if the use site is a food or feed crop).
- Any other intervals that may be necessary based on the residue data (e.g., preslaughter interval)

The SLN must also clearly state:

- Application method(s) and minimum application volume(s) (see "Application Methods" below)
- Application timing (when may the product be applied under the SLN label?).
- Grazing restrictions (if applicable).
- Any other precautions, restrictions, or directions necessary to ensure that the product,
 when applied under the SLN label, is safe and effective.

Application Methods

- Ground: If the product is to be applied by ground application, the SLN label must state the minimum application volume (e.g., "20 gallons per acre by ground application").
- Aerial: If the product is to be applied by aerial application, the SLN label must state the minimum application volume (e.g., "5 gallons per acre by aerial application"). If the product is not to be applied aerially, the SLN label must explicitly state this (e.g., "Do not apply this product by aerial application.")
- Chemigation: If the product is to be applied by chemigation, the SLN label must meet the requirements of Pesticide Registration Notice (PR) 87-1. If the Section 3 label already has the information required by PR 87-1, then the SLN label must refer the applicator to that section of the main container label (e.g., "When applying by chemigation, follow all applicable directions, restrictions, and precautions in [section title] of the label affixed to the main container of [product name]." If the product is not to be applied by chemigation, then the SLN label must state "Do not apply this product through any type of irrigation system."

Best practices and tips

- Where applicable, use the crop name(s) found in 40 CFR 180.41 or 40 CFR 180.1.
- Application rates must at least be expressed "per year." If application rates are expressed "per season", "per crop," or "per crop cycle," then the label must state how many seasons, crops, or crop cycles there are per year.
- Express application rates in terms of both product per acre and pounds of active ingredient per acre.
- Separate precautions from restrictions. For example, have an "Application Restrictions" section followed by an "Application Precautions" section, rather than a single "Application Restrictions and Precautions" section.
- Generally, the following are not required on an Oregon SLN label, even if they appear on the Section 3 label:
 - o Resistance management information (other than the Mode of Action box).
 - Spray drift advisories and spray drift management restrictions
 - <u>EXCEPTION:</u> If the Section 3 label requires a buffer, the buffer should be stated on the label with a reference to the Section 3 label for the rest of the spray drift information.
 - EXAMPLE: "Buffer Requirements: Do not apply by ground within 25 feet or by air within 50 feet of lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, or commercial fish farm ponds. Follow all applicable directions, restrictions, and precautions in the Spray Drift Precautions and Spray Drift Management sections of the label affixed to the main container of [product name]."
 - Rotational crop restrictions (unless there is information specific to use under the SLN that is not present on the Section 3 label).
 - Agricultural Use Requirements box and other Worker Protection Standard information.

EXCEPTIONS:

- If the use site on the SLN label has a unique Restricted Entry Interval (REI) compared to the use sites on the Section 3 label, include a statement such as "Restricted Entry Interval: 12 hours.
 Refer to the label affixed to the main container of [product name] for additional Worker Protection Standard requirements."
- If use under the SLN requires unique Personal Protective Equipment (e.g., due to a Registration Review Interim Decision), then this must be included on the SLN label.

 $\underline{\text{Additional resources:}} \ \underline{\text{40 CFR 156.10(i)}} \ \text{and} \ \underline{\text{EPA Label Review Manual Chapter 11: Directions for}} \\ \underline{\text{Use}}$

Appendix C: Special Crop Use Restrictions

There are two potential options for how this label element may be written.

Option 1: Use this version if a tolerance has not been established by EPA for ANY crop on the SLN label, at any residue level. Select the singular or plural term (highlighted) depending on how many crops are on the SLN label. The highlighting is for emphasis only; do not highlight the text on your SLN label.

Special Crop Use Restrictions

The pesticide applicator, the producer of [the crop/these crops], and the seed conditioner must be aware that use of this product according to this labeling is deemed a non-feed/non-food use by the Oregon Department of Agriculture and is regulated by the Oregon Administrative Rule (OAR) 603-057-0535, Pesticide Use on Crops Grown for Seed. If the applicator of this pesticide is not the producer, the applicator must provide a copy of this labeling to the producer of the crop. Producers of [this crop/these crops] who use this product, or cause the product to be used on a field they operate, must provide a copy of this pesticide label to the seed conditioner.

This pesticide does not have an established pesticide residue tolerance for [this crop/these crops]. Consequently, no portion of [this seed crop/these seed crops] may be used or distributed for food or feed for 1 year (365 days) after the last application of this product. This restriction pertains to, but is not limited to, green chop, forage, hay, pellets, meal, whole seed, cracked seed, straw, roots, bulbs, foliage or seed screenings, and to the grazing of the crop field, stubble or regrowth. All seed screenings shall be disposed of in such a manner that screenings cannot be distributed or used for food or feed purposes, as indicated in OAR 603-057-0535. Additional regulations concerning seed screenings are stated in OAR 603-0535.

Any seed from a field treated with this pesticide product shall bear specific and conspicuous container labeling, or if shipped in bulk, on the shipment invoice or bill of lading. The labeling shall contain the following statement:

"This seed was produced using one or more products for which the United States Environmental Protection Agency has not established pesticide residue tolerances. This seed, in whole, as sprouts, or in any form, may not be used for human consumption or animal feed. Failure to comply with this condition may violate requirements of the

Federal Food and Drug Administration, the Oregon Department of Agriculture and other regulatory agencies."

Option 2:

Use this version if a tolerance has been established by EPA for at least one crop on the SLN label. In this case, the SLN label would permit directions for use not necessarily covered by the established tolerance, and the use would need to be considered non-food/non-feed and be subject to the restrictions under OAR 603-057-0535. Select the singular or plural term (highlighted) depending on how many crops are on the SLN label. The highlighting is for emphasis only; do not highlight the text on your SLN label.

Special Crop Use Restrictions

The pesticide applicator, the producer of [the crop/these crops], and the seed conditioner must be aware that use of this product according to this labeling is deemed a non-feed/non-food use by the Oregon Department of Agriculture and is regulated by the Oregon Administrative Rule (OAR) 603-057-0535, Pesticide Use on Crops Grown for Seed. If the applicator of this pesticide is not the producer, the applicator must provide a copy of this labeling to the producer of the crop. Producers of [this crop/these crops] who use this product, or cause the product to be used on a field they operate, must provide a copy of this pesticide label to the seed conditioner.

This pesticide does not have an established pesticide residue tolerance for use on [this crop/these crops] as specified under this SLN labeling. Consequently, no portion of [this seed crop/these seed crops] treated under this SLN labeling may be used or distributed for food or feed for 1 year (365 days) after the last application of this product. This restriction pertains to, but is not limited to, green chop, forage, hay, pellets, meal, whole seed, cracked seed, straw, roots, bulbs, foliage or seed screenings, and to the grazing of the crop field, stubble or regrowth. All seed screenings shall be disposed of in such a manner that screenings cannot be distributed or used for food or feed purposes, as indicated in OAR 603-057-0535. Additional regulations concerning seed screenings are stated in OAR 603-057-0535.

Any seed from a field treated with this pesticide product shall bear specific and conspicuous container labeling, or if shipped in bulk, on the shipment invoice or bill of lading. The labeling shall contain the following statement:

"This seed was produced using one or more products for which the United States Environmental Protection Agency has not established pesticide residue tolerances. This seed, in whole, as sprouts, or in any form, may not be used for human consumption or animal feed. Failure to comply with this condition may violate requirements of the Federal Food and Drug Administration, the Oregon Department of Agriculture and other regulatory agencies."