

FIFRA Section 24(c) Guidance

AAPCO/SFIREG/POM Draft

Submitted to EPA May 2019

Table of Contents

I. Introduction.....	4
II. Section 24(c) of FIFRA.....	4
A. Defined	4
B. Special Local Need Identified/Research Conducted.....	5
C. Base Conditions for a Section 24(c) Registration.....	5
D. Who can Apply for Section 24(c) Registrations?	6
E. Reasons Section 24(c) Registrations are Approved.....	6
F. Section 24(c) Registrations Which Require Specific Label Language	7
G. Section 24(c) State Registration Number Format	10
H. Circumstances When Section 24(c) Registrations Cannot be Approved	11
III. SLA Review and Decision Process for Section 24(c) Applications.....	12
A. SLA Checklist and Initial Questions.....	12
B. SLA Approval/Denial Decision	13
C. Multiple Section 24(c) registrations in a state for the same use	11
D. SLA and Registrant Responsibility to Provide Section 24(c) Labels to Users	15
IV. Section 24(c) Approval Notification to EPA.....	15
A. Contents of Notification Submission to EPA	15
B. Where and How to Submit 24(c) Notifications	17
V. EPA Review Process	17
VI. Maintenance of Section 24(c) Registrations.....	19
A. When to Notify EPA of Changes: Revised labels.....	19
B. Cancellation of Section 24(c) Registrations.....	20
C. When Changes Suggest a New Section 24(c) Registration: Company Consolidations, Product Transfers or Changes in Formulation	20
VII. General Policies, Questions and Answers About Section 24(c) Registrations.....	21

Appendices.....	23
Appendix 1. Roles and Responsibilities of Participants Involved in Section 24(c) Registrations.....	23
Appendix 2. Types of Registrations or Pesticide Use Authorizations Under FIFRA (Other Than Section 24(c) Registrations).....	25
A. Section 3 Registrations.....	25
B. Section 2(ee) Recommendations.....	26
C. Federal Supplemental Labels	28
D. Section 18 Emergency Exemptions.....	28
Appendix 3. Main Differences Between FIFRA Section 24(c) Registrations and FIFRA Section 18 Emergency Exemptions	30
Appendix 4. More Information Regarding Supplemental Distributors	31
Appendix 5. Example Letter for a Replacement Section 24(c) Registration.	

I. Introduction

This guidance document clarifies the regulations implementing Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to assist FIFRA state lead agencies (SLAs) in submitting complete Section 24(c) notification submissions to EPA; and to facilitate EPA's review. Stakeholders may also find this guidance helpful to better understand the purpose and processes of Section 24(c) registrations.

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. 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 Agency's reviews, evaluations and actions on Section 24(c) registrations.

The FIFRA 24(c) regulations can be found in Title 40 of the Code of Federal Regulations (CFR) Part 162.

II. Section 24(c) of FIFRA

A. Defined

Section 24(c) of FIFRA provides authority to states to register an additional use of a federally registered pesticide product, or a new end use product to meet special local needs, if certain conditions are met. These 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 pesticides.

The following defines "special local need" that must exist for states to issue a Section 24(c) registration for an additional use of a federally registered pesticide product, or a new end use product.

Under 40 CFR 162.151, a "Special Local Need" is defined 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.

- "*...existing or imminent pest problem...*" means a problem which already exists or is likely to exist.
- "*...based upon satisfactory information... an appropriate federally registered pesticide is not sufficiently available...*" means a state can document that a federally registered product:
 - is not available in the state for the desired site(s) to adequately control the target pest(s), or
 - cannot be applied without causing unacceptable risks to human health or the environment, or

- is necessary to maintain an IPM, resistance management, or minor use pest control program, or
- could be replaced by a formulation that poses less risk to man or the environment.

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 has developed resistance to pesticides which previously controlled it;
- The introduction of a new pest and pesticides are insufficiently available 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. Data used to support the EPA established tolerance are typically generated by IR-4 or the registrant.

C. Base 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) 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 a SLA, a registrant has the responsibility to determine whether these criteria are met. If a registrant or a SLA has any questions, they should contact EPA.

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) The Federal Pesticide Act 1978, which amended §24(c) of FIFRA, provided the States with greater flexibility and independence in issuing registrations for "special local needs." Most Section 24(c) registrations 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 at:

<https://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:1:0::NO:1> 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 may want to 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 may not apply).
- A third party, such as an officially recognized grower organization, or governmental entity may also apply for a Section 24(c) registration, as long as the applicant has a Letter of Authorization from the registrant allowing the third party to be the Section 24(c) registrant. Without a Letter of Authorization, there may be unknown data compensation or other issues.

E. Reasons Section 24(c) Registrations are Approved

A Section 24(c) registration can be approved by a state 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;
- Adding and/or amending restrictions provided on the Section 3 label;
- Increasing worker or environmental safety;
- Promoting resistance management;
- Meeting export needs; or
- Modify voluntary or mandatory restrictions on a Section 3 label.

The vast majority of Section 24(c) requests submitted to SLAs for possible approval, do not require a full risk assessment by EPA. 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.

However, in the event that a Section 24(c) registration would require a full risk assessment, this would trigger a fee for service under the Pesticide Registration Improvement Act (PRIA). FIFRA amendments passed by Congress in 2004 created a registration service fee system for applications involving amended registrations. **This is a significant change from EPA's 1996 Section 24(c) guidance.**

If a registrant is questioning whether a particular use may trigger a full risk assessment, they should contact EPA 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 also contact EPA. EPA can help a state determine what types of data have been previously submitted and reviewed. An example of a registration which may require a full risk assessment, 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.

E. Reasons a SLA might contact EPA prior to approving a registration under FIFRA Section 24(c).

There are many reasons that a 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 a tolerance on the crop, for example there may be some lack of clarity because of changes in Crop Groups, Crop Subgroups and crop definitions.
- The use pattern, type of application (ex. soil vs. foliar) or rate is supported by the tolerance.
- EPA may have health or environmental concerns about an ingredient contained in the pesticide product; or there have been, or there is an ongoing regulatory action.

- The proposed use is considered a similar use pattern to one that exists on a Sec. 3 label, or would the proposed use not be similar, and trigger new data requirements. A full risk assessment under PRIA will likely be required by EPA if the proposed use is not a similar use pattern.

EPA may also be contacted to determine:

- The eligibility of a seed crop as a non-food/non-feed crop, and whether EPA considers current state laws adequate.
- What types of data 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.

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

Crops Grown for Seed

Under limited conditions, 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 Sec. 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, no parts of the crop will be diverted for use as human food or livestock feed; and 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 & 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, 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.

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/non-food 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.

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. Please contact EPA if you have a question regarding eligibility of a seed crop.

Non-Bearing Crops

Under limited conditions, an SLA may grant 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 Sec. 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.

Waiver of Liability Statements on Sec. 24(c) Labels

Waiver of liability statements are used to limit product liability and only apply for crops grown on very limited acreage, such as some seed crops. EPA opposes enforcing limits on user's rights, and will only allow certain waiver of liability language on Section SLN labels. Additional information on this issue is available on the EPA website:

(<https://www.epa.gov/sites/production/files/2016-09/documents/warranty.pdf>)

The following is an example of waiver of liability language that is acceptable to EPA:

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

(Registrant) intends that this Section 24(c) label be distributed only by the (Grower Association) and only to end users and/or growers who agree in writing to the terms and conditions required by the (Grower Association) including a waiver and release from all liability and indemnification by the user and/or grower of (Registrant), (Grower Association), and others for failure to perform and crop damage from the use of (Product) on (Crop). If such terms and conditions are unacceptable, return (Product) at once unopened.

This product when used on (Crop) may lead to crop injury, loss, or damage. (Registrant) recommends that the user and/or grower test this product in order to determine its suitability for such intended use. The (Grower Association) and (Registrant) make this product available to the user and/or grower solely to the extent the benefit and utility, in the sole opinion of the user and/or grower, outweigh the extent of potential injury associated with the use of this product. The decision to use or not to use this (Pesticide) must be made by each individual (Product) user and/or grower on the basis of possible crop injury from (Product), the severity of (Pest) infestation, the cost of alternative (Pest) controls, and other factors. (Registrant) intends that because of the risk of failure to perform or crop damage that all such use is at the user's and/or grower's risk, to the extent consistent with applicable law.

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

When a waiver of liability statement is included on the Sec. 24(c) label, it must be placed on the last page. A sentence referring the user to the waiver of liability statement (example below) 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).

Waiver of liability certificates are not part of the SLN label. These certificates are agreements between the registrant, the grower association and the users.

G. 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 the 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 2019, then the Section 24(c) registration number would be EPA SLN No. FL-190005. 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.

H. Circumstances When Section 24(c) Registrations Cannot be Approved

Below is a list of circumstances which would prevent the appropriate issuance of a Section 24(c) registration by a SLA.

- 1) If 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) If 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 therefore constitutes a new use.
- 3) When there is an available Section 3 registered pesticide product for such use with the 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 chemical review manager or go to the registration review schedule generally found on EPA's Pesticide Re-evaluation website page.
- 7) If 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 Sec. 24(c), they should contact the product manager responsible for the chemical/use pattern; or other appropriate EPA personnel.

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.

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

Quick Basics 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?
- Have adequate supporting data, documentation, and fees been submitted?
- Is this truly a legitimate need for your state?
- Have potential risks been mitigated?

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

Many states review 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.

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 should 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, 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 will 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.

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 and 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 should 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, is authorized for distribution and use only within that State. 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.

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

Another reason is that the registrant has not provided sufficient information for a state to evaluate a Section 24(c) application. SLAs typically provide an Intent to Deny letter with an adequate time-period for the registrant to submit supporting data. If registrants do not have the required data, they commonly withdraw the application. Otherwise, the SLA may provide a written letter of denial.

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

Limited Availability

There are instances in which a SLA may grant multiple Section 24(c) registrations for the same use pattern and same active ingredient. This may happen because some dealers may only market certain pesticides or the pesticides of certain registrants, and the Section 3 product associated with the Section 24(c) registration is considered by the SLA to be "not sufficiently available".

SLAs should be aware of what entity generated the data to support the original 24(c), to avoid potential data compensation issues. If the data were generated by the university extension or other public entity, some SLAs will simply accept a "me-too letter" from the second potential 24(c) registrant; other SLAs will require the second potential 24(c) registrant to submit the same data or similar data, in order to have a complete submission package for their state files. SLAs should have a written policy.

Product Availability Transition Period

Another instance in which a SLA may grant an additional Sec. 24(c) registration, is during a marketing transition period. As part of normal business practices, pesticide products or active ingredients may be sold or marketed by a different company. There can be a period of time in which a product that no longer being actively marketed by the original company is still in channels of trade. To prevent possible disposal issues, the SLA may choose to maintain the Sec. 24(c) registration associated with the original Section 3 product, until the Sec. 3 product has cleared the channels of trade. In the meantime, the SLA will also grant a new Sec. 24(c) registration for the product that is now being sold or marketed by the new company. Both registrations will have their own unique Sec. 24(c) number. See Appendix 5 for an example letter.

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

It is ultimately the responsibility of the pesticide registrant to ensure that pesticide users have access to Section 24(c) labels. 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.

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 submission.

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 Notification Submission to EPA

For a newly issued Section 24(c) registration, the state must include the following items in the Section 24(c) approval notification submission to EPA:

- A properly completed Notification of State Registration of a Pesticide to Meet a Special Local Need Form (EPA Form 8570-25). All requested information on the notification form must be provided and the latest revised form must be used. (See Appendix X [not included at this time].)
- The SLA must provide a cover letter with a description of the special local need and a clear and concise explanation of how the definition of the special local need is met by issuance of the Section 24(c) registration, and that the use is not on any currently available Section 3 labeled products.
- An Unreasonable Adverse Effects Determination Statement (which summarizes the state's assessment of risks and benefits and supports the conclusion that no unreasonable adverse effects will occur) is only required if:
 - The product is not substantially similar in composition and use pattern to a federally registered product, or
 - Other uses of the same product, or of a product with similar composition, have had registration denied, disapproved, suspended or canceled by the Administrator.

- If data were submitted to the SLA in support of the Section 24(c) registration, the SLA should include a summary of the data. The full studies or raw data should not be submitted as part of the notification. EPA will not review studies or raw data.
- A copy of the Section 24(c) label approved by the state. The label should include the final SLN No., the active ingredient statement, the expiration date, and must prominently display “FIFRA Section 24(c) Special Local Need Label” (or a similar statement). Note: In the case of a restricted use pesticide, no information, statements or logos can 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.
- 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.
- For Section 24(c) registrations intended for use on crops grown for seed for nonfood and nonfeed uses, the SLA must cite a state regulation adequate to regulate the seed and by-products; or a detailed explanation why the state regulation is not needed.

For an amended Section 24(c) registration, the SLA Section 24(c) notification 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.
- A copy of the amended Section 24(c) label approved by the state.

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

The SLA should submit a complete Section 24(c) approval notification submission for each registration to the following addresses based on the use of a courier service or standard mail:

By Courier: Address for FedEx, UPS, DHL, Courier deliveries ONLY

*****PLEASE NOTE THAT MAIL SENT VIA THE US POSTAL SERVICE TO THE ADDRESS BELOW WILL NOT BE DELIVERED*****

U.S. EPA Office of Pesticide Programs
Document Processing Desk (SLN)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

By Standard Mail: Address for U.S. Postal Service deliveries ONLY

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

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

V. EPA Review Process

Once EPA has received notification of a Section 24(c) registration, it is processed through EPA's front-end Document Processing Desk. The front-end processing staff extracts data from the EPA Form 8570-25 and cover letter and inputs the information into the Agency's tracking database. A decision number is then created for the submission and 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 missing, the notification submission is considered incomplete and the Section 24(c) registrations will be considered invalid as issued. The EPA 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 will 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

EPA can disapprove of a Section 24(c) registration for reasons listed in "Section II. H" or can issue Special Disapprovals if the Administrator determines that use of the product under the Section 24(c) registration: would constitute an imminent hazard; or 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.

If it is determined that a disapproval is likely, the EPA will issue a Notice of Intent to Disapprove the state registration which will provide the reasons for disapproval. Prior to issuance, the SLA will be informally notified that there is a likely pending disapproval. This notice will generally require the SLA to respond within 10 days of receipt of the notice and will invite the SLA to consult with the appropriate Agency designee [see 40 CFR 162.154 (a) (2)]. Within 10 days of receipt of this notice, the SLA may request, consultation with the EPA prior to EPA's final decision on disapproval.

Section 24(c) Amendments

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 will 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 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 under PRIA.

Additionally, it should be noted that data/studies are not to be submitted in support of a Section 24(c) registration for the EPA to review. Any new data for the Agency to consider in support of a pesticide registration must come in under PRIA or in response to a data call-in (DCI). **This is a significant change from EPA's 1996 Section 24(c) guidance.**

Registration Review

All active Section 24(c) registrations 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. 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.

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; or
- An active ingredient undergoing the registration review program impacts the Section 24(c) registration.

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. See Section IV. “Section 24(c) Approval Notification to EPA” for what must be included in the notification and the timeline for doing so.

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. EPA will process the cancellation in accordance with FIFRA 6(f).

The SLA should submit a letter* to EPA with a statement that indicates the registrant:

- Is voluntarily cancelling the registration, and
- Requesting to waive the 180-day comment period in the federal register.

The SLA should also attach a copy of the supporting letter or email from the registrant.

* Many SLAs also include the reason why the registrant is cancelling the Sec. 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 Sec. 24(c) registration has been canceled. Note - these parties are often highly interested in why a Sec. 24(c) registration was canceled, for example the use was added to the Sec. 3 label and therefore the Sec. 24(c) was no longer necessary.

Registrants will also commonly contact EPA regarding a cancellation and cease paying the Maintenance Fee. 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.

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 confusing on many levels to have a Section 24(c) number essentially "recycled". Significant formulation changes refers 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 helps with inventory management for both the SLA and EPA. It may also cause confusion among pesticide users (and recordkeeping requirements) to have a single Section 24(c) number associated with different registrants, formulations or EPA Reg. Numbers. 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

(The Q/A below is from the current guidance)

When does a pest problem become regional or national in scope so that it should no longer qualify for §24(c) registration? How can states know whether a registrant is using §24(c) to avoid federal registration?

Response: The term "special local need" does not include situations such as interregional or nationwide pest problems. The purpose of this exclusion is to prevent a registrant from seeking special local needs registrations in many states rather than applying for and obtaining a federal registration. States are strongly encouraged to ensure that this does not occur.

Generally speaking, If the same §24(c) registration is issued in more than five states, states should start to question if the pest problem is a "special local need" and not "interregional" or "national" in scope. If the same §24(c) registration is issued in 15 states, generally, further §24(c) registration will be denied and the Agency will contact the registrant involved to discuss the situation.

In situations where a commodity is grown in a limited number of states, the Agency may seek consultation with the registrant involved if a §24(c) registration is issued by all most or all the states growing the commodity. The Agency realizes there are situations such as third party registration for a widely used herbicide where a 24(c) registration may be needed in multiple states based on local needs in each state. In this situation, states should provide an explanation as to why the situation is a "special local need".

AAPCO/SFIREG/POM Draft

Appendices

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

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 Sec. 24(c) application
- Provide testimonials about the special local need pest problem, letters of support for the Sec. 24(c) application
- Consult with SLA during Section 24(c) review process

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

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

Pesticide Registrants:

- Submit Sec. 24(c) registration applications to SLA
- Consult with SLA during Sec. 24(c) submission and review process
- Authorize use of supplemental distributor products under 24(c)s
- Authorize third-party registrants to obtain Sec. 24(c) registrations
- May need to register 24(c) and submit payment for Sec. 24(c) registration to SLA
- Provide Sec. 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:

- May submit Sec. 24(c) registration applications to SLA
- Obtain consent/legal authority from primary registrant to register Sec. 24(c)
- Consult with SLA during Sec. 24(c) submission and review process
- May need to register Sec. 24(c) and submit payment for Sec. 24(c) registration to SLA
- Provide Sec. 24(c) registration maintenance fees to EPA, or request waiver

Supplemental Distributor Registrants:

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

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 Sec. 24(c) registrations, and submit to EPA if approved
- Amend or revise Sec. 24(c) registrations as required by EPA
- May require state registration of Sec. 24(c)s
- May mandate expiration dates for Sec. 24(c) labels, and periodic review and renewal of Sec. 24(c) registrations
- Depending on state law, may refuse to continue to register a Sec. 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 a SLA, provide consultation to states on proposed Sec. 24(c) registrations prior to submission
- Review of Sec. 24(c) registrations submitted by SLA
- Authority to disapprove Sec. 24(c) registration, or require revisions to Sec. 24(c) within 90 days of Sec. 24(c) approval
- May require revisions to Sec. 24(c) label per Registration Review for the pesticide
- May require cancellation of Sec. 24(c) registration if Sec. 3 registration of pesticide is cancelled
- Require Sec. 24(c) registration maintenance fee (or grant waiver)
- Cancel Sec. 24(c) registration
- Request that the Sec. 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, 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, 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 will use. 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. States can be more stringent or restrictive than EPA, but they can not be less.

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 labels, 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) Label Review Manual.

Generally Allowable and Non-allowable Recommendation. The table below represents common examples of categories of interest.	
Generally Allowable to Recommend:	Not Allowable to Recommend:
Applying a pesticide at a rate or concentration lower than the Section 3 label. For example, a registrant might recommend to use a lower application rate if an herbicide is used on sandy soils.	Increasing the rate of application, or concentration. For example, if the Section 3 label indicates, "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 a crop 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, a Section label indicates, make 1 application (1 pt.) in the spring; a 2(ee) can not specify to apply 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 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.	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. FIFRA Section 2(ee) recommendations cannot be used for antimicrobial pesticides targeted against human pathogens. (40 CFR 168.22(b)(5)). Uses not in accordance with PRN 96-7: Termiticide Labeling. Uses patterns that are dissimilar from the Section 3 label, and have not been fully evaluated by EPA. For example, use of a Molluscicide as an avicide.
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 method of application not prohibited by the labeling, unless the label states that the product may be applied only by the method(s) specified on the label. 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). This has been a hotly debated topic, and will	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. 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. (for example soil vs. foliar applications).

<p><i>be even more hotly debated now that UAVs are in the market. Please review and respond carefully.</i></p>	<p>The addition of chemigation as an application method.</p>
--	--

C. Federal Supplemental Labels

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.

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.

Another 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.

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

Main Differences between FIFRA Sec. 24(c) registrations & Sec. 18 Emergency Exemptions	
Section 24(c)	Section 18
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 does 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. from local experts	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 current EPA evaluations.	EPA only allows use for a specified number of months, and it must be applied for by the state each year (as necessary). EPA may allow the 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.	The registrant must demonstrate progress toward getting the use registered (i.e. Section 3 or Sec. 24(c)).
Can be approved for a variety of reasons, including resistance management	Approved when there is an urgent and non-routine situation with no effective

purposes. Urgency and economic loss do not have to be proven.	alternatives. For Specific exemption, data showing Significant Economic Loss due to emergency must be provided to EPA.
Many SLAs usually approve complete applications within 30 - 60 days. Certain applications may take longer.	EPA usually reviews complete applications within 60 days. The process is faster for previously approved requests.

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 can also distribute a Sec. 24(c) label based on a primary registrant's Sec. 24(c) label, with the SLA and primary registrant's approval. The name of the primary registrant for the Sec. 24(c) must be provided on the distributor Sec. 24(c) label, see example below. The Sec. 24(c) numbers on both labels must be identical, and based on the Sec. 24(c) number assigned to the primary registrant. A FIFRA Sec. 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 Sec. 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>Last page - bottom</i></p> <p>24(c) Registrant: Acme Chemical Corp. 1520 Industrial Way Zenith, XX</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>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, 2019

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-1900XX
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-1900XX. 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-1900XX 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-1900XX has an expiration date of December 31, 2024, 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