COLORADO DEPARTMENT OF AGRICULTURE
Division of Plant Industry
305 Interlocken Parkway, Broomfield, Colorado, 80021
Tel: (303) 869-9050 Fax: (303) 466-2860 www.colorado.gov/ag/dpi

A GUIDE FOR REQUESTING SECTION 24(c) SPECIAL LOCAL NEED REGISTRATIONS IN COLORADO

9/4/2015 LSQ

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A GUIDE FOR REQUESTING SECTION 24(c) SPECIAL LOCAL NEED REGISTRATIONS IN COLORADO

The Colorado Department of Agriculture is the designated lead agency for the regulation of pesticides in the state of Colorado. CDA 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 CDA, become federal registrations under Section 3 of FIFRA, but can only be distributed and used within the state of Colorado. 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, disapprove 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, development of resistance in a pest, or need for a less hazardous formulation. 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.

It is the EPA pesticide registrant that applies to CDA for an SLN registration. Although in some cases the registrant for the normal Colorado state registration of a product is the distributor, not the EPA registrant, the SLN application (EPA from 8570-25) must be from the EPA registrant, and be signed by the EPA registrant. The following instructions are intended to help applicants ensure that all the necessary information is submitted to CDA. A complete request will expedite CDA'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 CDA SLN application checklist (Part V). No fee is required to request an SLN registration in Colorado.

Most Colorado SLN's add a use to a product that already has a Colorado state registration. If the underlying product is not already registered with CDA, then a normal state registration application must be submitted (with the $165 registration fee) before or with the SLN application.

Although FIFRA does allow SLN registrations for new products under certain circumstances, these are very rare.

SLN applications can be submitted as email attachments. If submitted via mail as paper documents, please also provide electronic pdf file versions of labels and supporting documents.

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.

   CDA maintains a database of all pesticide products currently registered in the state of Colorado. This information is combined with EPA data by the National Pesticide Information Retrieval System associated with Purdue University. This subscription database allows searching products registered with CDA by all of the sites and pests that are on the EPA master label. If you do not subscribe to this database contact the CDA Pesticide Registration Coordinator and she can assist with this.

   CDA depends heavily on the technical expertise of CSU 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 a letter of support from such experts (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.

B. LETTERS OF SUPPORT

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

A. A CSU 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).

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. Submit data showing that the proposed use will not result in crop residues exceeding the established tolerances 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/ocspp/pubs/frs/publications/Test_Guidelines/series860.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 attesting to one of the following: (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 and crop injury data.

CDA usually relies on CSU experts to assess the efficacy and crop injury potential of the proposed use. In some cases the CSU expert will already be familiar with the efficacy and crop tolerance. If not, submission of efficacy data will be required.

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 Colorado. Efficacy data generated in areas outside Colorado 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 Colorado.

(3) 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. CDA may require that registrants submit toxicity data for beneficial and/or pollinating insects, especially for foliar or systemic uses of insecticides and fungicides.

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/registration review? 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, CDA 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, terrestrial use to aquatic use or 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. CDA will review potential risks and proposals to mitigate risks. When appropriate, CDA will consult with other state agencies (e.g. Colorado Parks and Wildlife, Colorado Dept. of Public Health & Environment) and/or federal agencies (e.g. EPA, FWS) to determine if proposed risk mitigation measures are adequate.

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

(1) Submit one (1) copy of the current federally registered product labeling, including an electronic pdf file version. 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 one (1) copy of the proposed SLN label which should 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.

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

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

c. The trade name of the product.

d. The EPA registration number and SLN number of the product*:*

"EPA Reg. No. Nnnnn-nnn"

"EPA SLN No.: CO--YYnnnn

*[Note: The applicant will be contacted and an actual SLN registration number will be assigned when the SLN request is approved.]

e. The signal word, if the pesticide is category 1.

f. The following expiration date statement is required for all SLN labels. In general, CDA requires expiration dates at the end of the fifth year of registration, unless a shorter period is appropriate:

"This label expires and must not be distributed or used after December 31, [Fifth year]."

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).

g. The statement:

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

h. The statement:

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

i. 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."***

j. Directions for use to meet the special local need. This should include the following:

i. crop/site,
ii. pest(s)
iii. application rate
iv. spray volume or concentration,
v. method(s) of application,
vi. frequency and timing of application
vii. restricted entry interval (REI)
viii. pre-harvest interval (PHI)
ix. maximum annual application rate
x. any other restrictions or precautions that are applicable to the intended use.

k. 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."

The SLN label must list the allowed types of irrigation systems for chemigation.

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 must list the allowed types of irrigation systems for chemigation.

m. The name and address of the SLN registrant (or distributor for SLN labels for distributor products).

n. For SLN's for pesticide use on alfalfa grown for seed, for which no tolerances exist for alfalfa, the following label statements are required on the SLN label:

SEED CONDITIONING REQUIREMENTS:

For use only on fields in production of alfalfa seed.

Not for use on fields producing alfalfa for livestock feed.

Do not graze current year's treated alfalfa seed crop.

Do not cut current year's treated alfalfa seed crop for hay or forge.

Treated alfalfa seed is not to be used for sprouting. All alfalfa seed treated with [product name] is to be tagged at the conditioning plant, "NOT FOR HUMAN OR ANIMAL CONSUMPTION". <u>It shall be the grower's responsibility to notify the conditioning plant of any alfalfa seed crop treated with [product name].</u>

Screens and seed from seed conditioning are prohibited from feed channels. All [product name] treated alfalfa seed screenings must be removed from the feed market.

For additional information, see Part I, Section H.

o. A label revision date (such as ***Rev. 01/01/2014***).

H. CROPS GROWN FOR SEED

The Colorado Seed act has rules with specific requirements for alfalfa or clover seed resulting from crops treated with pesticide registered under Section 24(c) of FIFRA. These rules allow for SLN uses for pesticides that do not have tolerances established for alfalfa or clover.

8 CCR 12-3, Part 16:

Part 16. PESTICIDE TREATED ALFALFA SEED AND CLOVER SEED.

16.1 The following provisions apply to alfalfa seed and clover seed resulting from crops treated with any pesticide registered under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act which requires such rules as a condition of registration for use in alfalfa seed or clover seed production, or any pesticide registered under Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act which requires such rules as a condition of registration for use in alfalfa seed or clover seed production.

16.2 Every person engaged in the business of seed conditioning shall keep records of individual growers' alfalfa and clover seed dirt weight and clean weight for three (3) years and shall furnish such records to the Commissioner upon request.

16.3 All seed screenings shall be disposed of at a controlled dump site, incinerator, or other equivalent disposal site. Every person engaged in the business of seed conditioning shall keep records of seed screening disposal which records shall include the disposal site, method, weight of disposed screenings and date of disposal. Every person engaged in the business of seed conditioning shall keep seed screening disposal records for three (3) years and shall furnish such records to the Commissioner upon request.

16.4 All seed shall be conspicuously tagged or labeled with the following statement, "NOT FOR HUMAN CONSUMPTION OR ANIMAL FEED."

16.5 No seed tagged as set forth in 16.4 above shall be sold, offered for sale or distributed for human consumption or animal feed.

I. 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.

Applications to CDA for an SLN registration must come from the primary registrant, not from the distributor ("sub-registrant"). However, an SLN issued can also cover distributor products and/or alternate brand names. The application form is the EPA 8570-25 form. This form must have only the two-part EPA registration number, the name of the EPA registrant, and must be signed by the EPA registrant, not the distributor. However, the primary registrant can designate the distributor to be the primary contact with CDA for the SLN application.

If the SLN use will be for the distributor product, the draft SLN labels submitted with the application should still include one under the primary registrant name and two-part EPA reg. # and also a draft label for the distributor product (with the distributor company name and 3-part EPA registration number). Both products should already have a normal Colorado state registration or an application for such state registration should be included with the SLN submission.

After the SLN is approved, both labels will be submitted to EPA. Only the labels for products that will be in distribution will be posted on the CDA SLN webpage.

J. THIRD-PARTY SLN REGISTRATIONS

CDA's current policy is that Colorado does not accept third-party SLN registrations. CDA is unaware of any Colorado grower groups that have been interested and willing to take this approach, which involves payment of maintenance fees to EPA and other obligations of a pesticide registrant under FIFRA.

EPA allows third-party SLN registrations, which are issued to a company other than the registrant when the registrant of the product is not willing to apply for an SLN registration. For example, a grower association may be willing to assume direct liability and responsibility for an SLN use when the registrant is unwilling too. However, the approval of the EPA registrant of the product is still required. 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. REVISIONS TO SLN LABELS

As with any pesticide label, any revisions to an SLN label must be submitted to CDA for approval prior to distribution in the state. After the revised label is reviewed and accepted, CDA will send a notification to EPA with the revised label, for EPA's records.

Changes to company name on the SLN label and/or changes to ownership, company name, or entity type may require a new SLN application and issuance of a new SLN. However, in most cases supporting data will not be required.

B. EXTENSION OF EXPIRATION DATE

CDA plans to initiate a label review each fall for the set of SLN's due to expire that December. This involves asking appropriate CSU experts to review the label and confirm that the special local need still exists. If we decide that the SLN use is still needed, we will contact the registrant and ask for a revised label with a revised expiration date allowing use for another five years. We encourage registrants to review the SLN label language carefully at this time to make sure additional updating of label language and restrictions is not needed.

If we determine that there is no longer a special local need, we will contact the registrant and ask them to provide us with a written cancellation request. We will then consider the SLN to be cancelled and forward this information and the registrant letter on to EPA. However, EPA may need a cancellation request letter directly from the registrant in order to cancel the SLN registration at the federal level and no longer bill the registrant for maintenance fees.

C. TRANSFERRING SLN REGISTRATIONS

CDA does not transfer SLN registrations to a different company. If the ownership, name, or entity type changes for the SLN, then a new SLN application needs to be submitted. However, CDA will refer to the supporting information for the original SLN.

D. WITHDRAWING OR CANCELING EXISTING SLN REGISTRATIONS

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

III. CDA CONTACT INFORMATION

Submit requests for new SLN registrations to:

Laura Quakenbush, Pesticide Registration Coordinator
Pesticide Registrations, Division of Plant Industry
Colorado Department of Agriculture
305 Interlocken Parkway
Broomfield, CO 80021
Laura.quakenbush@state.co.us
303-869-9060

SLN applications can be submitted as email attachments. If submitted via mail as paper documents, please also provide electronic pdf file versions of labels and supporting documents.

IV. CDA SLN LABEL FORMAT EXAMPLE

FEDERAL RESTRICTED USE PESTICIDE STATEMENT (WHEN APPLICABLE)

SECTION 24(c) SPECIAL LOCAL NEED LABEL

FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF COLORADO

PRODUCT NAME

EPA REG. NO. 123-456 EPA SLN NO. CO-YYnnnn

DANGER or DANGER / POISON (When applicable)

"This label expires and must not be distributed or used after December 31, [Fifth year]."

- 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.
- Application method(s) / Frequency / Timing.

Restrictions / Precautions

- Restricted entry interval (REI), pre-harvest interval (PHI), maximum annual application rate.
- Aquatic toxicity, chemigation, endangered species, groundwater, herbicide drift, pollinator protection, seed crop, surface water, etc. (when applicable).

24c Registrant:

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

Rev. 01/01/2014

V. CDA 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 (1 copy) - all SLN registrations
3. Current federal label (1 copy) - all SLN registrations. (If in ALSTAR, CDA can retrieve current label)
4. Completed EPA SLN application form
5. Letter of support from a Colorado State University (CSU) researcher, extension specialist or other unaffiliated expert verifying the special local need
6. Letter of support from commodity organization and/or individual grower
7. Residue data - required if food or feed use
8. 40 CFR 180 citation for tolerance or tolerance exemption
9. Efficacy data – may be required
10. Phytotoxicity data – may be required
11. Effects on beneficial insects – data may be required if foliar or systemic use of insecticide or fungicide
12. EPA transfer letter - required if product was transferred to a new EPA registrant

WHAT IS THE PRODUCT REGISTRATION STATUS?

1. Is the product currently registered with EPA?
2. Has registration for the proposed use or other uses of product been denied, disapproved, suspended, or canceled?
3. Is the product under special review at the EPA?
4. Is the pesticide undergoing Reregistration or registration review?
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 CDA GUIDELINES?

1. Federal RUP statement (when applicable)
2. A statement clearly indicating that this label is an SLN label, followed by: “FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF COLORADO”

3. Product Brand Name
4. EPA Reg. No.
5. EPA SLN No. CO-YYnnnn (assigned by CDA)
6. Signal word (if the pesticide is category 1)
7. Expiration date statement
8. “It is a violation of federal law to use this product in a manner inconsistent with its labeling.”
9. “This labeling must be in the possession of the user at the time of application.”
10. “Follow all applicable directions, restrictions, Worker Protection Standard requirements, and precautions on the EPA registered label.” (WPS use) OR “Follow all applicable directions, restrictions, and precautions on the EPA registered label.” (Non-WPS use)
11. Directions for use:
    - Crop or site to be treated / Pest(s) to be controlled
    - Application rate and concentration
    - Application method(s) / Frequency / Timing
12. Restrictions / Precautions
    - Restricted entry interval (REI), pre-harvest interval (PHI), maximum annual application rate
    - Chemigation, endangered species, groundwater, herbicide drift, pollinator protection, seed crop, surface water, etc. (when applicable)
13. Name and address of the SLN registrant
14. Label identification code (such as the revision date)