



## Pesticide Operations and Management Working Committee

# SFIREG FIFRA Section 24(c) Guidance

March 1, 2024

This guidance document clarifies the regulations implementing Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to assist state lead agencies (SLAs) in reviewing requests and applications or inquiries received; submitting complete Section 24(c) notification submissions to U.S. Environmental Protection Agency (EPA); and facilitating EPA's review.

State Lead Agencies (SLA) should review Title 40 CFR and EPA's 24(c) guidance webpage. The FIFRA Section 24(c) regulations can be found in Title 40 of the Code of Federal Regulations (CFR) Part 162 ([eCFR :: 40 CFR Part 162 -- State Registration of Pesticide Products](#)). Information presented in this document is in addition to the content of EPA's Guidance on FIFRA 24(c) registrations webpage ([Guidance on FIFRA 24\(c\) Registrations | US EPA](#)).

## Table of Contents

I.	Legal Language for Guidance Document.....	4
II.	Section 24(c) of FIFRA.....	4
A.	Defined .....	4
B.	Special Local Need Identified/Research Conducted.....	5
C.	Conditions for a Section 24(c) Registration.....	6
D.	Who can Apply for Section 24(c) Registrations?.....	7
E.	Reasons an SLA might contact EPA prior to approving a registration under FIFRA Section 24(c).....	7
F.	Section 24(c) Registrations Which Require Specific Label Language.....	8
G.	Waiver of Liability Statements on Section 24(c) Labels .....	10
H.	Section 24(c) State Registration Number Format .....	10
I.	Circumstances When Section 24(c) Registrations Should Not Be Issued.....	10
III.	SLA Review and Decision Process for Section 24(c) Applications .....	11
A.	SLA Checklist and Initial Questions.....	11
B.	SLA Approval/Denial Decision.....	13
C.	Multiple Section 24(c) registrations in a state for the same use.....	14
D.	SLA and Registrant Responsibility to Provide Section 24(c) Labels to Users .....	14
IV.	Section 24(c) Approval Notification to EPA.....	14
A.	Contents of New Submission to EPA .....	14
B.	Where and How to Submit Section 24(c) Notifications .....	15
V.	EPA Review Process .....	15
VI.	Maintenance of Section 24(c) Registrations.....	17
A.	When to Notify EPA of Changes: Revised labels.....	17
B.	Cancellation of Section 24(c) Registrations.....	18
C.	When Changes Suggest a New Section 24(c) Registration: Company Consolidations, Product Transfers or Changes in Formulation .....	19
VII.	General Policies, Questions and Answers About Section 24(c) Registrations.....	19
VIII.	Appendices .....	20
	Appendix 1. Roles and Responsibilities of Participants Involved in Section 24(c) Registrations.....	20

Appendix 2. Types of Registrations or Pesticide Use Authorizations Under FIFRA (Other Than Section 24(c) Registrations) .....	22
A. Section 3 Registrations .....	22
B. FIFRA Section 2(ee) Product Bulletins or Use Recommendations .....	23
C. Additional Federal Labeling .....	25
D. Section 18 Emergency Exemptions.....	25
E. Experimental Use Permits.....	26
Appendix 3. Main Differences Between FIFRA Section 24(c) Registrations and FIFRA Section 18 Emergency Exemptions.....	27
Appendix 4. More Information Regarding Supplemental Distributors.....	29
Appendix 5. Example Letter for a Replacement Section 24(c) Registration. ....	30
Appendix 6: EPA Policy and Criteria Notice 2105.1.....	31
Appendix 7: EPA Guidance on Warranty Statements .....	34
Appendix 8: Document Revisions Statement.....	45

## I. Legal Language for Guidance Document

This guidance document is an instructional tool that does not change legal requirements or establish new guidance, but instead compiles interpretations of statutory and regulatory provisions and reiterates existing EPA policies. This guidance document is not intended to replace the Section 24(c) regulations in 40 CFR part 162, rather to clarify the regulations and to provide additional guidance. Should there be any conflict between this guidance document and the applicable statutory and regulatory provisions, the contents of the statute and regulations will govern the EPA's reviews, evaluations and actions on Section 24(c) registrations.

This document is intended solely as guidance and does not represent final EPA action. It is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States or states. EPA officials may decide to follow the guidance provided in this document, or to act at variance with such guidance, based on analysis of specific circumstances raised by a given 24(c) action.

## II. Section 24(c) of FIFRA

### A. Defined

Section 24(c) of FIFRA allows states to register to register additional uses of federally registered pesticide products, or a new end use product to meet special local needs, if certain conditions are met., but it does not provide for states to issue more restrictive registrations. Section 24(c) registrations are also referred to as “Special Local Need” (SLN) registrations. A special local need most commonly refers to a pest problem occurring in a particular state that is not being adequately controlled by currently available registered pesticides.

40 CFR 162.151, defines a “special local need” as an existing or imminent pest problem within a state for which the SLA, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.

A Section 24(c) registration may be approved by an SLA for many reasons. The most common reasons are to allow for the use of a pesticide to control a specific pest within the state or modify existing use directions. However, Section 24(c) registrations have also, on occasion, been used as a state specific mechanism to reduce possible risk of pesticide exposure to: people, non-target and target crops, listed species, surface and ground water, and the environment.

Specific examples of why a Section 24(c) registration may be approved by an SLA, include but are not limited to:

- addition of a crop or use site;
- addition of an alternate application method, such as chemigation or aerial;
- change in the timing of applications or conditions;
- increase in the rate or number of applications;
- reduction of Pre-Harvest Interval;

- increasing worker or environmental safety;
- promoting resistance management;
- meeting export needs; or
- modification of voluntary or mandatory restrictions on a Section 3 label.

There are many roles and responsibilities different entities have in the Section 24(c) process. For detailed information on the roles and responsibilities, please refer to Appendix 1.

## B. Special Local Need Identified/Research Conducted

Growers are frequently the first to notice when a pest problem develops and may contact county extension agents or commercial field persons for additional ways to manage difficult to control pest(s). Typically, this results in commodity groups, university researchers, registrants, and SLAs being contacted about a possible special local need registration.

Some of the more common types of imminent pest situations affecting growers that may be addressed by a Section 24(c) registration include:

- a pest developing resistance to pesticides which previously controlled it;
- the introduction of a new pest with no adequate available registered pesticides to manage it, either due to lack of products labeled for the needed application site, or due to lack of efficacy;
- loss of registered products, or uses of products, due to regulatory changes such as the cancellation of registered uses of older pesticides; or
- those caused by unusual weather conditions.

University extension researchers or pesticide consultants commonly generate efficacy and crop safety (phytotoxicity) data provided to the SLA in support of the Section 24(c) registration request. Some trials are funded or conducted by commodity groups, registrants or other entities. Environmental and safety data are commonly provided by the registrant. Residue data to support the EPA established tolerance are typically generated by [IR-4](#) or the registrant.

The vast majority of Section 24(c) requests submitted to SLAs for possible approval, would not require additional data submissions for a Section 3 registration to be issued. They are granted for a *similar use pattern*, which means a use of a pesticide product which, when compared to a federally registered use of a product with a similar composition, does not require a change in precautionary labeling, and which is substantially the same as the federally registered use.

If a registrant is questioning whether a particular use may trigger additional data requirements, they should contact the [Product Manager](#) at EPA responsible for the chemical prior to submittal to a state, in order to clearly understand the decision review time and associated PRIA fees. If states have questions or concerns, they should contact EPA's Senior Regulatory Specialist in the Minor Use and Emergency Response Branch in the Registration Division. EPA can help a state determine what types of data have been previously submitted and reviewed. An example of a registration which may require additional data requirements, would be if all the Section 3 labeled uses are on terrestrial crops, and a state is considering granting a 24(c) for an aquatic use, or an indoor residential use.

## C. Conditions for a Section 24(c) Registration

In addition to meeting the definition of a special local need, the following conditions must exist for the SLA to approve a Section 24(c) registration:

- 1) If applicable (e.g., food or feed uses), the additional use is covered by necessary tolerances, tolerance exemptions or other clearances under the Federal Food, Drug, and Cosmetic Act (FFDCA).
- 2) Registration for the same use has not been previously denied, disapproved, suspended, or canceled by the Administrator, or voluntarily canceled by the registrant subsequent to issuance of a notice of intent to cancel because of health or environmental concerns about an ingredient contained in the pesticide product. If new data becomes available that resolves the Agency's health or environmental concerns, a Section 24(c) registration may be submitted. Prior to submittal to an SLA, a registrant has the responsibility to determine whether these criteria are met. If a registrant or an SLA has any questions, they should contact the EPA Product Manager or EPA Senior Regulatory Specialist for Minor Use and Emergency Response Branch of the Registration Division.
- 3) Registration is not contrary to the purposes of FIFRA.
- 4) If the proposed use or product falls into one of the following categories, then the state must have determined that it will not cause unreasonable adverse effects on man or the environment:
  - use of a product which has a composition not similar to any federally registered product;
  - use of a product involving a use pattern not similar to any federally registered use of the same product or a product of similar composition; or
  - use of a product for which other uses of the same product, or uses of a product of similar composition, have had registration denied, disapproved, suspended, or canceled by the Administrator.
- 5) Section 24(c) registrations generally amend federally registered products. However, the state, under certain conditions, may also register a new end-use product (not federally registered) as a Section 24(c) registration. The ingredients (both active and inert) of the new end-use product must be contained in one or more federally registered Section 3 products, (CFR 162.152(b)(2)(ii)). To determine if an inert is cleared for a specific use, access the [InertFinder](#) or the Federal Register and the Code of Federal Regulations ([Part 180 Tolerances and Exemptions for Pesticide Chemical Residues in Food](#)). If the active ingredient and/or inert ingredients are not federally registered, and if certain criteria are met, the Section 18 emergency exemption process may be an option. The SLA should consult with the EPA to determine if a Section 18 is feasible for the proposed use.

## D. Who can Apply for Section 24(c) Registrations?

- The Section 3 pesticide registrant of the product is the most frequent applicant for a Section 24(c) registration. (Supplemental distributors cannot apply).
- A third party, such as an officially recognized grower organization, or governmental entity may also apply for a Section 24(c) registration. It is recommended that such an applicant have a letter from the registrant authorizing the third party to be the Section 24(c) registrant.

## E. Reasons an SLA contacts EPA prior to approving a registration under FIFRA Section 24(c)

According to 40 CFR 162.152 (b)(1)(ii)-(iii) there are two circumstances that require an SLA to consult EPA prior to submitting a Section 24(c) registration.

- (ii) A State may register any use of a federally registered product for which registration of other uses of the product was denied, disapproved, suspended, or cancelled by the Administrator, provided that the State may register a use not considered by the Administrator in reaching such a determination only after the State consults with appropriate EPA personnel.
- (iii) Except as provided in paragraph (a)(3) of this section, a State may register any use of a federally registered product for which registration of some or all uses has been voluntarily cancelled by the registrant, provided that a State may register such a use only after the State has consulted with appropriate EPA personnel.

There are many other reasons that an SLA might consider contacting EPA when reviewing a submission for a proposed Section 24(c) registration. A few examples are listed below.

There is uncertainty whether:

- there is an adequate tolerance(s) to support a food or feed use; for example, there may be lack of clarity because of changes in crop groups, subgroups, or commodity definitions;
- the use pattern, type of application (e.g., soil vs. foliar), or rate is supported by the tolerance;
- EPA has health or environmental risk concerns for an ingredient contained in the pesticide product, or there have been, or there are ongoing regulatory actions; or
- the proposed use is considered a similar use pattern to one that exists on a Section 3 label, or would trigger new data requirements.

EPA may also be contacted to determine:

- the eligibility of a seed crop as a nonfood/nonfeed crop, and whether EPA considers current state laws adequate;
- types of data that have been previously submitted and reviewed by EPA;
- if the proposed active ingredient has undergone registration review and no longer meets the FIFRA safety standards;
- if the Section 18 emergency exemption process is an option when the proposed product's active ingredient and/or inert ingredients are not federally registered (provided emergency criteria are met); or
- if there are any potential conditions or concerns related to crops grown for seeds or non-bearing crops.

An SLA can consult with EPA if there are questions about any particular scenario.

## F. Section 24(c) Registrations Which Require Specific Label Language

### **Crops Grown for Seed**

An SLA may grant a Section 24(c) registration for the use of a pesticide on certain crops grown for seed, when there is not an established tolerance or tolerance exemption for the pesticide on the food or feed crop. For example, there is not a tolerance for a specific pesticide on "alfalfa" or associated Crop Groups, but the SLA intends to grant a Section 24(c) registration on "alfalfa grown for seed."

These certain crops grown for seed may be designated as a nonfood or nonfeed use when post-treatment, only if: (1) no parts of the crop will be diverted for use as human food or livestock feed and, (2) there is no likelihood of residues in crops grown from the harvested seed (for example with the use of a desiccant).

A primary condition to allow use when there is not a tolerance, is when the SLA has a law\* in place to ensure that the area treated will not be grazed by livestock, and seed and seed by-products will not enter the food or feed chain. The law may address specific restrictions and labeling requirements, and also the roles and responsibilities of the pesticide applicator, the producer of the crop, and the seed conditioner.

\* If there is not a state law in place addressing the issue, the State Lead Agency should provide a detailed explanation on how they intend to enforce seed and by-production segregation, or restrictions which may involve seed conditioners or other non-applicator entities.

Example of a possible limitation: Certain seed crops which are typically grown for food, oil or seed production may not be eligible to obtain a nonfood/nonfeed status. These crops may include, but are not limited to cereal grains, including corn; legume vegetables (succulent or dried); potatoes; pumpkins; and oil seed crops such as sunflowers.

The following language represents an example of special use restrictions typically found on Section 24(c) labels:

The pesticide applicator, the producer of the crop, and the seed conditioner must be aware that use of this product according to this labeling is deemed a nonfeed/nonfood use by the XXX Department of Agriculture and is regulated by Law XXX.

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 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. Consequently, no portion of this seed crop may be used or distributed for food or feed for one 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 the screenings cannot be distributed or used for food or feed purposes. 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.

### **Non-Bearing Crops**

An SLA may issue a Section 24(c) registration for the use of a pesticide on a non-bearing food or feed crop, when there is not an established tolerance or tolerance exemption for the use of the pesticide on the food or feed crop. For example, there is not a tolerance for a specific pesticide on "apple" or associated Crop Groups, but the SLA would like to grant a Section 24(c) registration on, "newly established non-bearing apples". These types of Section 24(c) registrations are typically approved for use during the first year of establishment after planting.

The Section 24(c) label must prohibit harvest for at least 365 days after the last application under the Section 24(c) registration.

A typical label restriction is:

- Do not harvest apples for at least 1 year (365 days) after the last date this product was applied.

Because of cropping practices, an SLA may include additional label restrictions such as:

- Do not apply to established apple trees; apple trees that have been previously harvested; or as a spot treatment to non-bearing apple trees within a field of established, bearing apple trees.

An SLA should consult with EPA if there are questions about a particular scenario.

### **24(c) Registrations for Uses on Food/Feed Commodities Intended for Export Only**

The EPA issued a policy in 1984 explaining that use of a pesticide on a food/feed commodity intended solely for export for which an appropriate tolerance or other clearance does not exist is allowed to be registered under section 3 or section 24(c) (Appendix 6). The policy explains that during the review period for section 24(c) registrations for any pesticide use of food intended only to be exported, the following are required:

- written confirmation from the foreign purchaser that the use is in accord with all local requirements,
- written confirmation from the importing government that allows the legal importation of the commodity, and
- the product is labeled for export only and not to be sold for domestic use.

Review Appendix 6 for full policy and criteria for Notice 2105.1

## G. Waiver of Liability Statements on Section 24(c) Labels

Waiver of liability, warranty, and/or disclaimer statements are used to limit product liability and only apply for crops grown on very limited acreage, such as some specialty and seed crops. EPA opposes enforcing limits on user's rights, and will only allow certain waiver of liability language on Section 24(c) SLN labels. Additional information and specific label wording examples are available on the [EPA Guidance on Warranty Statements](#), available as Appendix 7.

When a waiver of liability statement is included on the Section 24(c) label, it should be placed on the last page. A sentence referring the user to the waiver of liability statement may be placed on the first page, related to required statements:

- Read and understand the (Registrant's) Special Conditions and Disclaimer for use before using (Product) on (Crop).

If the Section 3 registrant of the SLN requires a waiver of liability certificate, the certificate is not a part of the SLN label. These certificates are agreements between the registrant, the grower association, and the users.

Review the [EPA Guidance on Warranty Statements](#), available as Appendix 7, for examples of acceptable language for disclaimers.

## H. Section 24(c) State Registration Number Format

A Section 24(c) registration is issued as a state specific registration number for a specific product and use. The number is written as "EPA SLN No." followed by the two-letter state designation, then the last two digits of the **calendar** year of issuance, and finally a four-digit number which is the consecutive number of registrations that the registering state has issued in that calendar year. For example: If company ABC applied for a Section 24(c) registration in the State of Florida and it was the 5th Section 24(c) registration granted by Florida in the calendar year 2024, then the Section 24(c) registration number would be EPA SLN No. FL-240005. For tracking and security reasons, SLAs should issue the 24(c) number immediately prior to granting the registration, rather than at the beginning of the review process.

## I. Circumstances When Section 24(c) Registrations Should Not Be Issued

Below is a list of circumstances which would prevent the appropriate issuance of a Section 24(c) registration by an SLA. If additional support is needed, reach out to the EPA Senior Regulatory Specialist for Minor Use and Emergency Response Branch of the Registration Division.

- 1) The proposed use is a food or feed use, and the use is not covered by necessary tolerances, tolerance exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 et seq.).

- 2) The active or inert ingredients are not approved for use in a currently registered product; or the use pattern is dissimilar to currently labeled use patterns and would trigger additional data requirements.
- 3) There is an available Section 3 registered pesticide product that has the same use and same requested active ingredient.
- 4) Registration for the same use has been previously denied, disapproved, suspended or cancelled by the Administrator, or voluntarily cancelled by the registrant subsequent to issuance by the Administrator of a notice of intent to cancel that registration, because of health or environmental concerns about an ingredient contained in the pesticide product, unless such denial, disapproval, suspension or cancellation has been superseded by subsequent action of the Administrator.
- 5) The registration is not in accordance with the purposes of FIFRA, or does not meet provisions, including but not limited to, 40 CFR 162.151 and 40 CFR 162.152.
- 6) Under the registration review program, if an active ingredient no longer meets the FIFRA safety standards, a Section 24(c) registration cannot be granted until such time as any missing data or mitigation measures are determined and implemented. To determine whether there are missing data to support different use patterns, or if there are new required mitigation measures, states can contact the EPA Product Manager, go to the registration review schedule generally found on [EPA's upcoming registration review actions website](#), or contact the [Chemical Review Manager](#) (CRM) in EPA's Pesticide Re-evaluation Division (PRD) that is assigned to that active ingredient.
- 7) A Section 24(c) registration would trigger further data requirements. Expanding the use pattern of a Section 3 label would be inappropriate if the added exposure would raise human or environmental risk concerns. If the state can demonstrate that the recommended Section 24(c) registration constitutes no added exposure or risks, or that the exposure or risks are mitigated, a Section 24(c) may be appropriate. If a state has questions about a proposed Section 24(c), they should contact the Product Manager responsible for the chemical/use pattern.
- 8) The SLN limits or restricts the use of an already registered Section 3 use. The appropriate authority for a State to implement limitations or restrictions on Section 3 labels is FIFRA Section 24(a).

### **III. SLA Review and Decision Process for Section 24(c) Applications**

#### **A. SLA Checklist and Initial Questions**

States may differ in their requirements for what they consider satisfactory supporting information when considering the issuance of a special local need registration under FIFRA Section 24(c). However, it is highly recommended that the SLA have written guidelines, requirements or policies and a process for evaluation. The burden of proof is on the pesticide registrant.

*Quick Basic Questions for the SLA Reviewer*

- Is the proposed use on a currently available Section 3 registered product?
- Is the proposed use, if on a food or feed crop, covered by current tolerances or exemption from tolerances? Have adequate supporting data, documentation, and fees been submitted?
- Is this truly a legitimate need for your state?
- Have potential risks been mitigated?

**Elements of the state review process for Section 24(c) registrations:**

- (1) Does the application meet the definition of a special local need registration under FIFRA Section 24(c), and all other requirements in the federal regulations, including but not limited to: 40 CFR 162.151-153?
- (2) Has a letter been submitted by the proposed Section 24(c) registrant, justifying why this is a special local need, EPA form 8570-25, and any state required forms?
- (3) Have letters of support from university researchers, extension scientists, USDA scientists, independent researchers, cooperative extension agents, commodity groups, pesticide registrant, or grower groups been submitted?
- (4) For proposed registrations on food or feed, has the registrant submitted all the necessary residue data or other documentation?

It is the SLA's responsibility to ensure that the proposed application method or rate of application is sufficiently supported by data used to establish the tolerance, and that the tolerance will not be exceeded.

Many states may use the protocols that were followed when the data were originally generated, to ensure that the proposed use is supported by the original data, and therefore the tolerance. Newer data may be used by the SLA if they determine the data was properly developed.

Scenario: the original protocol was based upon a spring soil application at 5 oz. a.i./acre with a 28-day PHI. However, the SLA receives a request for a foliar application, different timing, rate of application, or PHI. In this scenario, the SLA should request additional residue data for the proposed use and consult with the EPA product manager.

Section 24(c) registration applications may be supported using General Tolerances, Tolerance Exemptions, or when appropriate, Tolerances with a Regional Registration. Indirect or Inadvertent Tolerances are intended to cover residues in rotational crops and Section 24(c) registrations may not be based on indirect or inadvertent tolerances.

In certain circumstances, EPA may request a data review from the state to support their Section 24(c) registration.

(5) Has the proposed Section 24(c) registrant submitted all necessary state-required data, which may include efficacy, residue, phytotoxicity, or other data pertaining to protecting pollinators, listed species, or the environment?

(6) Does the proposed use potentially pose unacceptable hazards to handlers, workers, or the environment, and if so, how are they mitigated? Some SLAs may informally consult with their state OSHA, environmental quality, or wildlife agencies.

(7) If the basis for the request includes claims of greater safety when the product is used according to label instructions, many states require comparative safety data demonstrating a significant margin of increased safety over the registered alternatives.

(8) Has a draft label been submitted that is supported by data? Most states amend the initial label submitted, and they may go through several revisions. States are strongly encouraged to place expiration dates on Section 24(c) labels.

(9) If the product is not federally registered, include a complete Confidential Statement of Formula (CSF), and ensure all active and inert ingredients are cleared for the use pattern.

The base check list above does not incorporate all of the requirements that specific states may have, such as additional data requirements, and requiring copies of the Section 3 market label, Section 3 Stamped Accepted label, Confidential Statement of Formula (CSF), or Safety Data Sheets (SDS).

## B. SLA Approval/Denial Decision

### Approval

After the SLA has approved the Section 24(c) registration, the SLA must notify the EPA. See Section IV. Section 24(c) Approval Notification to EPA, for what must be included in the notification and the timeline for doing so.

The SLA may provide a copy of identical approval notification documents to the pesticide registrant, and may also include a separate letter with instructions and requirements.

SLAs typically provide copies of the recently granted Section 24(c) registration to individuals who provided letters of support and other interested parties.

After 90 days, a Section 24(c) registration which has not been disapproved is considered federally registered; however, it is authorized for distribution and use only within that State.

### Denial

The SLA may deny a request for many reasons, including the application does not meet the requirements for a Section 24(c) registration. Additional possible reasons include, but are not

limited to: insufficient data or the proposed registration may pose unreasonable risks to humans, crops and non- target plants, wildlife and the environment.

### C. Multiple Section 24(c) registrations in a state for the same use

#### **Limited Availability**

There are instances in which an SLA may grant multiple Section 24(c) registrations for the same use pattern and same active ingredient. This may happen because a Section 3 or current SLN may not be “sufficiently available” to the grower/impacted community.

Another instance in which an SLA may grant an additional Section 24(c) registration, is during a marketing transition period, when pesticide products or active ingredients may be sold or marketed by a different company. The SLA may choose to maintain the Section 24(c) registration associated with the original Section 3 product, until the Section 3 product has cleared the channels of trade. In the meantime, the SLA will also grant a new Section 24(c) registration for the new product that is now being sold or marketed by the new company. Both registrations will have their own unique Section 24(c) number. See Appendix 5 for an example letter.

### D. SLA and Registrant Responsibility to Provide Section 24(c) Labels to Users

Section 24(c) labels are typically available online, and posted on registrant, SLA, commodity group, and pesticide label management websites. However, it is the pesticide registrant's responsibility to keep known websites, other than the SLA's, updated. For more information on providing labels see [40 CFR 162.153\(e\)\(4\)](#)

## IV. Section 24(c) Approval Notification to EPA

A complete Section 24(c) approval notification for each state pesticide registration for a special local need must be submitted to the EPA by the SLA within 10 days of the date of issuance in accordance with FIFRA Section 24(c). After 90 days, a Section 24(c) registration which has not been disapproved by EPA is considered federally registered and is authorized for distribution and use only within the State that approved the registration. If the state does not notify the EPA of the issuance of the registration within 10 days of its effective date, then the 90-day “clock” begins on the date that the EPA receives the 24(c) approval notification.

EPA may disapprove the registration at any time if it is believed that the use constitutes an imminent hazard or may result in excessive residue levels.

### A. Contents of New Submission to EPA

See [EPA Guidance on FIFRA 24\(c\) Registrations webpage](#) for submission requirements. Here are some additional clarifications about what to submit:

- A copy of the Section 24(c) label approved by the state. The label must prominently display “FIFRA Section 24(c) Special Local Need Label” (or similar language). Additionally, the following elements as listed at [40 CFR 162.53](#) must be included on

the label: identification of State where registration is valid; directions for use; trade name and EPA registration number of the product; name and address of the section 24(c) registrant; the SLN registration number; and a statement prohibiting use inconsistent with all applicable directions, restrictions, and precautions on the federal product labeling and accompanying supplemental labeling. Note: In the case of a restricted use pesticide, no information, statements, or logos may be placed above the RUP box on the label.

- If the product is not federally registered, include a **complete** Confidential Statement of Formula (CSF), and ensure all active and inert ingredients are cleared for the use pattern. Contact EPA's Senior Regulatory Specialist in the Minor Use and Emergency Response Branch in the Registration Division for a confidential link to submit confidential information.
- For Section 24(c) registrations intended for use on a commodity for export to a foreign country, the SLA should include a letter from the receiving country stating the rationale for the requirement of a specific pesticide application. The letter will be retained in the Agency's files for future reference in the event an amendment is necessary. Review Appendix 6 for additional requirements.
- Per the 2022 Minor Use and Emergency Response Branch Annual State Letter from EPA, when submitting a Section 24(c) package to the Section 24(c) mailbox (OPP-Sec24c-Mailbox@epa.gov), it is recommended to include in the subject line the SLN No., the associated active ingredient, and indicate in parentheses whether the action is new, an amendment, or a cancellation. For example: XX240001 S-Metolachlor (New).

## B. Where and How to Submit Section 24(c) Notifications

The SLA should submit a complete Section 24(c) approval notification for each registration electronically to OPP-Sec24c-Mailbox@epa.gov.

It is recommended the state also provide a copy of the notification to the applicable registrant, industry principals and relevant stakeholders.

## V. EPA Review Process

Once EPA has received notification of a Section 24(c) registration, it is processed through EPA's SLN Document Processing Desk. The SLN processing staff extracts data from the EPA Form 8570-25 and cover letter and inputs the information into the Agency's tracking system.

This creates a decision number for the submission, which is then forwarded to the appropriate regulatory division point of contact based on the product registration.

The regulatory division point of contact assigns the submission to a reviewer. The reviewer then screens the notification package to ensure that the previously mentioned items in "Section IV.A" of this document were included, specifically ensuring that the most current EPA Form 8570-25 is filled-in accurately and fully, and that the cover letter clearly defines the special local need.

If any of the items are not properly completed or are missing, the notification submission is considered incomplete, and the Section 24(c) registrations will be considered invalid as issued. The EPA reviewer will notify the SLA of any deficiencies and give the SLA an opportunity to correct their submission within a reasonable amount of time.

If the notification submission is complete and accurate, the EPA reviewer should issue an acknowledgment letter to the SLA acknowledging the Section 24(c) registration has been reviewed by EPA and a copy will be placed in the Agency's files.

### **Notice of Intent to Disapprove and Special Disapprovals**

See [EPA Guidance on FIFRA 24\(c\) Registrations webpage](#) for notice of disapprovals. Here are some additional clarifications:

- EPA can issue a Notice of Intent to Disapprove a Section 24(c) registration for reasons listed in Section II.
- EPA can issue special disapprovals if the Administrator determines that use of the product under the Section 24(c) registration: would constitute an imminent hazard; may result in a residue on food or feed exceeding, or not covered by, a tolerance, a tolerance exemption, or other clearance under the Federal Food, Drug and Cosmetic Act; or for use on a crop listed in Schedule 1 of the Controlled Substances Act. EPA is not required to issue a notice of intent to a state prior to a special disapproval of an SLN but should advise the SLA of the action.

### **Section 24(c) Acknowledgement**

The EPA must ensure that there have not been any regulatory actions that would preclude the Agency from continuing to support the Section 24(c) registration. Upon completion of the review, the EPA should issue an acknowledgment letter to the SLA acknowledging the Section 24(c) registration action has been reviewed and a copy will be placed in the Agency's files.

### **PRIA vs. Non-PRIA**

The Consolidated Appropriations Act of 2004 established a new system for registering pesticides, called the Pesticide Registration Improvement Act, or PRIA. The new FIFRA Section 33 created a registration service fee system for applications for specified pesticide registration, amended registration, and associated tolerance actions. The goals of this fee system are to:

- create a more predictable evaluation process for affected pesticide decisions, and
- couple the collection of individual fees with specific decision review periods.

There are certain Section 24(c) registrations that modify the use pattern of the federally registered product to a point where the Section 24(c) use pattern may not be supported by existing data or a previous risk assessment. Examples of this are decreasing the pre-harvest interval, increasing the single and maximum application rates, and changing the method of application. When the Agency encounters such an issue, the rule of thumb is to make a rapid determination if the existing reviews can support the Section 24(c) use pattern. If a rapid determination cannot be made, it is generally recommended that the use be submitted by the registrant under PRIA. It is recommended that data/studies not be submitted in support of a Section 24(c) registration.

For more information and specific scenarios see the [EPA Guidance on FIFRA 24\(c\)](#)

[Registrations webpage.](#)

### **Registration Review**

All active Section 24(c) registrations are required to undergo the [registration review](#) process whenever the EPA re-evaluates an active ingredient (and all the applicable registered pesticide products) to determine whether it continues to meet the FIFRA standard for registration. As part of the registration review process, any risk mitigation measures generated from the registration review process for Section 3 registrations need to be implemented for the relevant Section 24(c) registrations as well.

1. Recommended process for 24(c) registrations as part of registration review: EPA Pesticide Re-evaluation Division (PRD) notifies registrant to submit 24(c) labels and to contact the SLA
2. Registrant contacts SLA
3. Registrant submits 24(c) labels to EPA PRD
4. EPA PRD sends acknowledgement letter to the registrant and the SLA
5. Registrant works with SLA if additional actions are needed

If a State requires additional revisions beyond those required under registration review, SLA submits revised Section 24(c) labels to EPA through the Registration Division's Minor Use and Emergency Response Branch.

## **VI. Maintenance of Section 24(c) Registrations**

### **A. When to Notify EPA of Changes: Revised labels**

There are many reasons that a state may revise a Section 24(c) label, including:

- The state mandated expiration date is expiring and there is interest in extending the registration for additional time.
- Use directions need to be modified.
- Additional risk mitigation measures are needed.

Amendments are required by EPA based on a recent review of the active ingredient.

- The registration review for an active ingredient impacts the Section 24(c) registration (See registration review section above).

After the Section 24(c) label is revised, the SLA must notify EPA of the changes. Because it is not a new registration, do not resubmit EPA form 8570-25.

The amended/revised Section 24(c) notification to EPA must include the following items:

- a cover letter with a brief description of the special local need, reasons for the amendments, and a list of the changes to the Section 24(c) registration; and
- a copy of the amended Section 24(c) label approved by the state.

## B. Cancellation of Section 24(c) Registrations

### **Voluntary Cancellation by Registrant**

When a registrant requests the cancellation of a Section 24(c) registration, the SLA needs to ensure that they receive a letter from the registrant indicating that the cancellation was voluntary, and they are requesting to waive the 180-day comment period typically provided for cancellations. EPA will process the cancellation in accordance with FIFRA 6(f).

The SLA should submit a letter\* to EPA (OPP-Sec24c-Mailbox@epa.gov) with a statement that indicates the registrant:

- is voluntarily cancelling the registration, and
- is requesting to waive the 180-day comment period in the Federal Register.

The SLA must also attach a copy of the supporting letter or email from the registrant. EPA cannot cancel an SLN without this supporting letter, unless it is for non-payment of maintenance fees. If EPA does not receive a copy of the supporting letter or registrant email, then the product may be cancelled at the state level, but not at the federal level.

\* Many SLAs also include the reason why the registrant is cancelling the Section 24(c) registration. This information is often important to pesticide user groups, and helps the SLA have more complete records. This is especially important if there is an inquiry at a later date.

SLAs should notify interested parties (extension, growers, etc.) that the Section 24(c) registration has been canceled. Note - these parties are often highly interested in why a Section 24(c) registration was canceled, for example, if the use was added to the Section 3 label and therefore the Section 24(c) was no longer necessary.

Registrants may contact EPA regarding a cancellation and cease paying the Maintenance Fee. The registrant should also contact the SLA. EPA is required to publish a notice of proposed cancellations in the Federal Register. Registrants have a specified timeline to contact EPA in writing to request corrections for any errors listed in notices or to withdraw a request for cancellation (e.g. registrant informed by SLA that there is still a special local need situation).

### **Cancellation by EPA Due to Non-Payment of Maintenance Fee**

It is a registrant's responsibility to notify the SLA that they wish to voluntarily cancel a state issued Section 24(c) registration. Unfortunately, on occasion, registrants do not notify SLAs that they have ceased paying maintenance fees to EPA or otherwise have cancelled a Section 24(c) registration at the federal level. Section 24(c) registrations are officially cancelled at the federal level when the listings are published in the [Federal Register \(FR\)](#), which is done quarterly. It is advisable for SLAs to review the FR regularly and have good communication with registrants.

### C. When Changes Suggest a New Section 24(c) Registration: Company Consolidations, Product Transfers or Changes in Formulation

When the name of the registrant or EPA Reg. No. changes, it is strongly advised that a new Section 24(c) registration is granted, rather than submitted to EPA as a revised Section 24(c) registration. One reason is because often the original registrant stops paying maintenance fees, and the Section 24(c) registration is canceled at the federal level. However, this depends on the specifics of the change.

It is strongly advised that a registrant submit a new Section 24(c) application when a product undergoes significant formulation changes and avoid submitting it as a revised Section 24(c). There may be significant changes in Personal Protective Equipment and other requirements. Section 24(c) registration numbers are product specific, and it would be confusing on many levels to have a Section 24(c) number essentially "recycled". Significant formulation changes refer to when a product's formulation is changed so greatly that a new EPA Reg. No. is assigned. For example, a product is marketed as a WP, but that formulation is discontinued, and now the product is marketed as a DF (with an EPA number that is different than the WP formulation). Note - A new Section 24(c) number does not need to be assigned every time there is some minor change in the CSF.

The issuance of new Section 24(c) numbers may help with inventory management for both the SLA and EPA. The issuance of a new Section 24(c) number also allows for better recordkeeping and communication across users to ensure that the correct 24(c) labeling is being utilized. Issuing a new Section 24(c) may also allow the state the additional opportunity to assess whether the registration is still supported by growers and other pesticide users, and therefore is still warranted.

## VII. General Policies, Questions and Answers About Section 24(c) Registrations

For the most recent questions, answers and updates about Section 24(c) registrations refer to: [EPA Guidance on FIFRA 24\(c\) Registrations](#)

## VIII. Appendices

### Appendix 1. Roles and Responsibilities of Participants Involved in Section 24(c) Registrations

Below is a general list of roles and responsibilities that may vary from state to state.

**Entities Affected by the Pest Problem:** (Individuals/growers, commodity groups, agencies responsible for pest control or invasive species control, etc.)

- Identify and quantify the special local need pest problem
- Cooperate with registrant and researchers to identify pesticide and generate data in support of Section 24(c) application
- Provide testimonials about the special local need pest problem, letters of support for the Section 24(c) application
- Consult with SLA during Section 24(c) review process

**University Research, Extension and USDA Scientists, Independent Researchers, Registrants:**

- Conduct efficacy, residue, crop safety, environmental impact research in support of proposed Section 24(c) use
- Cooperate with registrant to develop Section 24(c) pesticide use directions and label
- Provide data and letters of support for the Section 24(c)
- Consult with SLA and registrant during Section 24(c) review process

**Pesticide Registrants:**

- Submit Section 24(c) registration applications to SLA
- Consult with SLA during Section 24(c) submission and review process
- Authorize use of supplemental distributor products under 24(c)s
- Authorize third-party registrants to obtain Section 24(c) registrations
- May need to register 24(c) and submit payment for Section 24(c) registration to SLA
  - There may be registration and renewal fees specific to states
- Provide Section 24(c) registration maintenance fees to EPA, or request waiver
- When appropriate provide a letter of cancellation to SLA and to EPA

**Third-Party Registrants:**

- Must obtain an EPA company number before they can become an SLN registrant
  - [Pesticide Registration Manual: How to Obtain a Company Number and Register an Official Address | US EPA](#)
- May submit Section 24(c) registration applications to SLA
- Obtain consent/legal authority from primary registrant to register Section 24(c)
- Consult with SLA during Section 24(c) submission and review process
- May need to register Section 24(c) and submit payment for Section 24(c) registration to SLA
  - There may be registration and renewal fees specific to states
- Provide Section 24(c) registration maintenance fees to EPA, or request waiver

**Supplemental Distributor Registrants:**

- Cannot be the primary Section 24(c) registrant, but may have a distributor label if agreed upon by the SLA and primary Section 24(c) registrant.
- Coordinate 24(c) registrations/label's with primary Section 24(c) registrant
- Consult with SLA during Section 24(c) submission and review process
- May need to register supplemental distributor Section 24(c) labels as state registrations with SLA
  - There may be registration and renewal fees specific to states

**State Lead Agency (SLA) for Pesticide Regulation:**

- Authority under FIFRA Section 24(c) to approve special local need (SLN) registrations
- Consult with university extension, pesticide registrants, other SLA's, EPA, or other applicable agencies on proposed 24(c) registrations.
- Review applications for proposed Section 24(c) registrations, and submit to EPA if approved
- Amend or revise Section 24(c) registrations as required by EPA
- May require state registration of Section 24(c)s
- May require expiration dates for Section 24(c) labels, and periodic review and renewal of Section 24(c) registrations
- Depending on state law, or other outstanding issues, may refuse to continue to register a Section 24(c).
- May cancel 24(c) registrations at state level, if requested by registrant, EPA or based on state law or need.

**EPA:**

- Upon request by an SLA, provide consultation to states on proposed Section 24(c) registrations prior to submission
- Review of Section 24(c) registrations submitted by SLA
- Authority to disapprove Section 24(c) registration, or require revisions to Section 24(c) within 90 days of Section 24(c) approval
- May require revisions to Section 24(c) label per Registration Review for the pesticide
- May require cancellation of Section 24(c) registration if Section 3 registration of pesticide is cancelled
- Require Section 24(c) registration maintenance fee (or grant waiver)
- Cancel Section 24(c) registration
- Request that the Section 24(c) registration is withdrawn from the SLA, and registrant submit the request directly to EPA as an amended Section 3 registration with the appropriate PRIA fee.

## Appendix 2. Types of Registrations or Pesticide Use Authorizations Under FIFRA (Other Than Section 24(c) Registrations)

### A. Section 3 Registrations

Section 3 of FIFRA outlines the authority given to EPA for pesticide registration and outlines the process through which EPA evaluates the pesticide registration application. EPA evaluates the pesticide to ensure that it will not have unreasonable adverse effects on humans, the environment and non-target species when used as labeled. Pesticides must be registered or exempted from pesticide registration by EPA's Office of Pesticide Programs before they may be sold or distributed in the United States.

In order for a pesticide product to be registered under Section 3 of FIFRA, registrants must submit: an application for pesticide registration, including the applicable fees, a copy of the product label, including all claims that will be made for the product, and a confidential statement of formula, which must include all of the ingredients in the pesticide product.

In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. Potential registrants must generate scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide. Over 100 studies are submitted for a typical registration.

There are separate data requirements for three categories of pesticides:

- Antimicrobials,
- Biopesticides, and
- Conventional pesticides.

Additional information on these requirements can be found in 40 CFR 158.

Before allowing the use of a pesticide on food crops, EPA sets a tolerance, exemption from tolerance, or maximum residue limit, which is the amount of pesticide residue allowed to remain in or on each treated food commodity. The tolerance is the residue level that triggers enforcement actions. That is, if residues are found above that level, the commodity may be considered adulterated and can be subject to seizure by the government.

In setting the tolerance, or exemption from tolerance, EPA must make a safety finding under the Food Quality Protection Act that the pesticide can be used with a "reasonable certainty of no harm." To make this finding, EPA considers the toxicity of the pesticide and its break-down products, how much of the pesticide is applied and how often, how much of the pesticide (i.e., the residue) remains in or on food by the time it is marketed and prepared.

The tolerance applies to food imported into this country, as well as to food grown here in the U.S. Tolerance levels and exemptions can be found at 40 CFR 180.

Once registered, a pesticide label providing use directions, limitations and restrictions is stamped "accepted" by EPA, and an EPA Registration Number is assigned. The EPA Reg. No. is

comprised of two parts: the first set of numbers is the company number assigned to the registrant, and the next set of numbers after the hyphen represents the sequential number of how many products that company has registered with EPA. The stamped accepted label (SAL) is also referred to as a “master label”.

Labels may be revised over time because of the addition of crops, changes in restrictions or other factors. Therefore, there may be several versions of a label in the channels of trade, also referred to as “market labels”. Market labels are based on the SAL, and applicators must use the directions on the market label on the container which they have in their possession. There could be multiple market labels targeted toward specific commodities or user groups, based off a single SAL.

Under certain conditions, a pesticide registrant may allow another company to distribute their product under the name of the distributor company (sometimes referred to as supplemental distributors). These market labels are typically referred to as distributor labels, and will have a three-part EPA Reg. No. (The first number is the EPA company number for the primary registrant, second number is the product number, and the third number is the EPA company number for the distributor). Registrants must communicate revisions to the SAL to distributor companies. Distributor companies have a responsibility to keep their labels updated. The primary registrant is responsible for the distributor product.

A FIFRA Section 24(c) registration cannot be granted to a distributor company. See this document for additional information regarding this topic.

After a pesticide is registered by EPA, states can register pesticides under specific state pesticide laws. A state may have more stringent requirements for registering pesticides for use in that state.

## **B. FIFRA Section 2(ee) Product Bulletins or Use Recommendations**

Section 2(ee) of FIFRA describes some exceptions to the FIFRA definition of “using a pesticide inconsistent with its labeling”. In other words, this provision presents special circumstances where it is permissible to use a pesticide in a manner which is not specifically stated on the label. Section 2(ee) Product Bulletins or Use Recommendations are not approved by EPA, and are not considered EPA accepted pesticide labeling, and should be clearly identified as Product Bulletins or Use Recommendations.

Some states require 2(ee) Product Bulletins or Use Recommendations to be submitted and approved. States are allowed to be more restrictive than FIFRA, and some states may have additional data requirements prior to allowing a 2(ee) use; or may not allow 2(ee) uses in their jurisdictions under any circumstances.

The intent of Section 2(ee) pertains to Section 3 labels. If additional pests, application methods, etc. need to be added to a Section 24(c) label, then the registrant should work with the SLA to revise the 24(c) label.

For additional information, see the Office of Pesticide Programs (OPP) [Pesticide Labeling Questions & Answers | US EPA](#)

<b>General Examples of Section 2(ee) Recommendations</b> The table below represents common categories of interest.	
<b>Allowed under 2(ee) :</b>	<b>Not Allowed under 2(ee):</b>
Applying at a lower rate or concentration than the Section 3 label specifies (unless prohibited by the label). For example, a registrant might recommend a lower application rate when an herbicide is used on sandy soils.	Increasing the rate of application or concentration from that on the Section 3 label. For example, if the Section 3 label states, "use 1 pt. in 100 gallons of water per acre"; a 2(ee) can not specify to "use 1 pt. in 5 gallons of water per acre".
Applying fewer applications than specified on the label (unless prohibited by the label). For example, making two applications of an insecticide instead of the three allowed by the Section 3 label.	Applying a pesticide more often than specified on the label (increasing the number of applications). For example, if a Section 3 label specifies to make one application (1 pt.) in the spring; a 2(ee) can not specify to make two applications by applying 0.5 pt in the early spring, and 0.5 pt in the late spring.
Reducing the frequency of application. For example, if a label indicates apply every two weeks, it may be appropriate to wait three weeks under certain conditions.	Reducing the Section 3 labeled exposure time for antimicrobial pesticides targeted against human pathogens.
Applying a pesticide for the control of a pest not specified on the label. For example, if the label indicates for use on apple maggot, use on codling moth would be allowed (provided the use pattern, rate, etc. remains the same).	<p>Claims against any public health pest that have not been evaluated by EPA. These pests may only be added by submittal of an application that includes efficacy data. Section 2(ee) recommendations cannot be used for antimicrobial pesticides targeted against human pathogens.</p> <p>Uses not in accordance with PRN 96-7: Termiticide Labeling.</p> <p>Uses patterns (sites) that are dissimilar from the Section 3 label and have not been fully evaluated by EPA.</p>
Mixing a pesticide with other pesticides or a fertilizer.	Mixing a pesticide with other pesticides or a fertilizer, when prohibited by the labeling.
Employing a different method of application, , unless the label states that the product may only be applied by the method(s) specified on the label.	If the label specifies "only" ground applications, a Section 2(ee) use recommendation cannot add a method of application which may require specific data to be submitted to EPA, such as aerial application.
If the label does not state "only" ground applications and the label rate and concentration will not be violated, there may be instances in which aerial application may be added via 2(ee).	<p>Method of application that may represent a higher risk to the applicator, or the environment; or it is not supported by data used to establish the tolerance. (e.g., soil vs. foliar applications).</p> <p>The addition of chemigation as an application method.</p>

### *C. Additional Federal Labeling*

An example of additional federal labeling is supplemental\* labeling. A registrant who has an existing Section 3 registration, may go through the EPA process of adding a new use or other significant label change. However, it can be a period of time between when the new use is accepted on the Section 3 label and when pesticide applicators have access to pesticide containers with the amended newer Section 3 label. A federal supplemental label detailing the new use, with language mirroring that on the amended Section 3 label, can serve as a "stop-gap" during this time period.

Federal supplemental labels now have to be approved by EPA and have an expiration date. It is suggested that registrants provide a proposed supplemental label to EPA at the same time that they provide the proposed amended Section 3 label.

It is the registrant's responsibility to ensure that federal supplemental labels are available to pesticide users, and that the new use is added to the Section 3 label. Typically, supplemental labeling will be incorporated into the master label at the next printing of the product label (final printed label) or within 18 months, whichever comes first.

\* "Supplemental" is a commonly used term but is not defined by the descriptions above.

### **D. Section 18 Emergency Exemptions**

Section 18 of FIFRA provides EPA the authority to exempt a state or federal agency from the requirements of FIFRA when an emergency exists.

Basically, a state or federal agency can apply to the EPA to authorize an emergency exemption to use a particular pesticide when growers or research scientists identify an urgent and non-routine situation where there are no registered pesticides or alternative practices that will effectively address the problem. Typically, most exemptions involve controlling a specific pest, however there are infrequent occasions where the situation might involve other pesticidal uses (such as plant growth regulators).

The characteristics of "urgent and non-routine" and "no registered pesticides or alternative practices" are referred to as "emergency conditions". All exemption requests must meet these conditions and clearly demonstrate that an emergency exists in order to be approved by EPA.

The emergency condition addresses the consequences or impacts of the problem. The consequences of the situation will determine which type of emergency exemption the SLA will apply for:

- Specific – Causes Significant Economic Loss (SEL)
- Public Health – Poses Significant Risks to Human Health
- Quarantine – Involves an Invasive Species
- Crisis – Any of the Above Situations with Very Limited Time

Emergency exemptions are limited to the specific geographic area where the emergency conditions exist and are for a specific pest/use site combination. If approved, the emergency exemption is valid for a limited time and must be renewed if the emergency continues.

Additional information on these requirements can be found in 40 CFR 166.

## **E. Experimental Use Permits**

Because some of the required testing during the registration process involves using a currently unregistered product or a use not previously approved, the EPA can allow distribution and sale for testing purposes through a federal experimental use permit. Refer to [EPA's Registration Manual Chapter 12](#) for information about experimental use permit applications.

Some states in the country have the ability to issue state experimental use permits (either under FIFRA – see 40 CFR 172, Subpart B, or state law) or other research type permits/registrations to generate missing data to support a 24(c) registration. The permits could be used, for example, to measure residue on foliage or evaluate efficacious rates and usage patterns. In contrast, a federal experimental use permit is not an option for generating data in the short term to address a special local need pest situation, but rather is used to support the Section 3 registration process.

## Appendix 3. Main Differences Between FIFRA Section 24(c) Registrations and FIFRA Section 18 Emergency Exemptions

Main Differences between FIFRA Section 24(c) registrations & Section 18 Emergency Exemptions	
Section 24(c)	Section 18
To the extent necessary, there is a General Tolerance, Tolerance Exemption, or Tolerance with a Regional Registration established on the particular food or feed crop.	There is not a General Tolerance, Tolerance Exemption, or Tolerance with a Regional Registration established on the particular food or feed crop. However, EPA will establish a “time – limited tolerance”
The active ingredient <u>does</u> need to be in a currently EPA registered product.	The active ingredient does not need to be in a currently EPA registered product.
To insure safe and efficacious use, most SLAs require efficacy and phytotoxicity data, as well as other data. Most SLAs require 2-3 letters of local support.	Data showing efficacy/crop safety of pesticide must be submitted. Residue data for food crops must be available.
SLA is the approving entity.  The pesticide registrant or other authorized entity submits an application with supporting data to state.  The state lead agency approves the registration. However, EPA can request modifications, or disapprove the registration.	EPA is the approving entity.  SLA submits an application to EPA and EPA may approve the application.
SLA may place an expiration date (commonly five years) on registrations. However, it can be renewed indefinitely, as long as uses are supported by the SLA and not inconsistent with current EPA evaluations.	EPA only allows use for a specified period of time, and it must be applied for by the state each year (as necessary).  EPA may allow the use of a Specific or Public Health exemption for up to one year, and it must be applied for by the state each year (as necessary). EPA may allow the use of Quarantine exemption for up to three years.
Number of acres and counties to be treated do not need to be specified.	Number of acres and counties to be treated must be specified.
There is not an expectation that the use will be placed on the main label, except if the use is on the same site in multiple states.	For specific exemptions, the registrant is expected to demonstrate progress toward getting the use registered (i.e. Section 3 or Section 24(c)).
Can be approved for a variety of reasons, including resistance management purposes.	Approved when there is an urgent and non-routine situation with no effective

Urgency and economic loss do not have to be proven.	alternatives. Typically for a Specific exemption, data showing Significant Economic Loss due to emergency must be provided to EPA. Situations that will present significant risks to threatened and endangered species, beneficial organisms, or the environment can also qualify as specific exemptions.
Many SLAs usually approve complete applications within 30 - 90 days. Certain applications may take longer.	EPA usually reviews complete applications within 60 days. The process may be faster for previously approved requests. New or complex requests may require additional time for review.

## Appendix 4. More Information Regarding Supplemental Distributors

Under certain conditions, a pesticide registrant may allow another company to distribute their product under the name of a distributor company (sometimes referred to as supplemental distributors). Distributor market labels can be readily identified because instead of a two part EPA Reg. No., they have a three part EPA Reg. No. The first set of numbers is the EPA company number for the primary registrant, second set of numbers is the product number, and the third set of numbers is the EPA company number for the distributor.

A supplemental distributor may also distribute a Section 24(c) label based on a primary registrant's Section 24(c) label, with the SLA and primary registrant's approval. The name of the primary registrant for the Section 24(c) must be provided on the distributor Section 24(c) label, see example below. The Section 24(c) numbers on both labels must be identical, and based on the Section 24(c) number assigned to the primary registrant. A FIFRA Section 24(c) registration cannot be granted directly to a distributor company. See the main portion of this document for additional information regarding this topic.

Registrants must communicate revisions to the SAL to distributor companies. The primary basic registrant is responsible for the supplementally distributed product, including Section 24(c)'s. Distributor companies have a responsibility to keep their labels updated.

Primary Registrant Sec. 24(c) Label	Distributor Sec. 24(c) Label
<p><i>First page - Top</i></p> <p>FIFRA Section 24(c) Special Local Need Label For Distribution and Use only in the State of Oregon</p> <p>Acme Broadleaf Herbicide EPA Reg. No. 1234-13 EPA SLN No. OR-190050</p>	<p><i>First page - Top</i></p> <p>FIFRA Section 24(c) Special Local Need Label For Distribution and Use only in the State of Oregon</p> <p>Douglas Broadleaf Crop Herbicide EPA Reg. No. 1234-13-6789 EPA SLN No. OR-190050</p>
<p><i>Last page - bottom</i></p> <p>24(c) Registrant: Acme Chemical Corp. 1520 Industrial Way Zenith, XX</p>	<p><i>Last page bottom</i></p> <p>Distributor: Douglas Specialty Company 4962 Eagle Crest Road Fir Junction, XX</p> <p>24(c) Registrant: Acme Chemical Corp. 1520 Industrial Way Zenith, XX</p>

## Appendix 5. Example Letter for a Replacement Section 24(c) Registration.

August 4, 2023

Document Processing Desk (SLN)  
Office of Pesticide Programs - (7504P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460-0001

RE : Replacement Section 24(c) registration

New Company/ Name of Product® Insecticide

Active Ingredient: XX

EPA Reg. No. XXX-XXX, EPA SLN No. OR-2300XX

Pest/Site- Control of Lygus Bugs (*Lygus* spp.) in Carrots Grown for Seed

The Oregon Department of Agriculture (ODA) is pleased to enclose a Special Local Need registration under FIFRA Section 24(c), to allow for the use of New Company/ Name of Product® Insecticide (a.i. XX) on carrots grown for seed, SLN OR-2300XX. The active ingredient XX in Product® Insecticide, has been shown to provide effective control of lygus bugs in carrots grown for seed. Lygus bug feeding during flowering and seed maturation reduces the viability of the carrot seeds.

EPA SLN No. OR-2300XX is a replacement for OR-0800XX (Original Company/ Name of Product®, EPA Reg. No. XXXX-XXX). EPA SLN No. OR-0800XX will be cancelled when the Section 3 product associated with this Section 24(c) registration has cleared the channels of trade.

There are no differences in the labels, except that OR-2300XX has an expiration date of December 31, 2028, and also has updated pollinator protection restrictions and advisory statements.

If you have any questions, please do not hesitate to contact me.

Sincerely,

SLA Signature Block

CC: Interested Parties

## Appendix 6: EPA Policy and Criteria Notice 2105.1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

*Effluent policy*

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

100-304

MEMORANDUM

SUBJECT: Policy and Criteria Notice 2105.1

TO: See Below

Attached is a policy notice which has been approved for use throughout the Division. This Division policy should be inserted into your Policy and Criteria Notebook in the proper place.

Questions, problems or suggestions for improvement on this notice should be directed to Jack E. Housenger, Registration Support and Emergency Response Branch, Room 716, 557-1192.

*Robert W. Brown for*  
Douglas D. Campt, Director  
Registration Division

Attachment

Addressees

Director/OPP (Carrie)  
Division Directors/OPP  
Branch Chiefs/RD  
Section Heads/RD  
Regional Branch Chiefs  
Ed Gray/OGC  
Director/PTSCMS  
Program Coordination Staff  
Policy and Special Projects Office  
Douglas Sutherland/BUD  
Recipients of PR Notices  
Office of International Activities (OIA)  
- OIA  
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POLICY AND CRITERIA NOTICE

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Guidelines for Processing Pesticide Registrations  
Involving Treatment of Raw Agricultural Commodities  
Intended for Export Only

PURPOSE: To establish Registration Division policy regarding registration of uses for treatment of raw agricultural commodities intended solely for export.

SCOPE: This policy applies to the processing of all registration actions under section 3 of FIFRA and for reviewing all state registration actions under section 24(c) of FIFRA.

BACKGROUND: Use of a pesticide on food/feed commodities intended for export only (for which an appropriate tolerance or other clearance does not exist) have, in the past, been permitted only under the section 18 program. Registration under section 3 or 24(c) was not permitted due to the lack of a tolerance or other clearance.

According to section 402 of the Federal Food, Drug and Cosmetic Act (FFDCA) a food (defined in section 201(f) as including, among other things, articles used for food or drink for man or other animals) is considered to be adulterated if it contains a pesticide chemical for which a tolerance or exemption from the requirement of a tolerance, in accordance with sections 408 and 409, does not exist.

Section 801(d)(1) of the FFDCA prescribes conditions under which a food, normally considered to be adulterated under section 402, would not be so considered. This section states that a food intended for export shall not be deemed adulterated if it "...

- (A) accords to the specifications of the foreign purchaser,
- (B) is not in conflict with the laws of the country to which it is intended for export,
- (C) is labeled on the outside of the shipping package that it is intended for export, and
- (D) is not sold or offered for sale in domestic commerce."

Therefore, if the above requirements are satisfied, the food in question would not be considered adulterated and a tolerance or exemption from the requirement of a tolerance would be unnecessary.

POLICY: It shall be the policy that use of a pesticide on a food/feed commodity intended solely for export for which an appropriate tolerance or other clearance does not exist be allowed to be registered under section 3 or section 24(c). However, prior to registration under section 3 and within the 90-day review period for section 24(c) registrations for any pesticide use of food intended only to be exported, the following must be insured:

(1) The use is in accord with the requirements of the foreign purchaser (written confirmation from the purchaser with English translation if confirmation is in a language other than English), ←

(2) the importing country has no laws which would preclude the importation of this commodity (written confirmation from the importing country's government ← with English translation if confirmation is in a language other than English), and

(3) that following treatment of the commodity, the shipping package is labeled that it is intended for export only and is not to be sold for domestic use (a pesticide registration labeling requirement).

Provided that the above requirements are met, there will be no need for a tolerance or other clearance under sections 408 and 409 of the FFDCA.

Registration Division will be required to keep accurate records of these uses which achieve registration to ensure that they do not inadvertently become registered for any use other than for treatment of commodities intended solely for export purposes.

IMPLEMENTATION: This policy is effective immediately. This policy does not preempt any other requirements of FIFRA or FFDCA.

## Appendix 7: EPA Guidance on Warranty Statements

### EPA Guidance on Warranty Statements



## **U.S. Environmental Protection Agency Office of Pesticide Programs (OPP)**

### **Guidance on Warranty Statements October 17, 2006**

## **WARRANTY STATEMENTS**

Most, if not all, pesticide labels contain some type of warranty disclaimer language. It is important, as always, that the Agency be consistent in reviewing such language when it is first submitted or subsequently amended. The Office of Pesticides Programs (OPP) has found warranty disclaimer statements that contain potentially false or misleading language, or words and phrases that are in some way objectionable. Additionally, OPP is frequently asked by applicants/registrants about warranty disclaimer language they wish to place on pesticide labels. Therefore, OPP is reissuing the Agency's guidance on warranty statements. As described more fully below, the updated guidance will include examples of improper warranty statements that go beyond what the agency considers acceptable, as well as examples of how to fix these statements. We will also include examples of statements that are acceptable under FIFRA, and that could be incorporated into FIFRA labels.

Warranty and Disclaimer statements containing language intended to limit liability of the registrant or act as disclaimers or warranties for the product are generally covered by state law or may fall under the jurisdiction of the Federal Trade Commission. The Agency will evaluate these statements to assess the extent to which the statements impact FIFRA label standards or the Agency's implementing regulations. In general, OPP will not accept: (1) disclaimers that attempt to limit liability for what is expressly warranted by statements on the label (e.g., "this product may not work as intended" or "seller makes no warranty of results to be obtained by use of the product"); and (2) statements that ignore that the possibility of warranty enforcement under state or other applicable laws governing warranties.

There are four types of label language associated with warranty disclaimers, and statements of limitations of liability that the Agency has found to be unacceptable under statutory and regulatory standards. It is important to recognize that these statements must be assessed on a case-by-case basis. Following are examples of statements that have been found unacceptable:

1. Overly broad statements negating or detracting from the Directions for Use or other label language (including precautionary statements and directions for use). For instance, the warranty statement that the product may not work would negate Directions for Use that explained how the product was to be used.

2. Label language asserting that the buyer has accepted the manufacturer's statement of his/her respective rights (e.g., manufacturer states buyer's rights are extremely limited or require a specific process to be realized). Because these statements are almost always incomplete (in terms of fully explaining a buyer's rights in the jurisdiction (state) of purchaser and because they can mislead buyers into thinking that they have no legal remedy, they may constitute "misbranding" under FIFRA).
3. Overly broad language implying buyer has no legal right to recover damages from manufacturer (e.g., "all such risks shall be assumed by the buyer").
4. Because Experimental Use Permit (EUP) labels must be used in strict accordance with the EUP program, the warranty on EUP labels may not disclaim control over use. As with No. 2 above, these statements can be considered to be misleading.

The proposed label must be checked for warranty disclaimer/liability language statements (like those above) which appear to negate or detract from Directions for Use or other language. Reviewers should make sure that the disclaimer statement makes it clear that it is the registrant's or manufacturer's warranty disclaimer, by using such statements like "To the extent consistent with applicable law..." or "It is the manufacturer's intention that...". This way it is clear that the language is coming from the registrant (and not EPA).

### **Section 24(c) Special Local Needs**

In 1997, OPP, in coordination with OGC and the regulated community, developed general guidance on language acceptable in waiver of liability statements that may be used on section 24(c) Special Local Needs labels. This guidance included:

1. The label statement may indicate that the registrant intends that the 24(c) only be distributed to users that have agreed in writing to the terms and conditions of the use including a waiver of liability. But, it is not acceptable to have label language that **requires** (appears to represent that EPA will enforce) a user to sign an agreement before purchasing it or using it. This guidance can be found at <http://www.epa.gov/opprd001/24c/addendum.htm>.

2. The special conditions and disclaimer for use do not require an action by growers that imposes an enforcement burden on the Federal or state government.
3. The label statement cannot require that the user be a member of a specific group in order to use the product.

Even though FIFRA restricts what can be placed on a label, the statute and implementing regulations allow for some warranty disclaimer statements. OPP needs to be sure these statements conform to FIFRA, most importantly that the statements do not contain false or misleading information. The following are examples of problematic warranty statements. The problematic portions of the label statements are stricken, and necessary language is added in red.

## **EXAMPLES OF PROBLEMATIC WARRANTY DISCLAIMERS**

Even though FIFRA restricts what can be placed on a label, the statute and implementing regulations allow for some warranty disclaimer statements. OPP needs to be sure these statements conform to FIFRA, most importantly that the statements do not contain false or misleading information. In general, OPP will not accept: (1) disclaimers that attempt to limit liability for what is expressly warranted by statements on the label; and (2) statements that ignores the possibility of warranty enforcement under state or other applicable laws governing warranties. Disclaimers that purport to limit liability for statements made or implied by the label are not acceptable (e.g., "this product may not work as intended" or "seller makes no warranty of results to be obtained by use of the product"). The following are examples of problematic warranty statements. The problematic portions of the label statements are stricken, and necessary language is added in red.

## EXAMPLE 1

### **IMPORTANT: READ BEFORE USE**

Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

**CONDITIONS:** The directions for use of this product are believed to be adequate and **should must** be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of XXXX. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** **To the extent consistent with applicable law**, XXX makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of XXX is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. **To the extent consistent with applicable law**, XXX disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** **To the extent consistent with applicable law**, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at XXX's election, the replacement of product.

## Reasons for corrections

The phrase “should follow directions” could mislead users to believe that the directions for use are only suggestions and not enforceable restrictions on how the product may be used; therefore, all statements relating to using the product in accordance with its labeling will be required to be mandatory (i.e., “must”).

The phrase, “to the extent consistent with applicable law” has been added to the disclaimers of liability and damages to avoid the statements being false or misleading. Some states or localities may not allow certain disclaimers of liability or damages; therefore, the user/buyer may have a remedy under other law governing warranties.

## EXAMPLE 2

### Warranty

The directions for use of this product are believed to be adequate and ~~should~~ must be followed carefully, it is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result due to such factors as weather conditions, presence or absence of other materials, or the manner of use or application, all of which are beyond the control of XXX, the manufacturer, or the seller.

To the extent consistent with applicable law, the products sold to you are furnished “as is” by XXX. The manufacturer and the seller are subject only to the manufacturer’s warranties, if any, which appear on the label of the product sold to you. Except as ~~warranted by this label expressly provided herein~~, XXX, the manufacturer, or the seller makes no warranties, guarantees, or representations of any kind to the buyer or the user, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold or use of the product, including, but not limited to, merchantability, fitness for a particular purpose or use, or eligibility of the product for any particular trade usage. ~~Except as expressly stated herein, XXX, the manufacturer, or the seller makes no warranty of results to be obtained by use of the product.~~ To the extent consistent with applicable law, Buyer’s or user’s exclusive remedy, and XXX, the manufacturer’s or the seller’s total liability shall be limited to damages not exceeding the cost of the product. No agent or employee of XXX, or the seller is authorized to amend the terms of this warranty disclaimer or the product’s label or to make a presentation or recommendation different from or inconsistent with the label of this product.

To the extent consistent with applicable law, XXX, the manufacturer, or the seller shall not be liable for consequential, special, or indirect damages resulting from the use, handling, application, storage, or disposal of this product or for damages in the nature of penalties, and the buyer and the user waive any right that they may have to such damages.

## Reasons for Corrections

Prior to legal use of a pesticide product the use must be registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA). Registration of a pesticide requires, in part, that the product be effective in controlling the pest(s) for which it is registered. In registering the product under FIFRA, the product must perform as purported when used in accordance with its labeling. The phrase, "Except as expressly stated herein, XXX., the manufacturer, or the seller makes no warranty of results to be obtained by use of the product," is overly broad and could be misleading to the consumer. Overly broad statements, which negate or detract from the Directions for Use, must be qualified by a phrase such as "Except as warranted in this label." Statements such as those used in the example above ("Except as expressly provided herein" and "Except as expressly stated herein") are not adequate qualifiers because they are misleading in that they do not clearly incorporate the warranty offered through the act of registration.

State and local laws may not allow the manufacturer to limit its liability by offering its product "as is." In addition, the same laws may not allow certain limitations of liability or remedy. Therefore "to the extent consistent with applicable law" has been added in appropriate places.

### EXAMPLE 3

#### LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read this Limitation of Warranty and Liability Before Buying or Using This Product. If the Terms Are Not Acceptable, Return the Product at Once, Unopened, and the Purchase Price Will Be Refunded.

It is impossible to eliminate all risks associated with the use of this product. Such risks arise from weather conditions, soil factors, off-target movement, unconventional farming techniques, the presence of other materials, the manner of use or application, or other unknown factors, all of which are beyond the control of XXX. These risks can cause: ineffectiveness of the product; crop injury, or; injury to non-target crops or plants.

XXX does not agree to be an insurer of these risks **beyond what is expressly warranted by this label**. When you buy or use this product, you agree to accept these risks.

XXX warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions.

**To the extent consistent with applicable law**, XXX makes no other express or implied warranty of fitness or of merchantability or any other express or implied warranty.

**To the extent consistent with applicable law**, in no event shall XXX or seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. Buyer's or user's bargained-for expectation is crop protection. **To the extent consistent with applicable law**, the exclusive remedy of the user or buyer and the exclusive liability of XXX or seller, for any and all claims, losses, injuries or damages (including claims based on breach of warranty or contract, negligence, tort or strict liability), whether from failure to perform or injury to crops or other plants, and resulting from the use or handling of this product, shall be the return of the purchase price of the product, or at the election of XXX or seller, the replacement of the product.

**To the extent consistent with applicable law allows such requirement**, XXX or its Ag Retailer must have prompt notice of any claim so that an immediate inspection of buyer's or user's growing crops can be made. Buyer and all users shall promptly notify XXX or a XXX Ag Retailer of any claims, whether based on contract, negligence, strict liability, or other tort or otherwise be barred from any remedy.

This Limitation of Warranty and Liability may not be amended by any oral or written agreement.

### Reasons for Corrections

See the explanations for Example 2 above.

### EXAMPLE 4

Note: Seller warrants that this product complies with the specifications expressed in this label. **To the extent consistent with applicable law**, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. **To the extent consistent with applicable law**, Seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. **To the extent consistent with applicable law**, Seller shall have no liability for consequential damages.

### Reasons for Corrections

See explanations for Examples 1 through 3 above.

## EXAMPLE 5--INDEMNIFICATION TYPE

### Conditions and risks of use for special local need

Use of XXX herbicide (the “product”) on clover grown for seed (the “crop”) for this special local need may result in crop injury, crop yield reduction and/or crop loss as further discussed below. Read and understand these conditions and risks of use for special local need before using the product on the crop.

This Product is available for use in the manner described in this Supplemental Labeling on the basis that, in the sole opinion of the user, the benefits and utility derived from the use of the Product on the Crop outweigh the potential risk of Crop injury, Crop yield reduction or Crop loss. The decision to use this Product in the manner described in this Supplemental Labeling must be made by each individual user on the basis of anticipated benefits versus (i) the potential risk of Crop injury, Crop yield reduction and Crop loss, (ii) the severity of the target pest infestation, (iii) the cost and availability of alternative pest controls and (iv) any other relevant factors.

By purchasing the Product for use, or using the Product, in the manner described in this Supplemental Labeling, you acknowledge and accept that, **to the extent consistent with applicable law:**

- (1) you assume all risk of Crop injury, Crop yield reduction and Crop loss;
- (2) XXX does not make, and do not authorize any agent or representative to make, any representations or recommendations regarding the use of this Product on the Crop other than the statements on this Supplemental labeling;
- (3) XXX does not make, and do not authorize any agent or representative to make, any warranties, express or implied, with respect to the use of the Product on the Crop and disclaim all warranties, expressed or implied, including any implied warranty of merchantability;
- (4) XXX disclaims all liability for any damages, losses, expenses, claims or causes of actions arising out of or relating to Crop injury, Crop yield reduction and/or Crop loss;
- (5) These Conditions and Risks of use for Special Local Need supersede any contrary representations or recommendations by XXX, or its respective agents or representatives, and any provisions in or recommendations by XXX, or its respective agents or representatives, and any provisions in or on any Product literature or labeling including any provisions on the label affixed to the Product container.

If these Conditions and Risks of Use for Special Local Need are not acceptable, the unopened Product may be returned to the seller for a refund or used for a different labeled use in accordance with the label affixed to the Product container.

This “Conditions and Risks of Use for Special Local Need” statement is required by XXX and not specified by the US EPA or the State of Oregon.

### Potential Concerns for 24(c) disclaimers

EPA believes that products bearing labeling that requires growers to waive their rights to bring suit as a condition of lawful use of a product are not consistent with FIFRA and should not, therefore, be registered by states pursuant to section 24(c). EPA believes the inclusion of such statements on product labeling may constitute misbranding pursuant to section 2(q)(1)(A) of FIFRA and 40 CFR 156.10(a)(5), because these statements may give growers the misleading impression that federal authorities have sanctioned such labeling and support the imposition of civil and/or criminal penalties against growers who choose to use a pesticide without first agreeing to waive their rights to bring civil actions for damages resulting from the use of the pesticide. The FIFRA enforcement scheme should not be used, nor does EPA believe it was intended to be used, as a means of enforcing private agreements regarding product liability. For this reason, EPA does not believe the use of such provisions on 24(c) labeling is consistent with the purposes of FIFRA.

EPA does not object to statements on 24(c) product labeling that merely references the existence of private liability agreements, or that disclaim liability to the extent permitted by law. These statements are distinguishable from those discussed above in that they do not require that growers sign away their legal rights as a condition of lawful use of the product. However, such statements must not provide false or misleading information to growers about the legal remedies available to growers in the event growers suffer damage resulting from the use of the product. As a general rule of thumb, EPA believes that any such statements should clearly indicate that they represent the position of the registrant only, or should be otherwise qualified to indicate clearly that the limitations on liability provided on the label may be inapplicable if a grower's state does not allow the limitations on damages asserted on the label.

The example above is made acceptable by including "to the extent consistent with applicable law."

## Appendix 8: Document Revisions Statement

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