

Guidance on FIFRA 24(c) Registrations

Important Information on Requests Under FIFRA 24(c)

Posted Spring 2019

Each year, EPA receives many notifications of special local needs registrations from states under section 24(c) of FIFRA. Section 24(c) states that "A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within the state to meet special local needs . . ." EPA currently receives approximately 300 notifications of 24(c) registrations annually. Many of these special local needs registrations are for additional uses not authorized by the federal label – e.g., applying the pesticide to a different crop to address an outbreak of disease, adding an alternative application method that suits the practices of that state, or adding a new pest species that is not on the federal label. However, rather than providing for state registration of additional uses not included on the federal label, some special local needs registrations are more narrow than the federal label, such as to add a more restrictive cut-off date, to add training and certification requirements, or to restrict the use directions by limiting the number of treatments permitted by the federal label.

Because section 24(a) allows states to regulate the use of any federally registered pesticide, and some states have instead used 24(c) to implement cut-off dates (and/or impose other restrictions), EPA is now re-evaluating its approach to reviewing 24(c) registrations and the circumstances under which it will exercise its authority to disapprove those registrations. Before making any changes in this regard, EPA intends to take public comment on any potential new approaches before adopting them.

EPA is not making any immediate changes in this area and does not expect any potential changes will impact 24(c) registrations that states approve ahead of the 2019 growing season.

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Introduction

As part of its streamlining and risk reduction efforts, the Agency has evaluated the 24(c) registration process and developed guidance and process improvements which will enable the states and EPA to process 24(c) registrations faster with fewer resources, and to promote EPA's goals of risk reduction and pollution prevention. The policies contained in this guidance document are effective immediately and are expected to result in significant benefits for all concerned. A new internal standard operating procedure is also being adopted to go along with the policies in this guidance document and to streamline the processing of 24(c) registrations.

Under the authority of §24(c) of FIFRA, states may register an additional use of a federally registered pesticide product, or a new end use product to meet special local needs. EPA reviews these registrations, and may disapprove the state registration if, among other things, the use is not covered by necessary tolerances, or the use has been previously denied, disapproved, suspended or canceled by the Administrator, or voluntarily canceled subsequent to a notice concerning health or environmental concerns.

In October 1991, EPA formed an internal work group, the Center for Excellence for Special Local Needs [24(c)] Registrations, to identify problems, propose solutions and to update policies and procedures related to 24(c) registrations. The work group focused on the procedures and issues which had proven to be problematic in administering the §24(c) program. The goals of the work group were to clarify the Agency's position on these issues, to streamline the process and to provide guidance within EPA as well as to the state lead agencies.

In July 1992, EPA held a workshop with states and EPA regional representatives to collect and address a list of 24(c) issues of concern. The participants reviewed the list, prioritized it and developed options for addressing the most significant issues. EPA committed itself to resolving as many of these issues as possible, to improving the 24(c) registration process and to providing clear guidance to the states and regions.

This document culminates the efforts of the 24(c) Center for Excellence to streamline the process, to empower the states to reduce risks and to clarify EPA's position on important policy issues. This guidance document is not intended to replace the §24(c) regulations at 40 CFR part 162, rather to clarify the regulations and to provide additional guidance. Specifically, this document describes the states' and EPA's roles in the 24(c) registration process, how states should submit notifications and EPA's position on numerous issues. Finally, this guidance document is intended to empower the states to operate as independently as possible to reduce the resources EPA uses to review 24(c)

applications and to assure the public that no unreasonable adverse effects will occur from 24(c) registrations.

Please note that this document is intended solely as guidance and does not represent final agency 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. 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.

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General Overview

This section provides background information on the states' and EPA's responsibilities under the law, how to submit 24(c) applications to EPA, and general policies.

A. States' Responsibilities

States have been granted the authority by FIFRA to issue special local needs registrations under certain conditions while EPA is responsible for overseeing the general program. States may register a new end use product for any use, or an additional use of a federally registered pesticide product, if the following conditions exist:

- **Special Local Need.** Special local need means an existing or imminent pest problem within a state for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available. Refer to Section IV (General Policies), Question 1, for the definition of Special Local Need.
- The additional use is covered by necessary tolerances or other clearances under the Federal Food, Drug, and Cosmetic Act (FFDCA).
- Registration for the same use has not previously been 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 24(c) may be submitted.
- If the proposed use or product falls into one of the following categories, the state has 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.

- 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.

In addition to these general conditions, states must follow the specific procedures set forth in the regulations. To assure that their 24(c) registrations are properly issued and reported to EPA, states should also follow the guidance in this document.

B. EPA's Responsibilities

EPA's role is to assure that each 24(c) registration meets the requirements of FIFRA since these registrations become federal registrations within 90 days unless EPA objects to them. EPA reviews the individual 24(c) registrations and broadly oversees the states' 24(c) registration programs.

EPA will limit its review of individual 24(c) registrations to a minimal level which empowers states to meet the requirements of FIFRA and which avoids any duplication of effort by EPA. As described in the General Policies section, EPA will generally not request data for amendments to federal products or new products which are substantially similar to currently registered products in composition and use. For 24(c) products which are not substantially similar, EPA will ask for only a brief summary of the data, the state's conclusions, and a certification that the product will not cause unreasonable adverse effects as defined in FIFRA for registration of pesticides. This approach will respect the states' independence and responsibilities while allowing EPA to carry out its review function with minimal resources.

EPA will also conduct general oversight by periodically reviewing its records of 24(c) registrations to assure that states and EPA have properly followed procedures and policies. If EPA finds problems, it will discuss and resolve them with the appropriate state(s). EPA will make every effort to work out problems with states, but as a last resort EPA has the authority to rescind a state's authority to issue 24(c) registrations if necessary.

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How to Submit a Notification of 24(c) Registration

Basic Steps

1. The state should submit a complete 24(c) notification package for each registration to the following address:

*Address for FedEx, UPS, DHL, Courier deliveries **ONLY***

U.S. EPA Office of Pesticide Programs

Document Processing Desk (SLN)

U.S. Environmental Protection Agency

2777 Crystal Drive

Arlington, VA 22202

*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*

The 24(c) application notifies the Agency of a state pesticide registration for a special local need issued under the authority of FIFRA §24(c). The application also indicates the date the state registration was issued. The state must notify the Agency within 10 days of the date of issuance of the registration. The Agency has 90 days from the date the state registration was issued to make a final decision on the 24(c) application. If the state does not notify the Agency of the issuance of the registration within 10 days of its effective date, then the 90-day "clock" begins on the date that the agency receives the application package [see [40 CFR 162.154\(c\)](#)].

The application package should include the following items [see [40 CFR 162.153](#)]:

- A properly completed Notification of State Registration (EPA Form [8570-25](#)). All requested information on the application form should be provided.
- A cover letter with a description of what special local need is being met by the issuance of the 24(c) and a clear explanation of how the definition of special local need is met.
- A copy of the labeling approved by the state.
- A properly completed copy of the Confidential Statement of Formula (CSF) Note: Only required if the product is not federally registered.

An Unreasonable Adverse Effects Determination Statement which summarizes the state's assessment of risks and benefits which supports its conclusion that no unreasonable adverse effects will occur.

Note: An Unreasonable Adverse Effects Determination Statement 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 a similar composition, have had registration denied, disapproved, suspended, or canceled by the Administrator.

2. When received at the Agency, the application package is processed by the Document Processing Desk and sent to the Front End Processing Unit (FEPU) of the Information Services Branch (ISB). The FEPU screens the application

package to ensure that the previously mentioned items are present (see [40 CFR 162.153](#)). If any of the items is not properly completed or is missing, the application package is considered incomplete and is considered to be an improper notification. The Head of the FEPU notifies the state, in writing, with a copy to the registrant of record, of the deficiencies in the package and that if proper notification is not provided, "the 24(c) registration will be considered invalid as issued".

3. The state applicant is allowed 14 days from the date of issuance of the FEPU's notice to respond to the Agency with a completed application package. If there are any questions concerning the notification, the applicant may contact the head of the FEPU at (703) 305-5264. The 90 day "clock" will begin upon receipt of the resubmission.

4. If the state does not respond within 14 days, the FEPU prepares a written response to the applicant, and a courtesy copy to the registrant, stating that the Agency was not properly notified of the state registration, and therefore, without the requested information, "EPA considers this registration to have been invalid as issued." The 24(c) registration will not be valid as of the date EPA issues this letter. The Information Services Branch (ISB) Chief signs the letter, which, with associated materials, is returned to the state via certified mail.

5. If the application package is complete, the FEPU enters pertinent information into an on-line tracking system. The FEPU also publishes the 24(c) in the Federal Register (FR) Notice summarizing all recent state registrations made under FIFRA § 24(c) [see [40 CFR 162.153\(i\)](#)] and sends the state an acknowledgement letter concerning the receipt and completeness of the application package.

6. At this point, the application and any accompanying data are forwarded to the Product Manager for review and determination as to whether the 24(c) registration is acceptable (refer to the Standard Operating Procedure for details). Any further communications would come either from the Product Manager (PM) or higher level officials as described in the SOP.

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Additional Information

- If the [EPA Form 8570-25](#) indicates in block 2 ("Product Is"), that the cited EPA Registration Number is a supplemental distributor registration, i.e., the Reg. No. is a three part number such as XXX-XX-XXX, the PM notifies the state that the 24(c) is invalid as issued. The 24(c) must be issued based on the §3 registration of the product on which the distributor registration is based (see issues 17 & 29).
- If data/studies are submitted in support of a 24(c) application, the following applies:
 - When full studies are submitted in support of a 24(c) application, they must comply with Pesticide Regulation Notice 86-5 format (PR Notice). Studies that pass the PR Notice 86-5 screen will be entered into the Agency maintained

collection of documents of regulatory significance called the Pesticide Document Management System (PDMS); and archived onto microfiche.

- When data are submitted that do not constitute a formal study or are embedded in correspondence, compliance with PR Notice 86-5 format is not a requirement. The data will be retained in the 24(c) file and will not be added to the PDMS collection.
- Provided it is validly issued, a 24(c) registration which is an amendment to a federally registered product that has a use pattern similar to the registered product may only be disapproved if that product: (a) has been previously denied, disapproved, suspended or canceled by EPA because of health or environmental concerns, or voluntarily canceled subsequent to a notice of intent to cancel, (b) would cause an imminent hazard (i.e., should be suspended), or (c) may result in food residues not covered by tolerances.
- A 24(c) registration which is a new product is either substantially similar to a federally registered product or not similar. A 24(c) that is substantially similar to an existing federal product has the same status as an amendment. A 24(c) registration which is determined not to be substantially similar to a federally registered product is subject to additional requirements and is subject to disapproval on reasonable grounds.
- If it is determined that a disapproval is likely, the product manager (PM) will issue a Notice of Intent to Disapprove the state Registration which will provide the reasons for disapproval. This notice will generally require the state to respond within 10 days of receipt of the notice and will invite the state to consult with the appropriate Agency designee [[see 40 CFR 162.154\(a\)\(2\)](#)]. The state applicant may request, within 10 days of receipt of this notice, that the PM Team consult with appropriate state officials prior to the final decision on disapproval.
- If an application falls under a general disapproval, disapproval must occur within a 90-day review period and prior to disapproval, the state shall be notified, in writing, of the Agency's intent to disapprove, and the reasons for disapproval.
- If an application falls under a special disapproval, that is, the registration would constitute an imminent hazard or may result in a residue on food or feed exceeding or not covered by a tolerance, exemption or clearance, disapproval may occur at any time. The state does not need to be notified prior to a special disapproval of the Agency's intent to disapprove as required for general disapprovals. EPA will notify the state as-soon-as practical of the special disapproval.
- If it is determined that labeling changes are necessary, the PM will prepare and issue a letter requesting that required labeling changes be made. The letter will

direct that one copy of the amended labeling be submitted from the registrant, through the state, and to the Agency.

- If the state applicant was issued a Notice of Intent to Disapprove, and it is determined that there are no longer reasons for disapproval, the PM team will prepare a letter to the state notifying them of the Agency's change in position.
- When a 24(c) is disapproved, the Product Manager prepares and publishes a Federal Register Notice which announces the disapproval of the 24(c) registration.
- **Rescission of Previously Issued Disapproval.** In order to rescind a previously issued disapproval, the PM Team must receive a submission from the state that issued the 24(c) addressing previously noted deficiencies. Upon completion of the review process, if it is determined that all previously noted deficiencies have been resolved, the PM will prepare a letter that rescinds the former disapproval. The letter addresses resolution of deficiencies and informs the issuing state that the disapproval is rescinded. The PM will publish a notice of the rescission of disapproval in the Federal Register
- **Request to Amend a 24(c) Registration.** In order to process an amendment, the PM Team must receive the amended 24(c) registration from the state that issued the 24(c).
- **Request to Withdraw a 24(c) Registration.** In order to process a withdrawal, the PM Team must receive a request to withdraw the 24(c) registration from the state that issued the 24(c).
- **Request to Voluntarily Cancel a 24(c) Registration.** In order to process a voluntary cancellation, the PM Team must receive a request from the registrant that maintains the 24(c) registration. Also, the registrant should send a copy of the voluntary cancellation request to the state that issued that 24(c). A Federal Register Notice will be issued which allows 90 days from date of publication for comment on the request. A cancellation order listing the 24(c) registration number will be prepared and signed. The cancellation order is then sent to the registrant via certified mail and cancellation information is posted to OPP data systems. A registrant can choose to withdraw a request for voluntary cancellation during the comment period by submitting a request in writing to the Agency. If a third party is interested in the continuance of the registration, they should contact the appropriate registrant.

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General Policies: Questions and Answers About §24(c) Registration Definition of Special Local Need

1. Issue: What is the definition of "Special Local Need"?

Response: 40 CFR 162.151 states that special local need (SLN) means an existing or imminent pest problem within a state for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.

EPA's current interpretation of this definition of SLN is as follows:

a. "...existing or imminent pest problem..." means a problem which already exists or is likely to exist.

b. "...based upon satisfactory information an appropriate federally registered pesticide is not sufficiently available..." means a state can document that a federally registered product a) is not available in the state for the desired site(s) to adequately control the target pest(s), or b) cannot be applied without causing unacceptable risks to human health or the environment, or c) is necessary to maintain an IPM, resistance management, or minor use pest control program, or d) could be replaced by a formulation that poses less risk to man or the environment.

States may consider uses such as the following as candidates for special local needs: new method or timing of application, new crop/new site, new pest, changed rate, application in particular soil type, new product/different formulation, and products useful in managing pesticide resistance in a particular crop.

States generally may not consider a price differential between products as a candidate for a special local need.

When submitting a 24(c) notification to the Agency, the state should include in the cover letter a description of what special local need is being met by the issuance of the 24(c) and a clear explanation of how the definition of special local need is met.

2. Issue: Are there circumstances under which §24(c) registrations should not be issued?

Response: Yes, a 24(c) registration should not be issued under any circumstance that would trigger further data requirements for a §3 registration to be issued. A 24(c) registration must meet all the requirements of a §3 registration, and there must be data to support the use. Expanding the use pattern of a §3 label would be inappropriate if the added exposure would raise human or environmental risk concerns. Situations such as the chemical is under special review or the §3 label restricts the use to specific geographic areas because of groundwater concerns, and the 24(c) would expand the use in a manner that could contaminate groundwater, a 24(c) should not be issued without consulting with the product manager responsible for the chemical/use pattern. If the state can demonstrate that the recommended 24(c) registration constitutes no added exposure or risks, or that the exposure or risks are reduced, a 24(c) may be appropriate. If a state has questions about a proposed 24(c), they should call the product manager responsible for the chemical/use pattern.

EPA will make every effort to work with the states on the 24(c) program, but if there is the need, the Administrator may suspend a state's registration authority due to lack of, or failure to exercise adequate control by the state over §24(c) program as outlined in 40 CFR 162.155.

3. Issue: Can states issue §24(c) registrations which negate or void voluntary or mandatory restrictions on §3 labels?

Response: §24(c) of FIFRA allows states to amend federally registered products to meet specific local needs. Such amendments may take the form of new uses or new use directions which may differ from those on the §3 label. However, to the extent that such provisions negate or void provisions of the §3 label in a manner that could raise risk concerns, the use of 24(c) would be inappropriate unless the state has data to demonstrate that the proposed change will not cause unreasonable adverse effects to man or the environment.

4. Issue: Can states use §24(c) registrations to impose more restrictive measures than are on §3 labels (e.g., reentry intervals, VOC programs, etc.)? Can states issue §24(c) registrations which limit the use of a §24(c) product to a subset of the uses on the §3 labels?

Response: Yes, under certain circumstances states may impose more restrictive measures than are on §3 labels, or limit use to a subset of uses on §3 labels. First, the state should determine by contacting the EPA Product Manager whether the labeling changes sought by the state may be accomplished by amendment to the §3 label of the product. If a label amendment is not feasible, the state would need to conclude that a special local need exists for a product with specific restrictions which are not currently available in that state and then proceed to issue a 24(c) registration. EPA encourages states to communicate their needs to the Product Manager and to work closely with the involved registrant(s) so that the most expeditious solution to the problem may be obtained.

5. Issue: Can §24(c) be used to implement special programs such as groundwater, endangered species, worker protection, etc. where the label will refer to or contain detailed, localized restrictions or use directions which are not on §3 labels?

Response: As stated in the response to issue 4, states may issue §24(c) registrations to implement more restrictive labeling under certain circumstances. If a state wishes to invoke these circumstances for broad programs covering many products, it may do so. However, EPA encourages the states to wait for EPA to initiate such programs nationally on §3 labels. In this way, labeling among products will be consistent and federally enforceable while still permitting requirements unique to each state. For example, EPA's groundwater program will involve a labeling statement which requires compliance with a state management plan developed by each state. Another example is EPA's endangered species program which will involve a labeling statement referring to a county-specific bulletin which describes where products may not be applied. While states may

choose to implement special programs sooner than EPA and to use §24(c) registrations as the vehicle, they may do so at a greater cost and may risk being inconsistent with EPA's programs.

6. Issue: Is offering growers a choice of products or a less hazardous formulation (to humans, non-target organisms, or other environmental component) an acceptable justification for a §24(c) registration?

Response: Yes. This would enable pollution prevention and risk reduction as determined by the state. The state would need to provide a clear explanation of the benefits and data to support the special local need. States must review the data prior to issuing the 24(c). This would include product chemistry data identifying the amount of active and inert ingredients, making sure all ingredients are cleared for food use by EPA, acute toxicity data on which the toxicity category and precautionary labeling would be based, and any additional data as needed such as residue, efficacy and environmental fate. In the case of a new formulation, the state generally will need to make a no unreasonable adverse effects finding.

7. Issue: Can states issue §24(c) registrations for the purpose of avoiding buildup of pest resistance?

Response: Yes. The avoidance of pest resistance can be described as a special local need if the state lead agency possesses satisfactory supporting information to document the need. Generally, such a finding can be supported only if the following criteria are met:

- The pesticide registered under the 24(c) must have a different mode of action from that already available or if registering two pesticides under a 24(c), they must have different modes of action.
- If there are currently registered pesticides, there is only one effective mode of action remaining.
- The pest has a history of developing resistance to existing or canceled pesticides which is documented through field studies or references to field studies. Information is needed on previously reported resistance incidences and economic impacts resulting from pest resistance.
- The currently registered pesticide has a history of resistance which is documented through field studies or references to field studies.
- Evidence must exist that the pest(s), use patterns, and climatic conditions for the proposed use under the 24(c) is the same or substantially similar to situations where resistance has been documented, i.e. similar pests, use patterns, and climatic conditions.
- A brief description of the implementation plan for resistance management and how the use under the 24(c) will fit into the plan.

8. Issue: 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 (5) 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 fifteen (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 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".

Some resources the states can use to determine what other states have already issued 24(c)s for particular situations are CERIS (Center for Environmental & Regulatory Information Systems), Pest Bank or the EPA Regional Office. CERIS' telephone number is (317) 494-6614 or 494-6616.

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Administrative

9. Issue: May a state issue a §24(c) registration for a use which has been voluntarily deleted from a federally registered product or lost through voluntary cancellation of products?

Response: A state may issue a §24(c) registration for a use which has been voluntarily deleted or canceled, but only if the state or registrant submits any missing data required to register or reregister that use. The Agency has already called in reregistration data for most products. If a registrant decides not to support certain uses, EPA publishes those uses in the Federal Register to determine if anyone else wants to support them. If no one wants to support them, they must be removed from the federal label. If a state wants to issue a §24(c) registration for an unsupported use, it must submit a letter, following the procedures given in the FR notice, describing the data to be submitted, if required, and providing a contact person. The state should contact the registrant if it has questions concerning what missing data are required to register or reregister a particular use. The Agency will then determine whether the studies to be provided are likely to be adequate. If so, the state will be advised to submit the studies with the §24(c) application. When received, the studies will be

reviewed by the Agency and a determination will be made on the acceptability of the §24(c) registration.

10. Issue: Should states set time limits for §24(c) registrations? If so, how long should the limits be? Why does EPA not recognize the states' expiration dates?

Response: The states are encouraged to set time limits. However, since §24(c) registrations are deemed by FIFRA to be §3 registrations after 90 days, EPA generally is not in a position to impose time limits on §24(c) registrations. So long as the §24(c) registrant complies with FIFRA requirements for maintaining the registration (e.g., fee payment), EPA will not cancel the registration even if the state has done so, unless the registrant voluntarily cancels the product or EPA has a cause to issue a notice of intent to cancel. Of course, the product may not be legally sold or distributed in the state if the state has canceled the registration. The state should encourage the registrant to cancel the 24(c) with EPA either by filing a voluntary cancellation request or by not paying the annual pesticide registration maintenance fee.

11. Issue: How does a registrant or state notify EPA in order to voluntarily cancel a §24(c) registration?

Response: It is necessary for EPA to receive a cancellation request from the registrant of record. It can be a copy of a letter sent to the state or can be sent directly from the registrant. Under present policies, the states cannot eliminate §24(c) registrations from EPA's system without receiving authorization from the registrant.

12. Issue: What is the status for use of a product in 90-day period between state approval and EPA denial (if denied)?

Response: When the state issues the §24(c) registration it is assumed to be valid and the product may be sold or distributed and used after that time. If a disapproval is issued, sale and distribution by the registrant or other persons would be in violation of §12(a)(1)(A) beginning on the date of disapproval. However, use may continue unless the disapproval notice states otherwise. EPA may rescind the right for a state to issue a 24(c) registration if the state's registrations are routinely denied or found unacceptable.

13. Issue: What is the status for use of a product when the state receives a certified letter from EPA indicating the registration is invalid as issued?

Response: Under EPA's new procedures, when an application package is incomplete, the Agency considers this to be an improper notification of state registration. The Head of FEPU notifies the state, in writing, of the improper notification and that if the proper notification is not provided, the §24(c) registration will be considered invalid as issued. If the state does not respond within 14 days, FEPU prepares a written response to the applicant (cc:registrant) stating that the Agency was not properly notified of the state registration, and therefore, without the requested information, EPA considers this registration to have been invalid as issued. The §24(c) registration is no longer valid.

14. Issue: Can a distributor request a §24(c) registration prior to the §3 being registered?

Response: No, distributor registrations are based on a federal registration and cannot differ from the basic registration except that the product name and the company name and address may be different than the basic manufacturers label or the distributor label may contain a subset of the uses from the basic registration. Until the basic registration has been accepted for other uses, the distributor cannot know what the accepted label will be. In addition, for the reason outlined above the basic registrant must request a §24(c).

15. Issue: How should states review a §24(c) request on a product which does not have federal registration?

Response: States may register new products only in accordance with 40 CFR 162.152(b)(2). Where such new products have a composition or use pattern different from a federally registered product, or where use of a similar product has previously been denied, disapproved, suspended, or canceled by EPA, the states must make a determination prior to registration that the use of the product will not result in unreasonable adverse effects on the environment. The state must certify to and provide a rationale for this determination in the notification of registration sent to EPA.

16. Issue: Can more than one §24(c) registration be issued for the same use in the same state?

Response: Yes, however, the state should ensure that additional §24(c) registrations are necessary to meet a state's special local need and adequate data have been submitted to support the use. Data submitted with the first §24(c) registration may satisfy this requirement.

17. Issue: Can states issue §24(c) registrations citing a supplemental distributor registration?

Response: A supplemental distributor product can be used for a 24(c). The 24(c) is issued on the §3 registration on which the distributor registration is based. The distributor product is the same as the §3 registration and is incorporated under the §3 registration. The 24(c) should be issued on the §3 registration even if the distributor product is the only product available in that state. A separate 24(c) registration is not needed for the distributor product. With the approval of the basic registrant, the distributor may produce a 24(c) label based on the basic registrant's label.

18. Issue: Can a state issue a §24(c) registration citing more than one §3 registration?

Response: No, each §24(c) registration must cite only one §3 registration.

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Enforcement

19. Issue: What should states do when they obtain information that other registrants are possibly misusing the §24(c) registration process?

Response: For clear enforcement issues, states should make referrals to the Regional enforcement office. If it is more of a policy issue question, state officials should call the §24(c) Coordinator through the Registration Division main office (currently 703-305-5447).

20. Issue: What should be done with old, expired §24(c) registrations? Some products were only used with §24(c) product labeling, their §3 usages being made obsolete by other better products.

Response: A state may choose to provide a period of use for existing stocks or may choose to prohibit the use of existing stock. However, the product would continue to be registered with EPA unless the fees were not paid or other appropriate action under §6 occurred. If EPA cancels or suspends the product, use will be permitted, if at all, in accordance with any existing stocks order issued by the Agency.

21. Issue: Can a product be used up according to the §24(c) product label as long as it is in the possession of the user?

Response: Yes, unless either the state, if it has such authority, or EPA has prohibited the use of the product as part of a cancellation order. To date this has been a rare occurrence.

22. Issue: What should states do when they discover that a §24(c) registration issued in one state is being used in another state?

Response: It is a misuse to use a §24(c) product in a state if it is not registered in that state. The state should inform the EPA Regional Office of enforcement and followup with appropriate enforcement action.

Data Requirements

23. Issue: What are EPA's guidelines relative to the age of residue data (applicability of older methods when recovery data are included)?

Response: There is no specific date before which residue data were generated that leads to automatic rejection of that data. Provided the analytical method has been properly validated (control, spiked, and treated samples) and measures the total residue of concern as expressed in present tolerances, and is otherwise consistent with current Agency requirements that residue data would be considered valid.

24. Issue: How restrictive should states be relative to accepting residue data and their conformity to GLP (# of replications, dosage rate relative to label rate, etc.)? Is non-GLP data acceptable for a §24(c) registration?

Response: Although any new data should follow GLP, non-GLP data are not automatically rejected. The data submitter should point out why the data do not meet GLP and submit a rationale as to why the departure does not invalidate the data. The key factors that EPA looks for in residue data are (1) evidence that the pesticide was applied according to label directions resulting in highest residues (maximum application rate, maximum number of applications, shortest interval between applications and shortest preharvest interval) and (2) recovery data showing the analytical method was capable of measuring the total residue of

concern. Any studies not meeting these two requirements are likely to lead to rejection of the §24(c) registration.

25. Issue: What data does EPA require to be submitted to EPA with a §24(c) registration? Residue and efficacy data have been the primary supporting data for most §24(c) registrations in the past. However, EPA has been turning down or requiring revisions of §24(c) registrations due to environmental and toxicological concerns. If this type of data is required with a §24(c) registration, states need to know.

Response: No data should be submitted to EPA unless it is requested or the state is unable to review it. If a state is issuing a §24(c) registration for a new product that meets any of the criteria in §162.153(c), the state is required to ensure that there are no unreasonable adverse effects. If the state is unable to make this determination, it should submit the data to the Agency with the §24(c) notification and EPA will review it and make the determination.

26. Issue: If a tolerance for a crop was issued many years ago and EPA no longer considers the residue data adequate, can states issue a §24(c) registration to add the new use covered by the tolerance? Would additional residue data be required?

Response: The state can issue a §24(c) registration as long as there is a tolerance in place. There is a possibility that the Agency may request additional residue data during review. In the circumstance where a regional tolerance exists, the state should contact the product manager to find out what additional data may be needed to allow consideration of a SLN.

27. Issue: What type of information does EPA need to keep a SLN for seed use non-food. If EPA has a legitimate concern about carryover to subsequent crop what kind of residue information is needed?

Response: The term "seed use" could be interpreted to mean direct application of a pesticide to seeds before planting (seed treatments) or application in the field to crops grown for seed. We will discuss these separately.

With regard to seed treatments the use can be considered non-food only if a radiotracer study shows no uptake of radioactivity into the aerial portion of the crop (or into the underground portion of root crops). Our experience with such studies is that it is quite unlikely a seed treatment will be considered a non-food use. In most cases a tolerance is established at the detection or quantitation limit of the analytical method on the crop grown from the treated seeds.

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Applications to crops grown for seed can be considered non-food uses if the following two conditions are met:

- (1) Subsequent to treatment no parts of the crop will be diverted to use as human food or livestock feed.
- (2) There is no likelihood of residues in crops grown from the harvested seed.

Each of these two conditions is discussed in more detail below.

In some instances the first condition may be met by the timing of the application. In other words, the condition is met if the pesticide is applied to the seed crop at a point when it is no longer fit for consumption. An example would be use of a desiccant on carrots or radishes near the time of seed harvest. At this time the roots would no longer be desirable as a food.

In those cases where the application timing does not satisfy the first condition, there are two other possible means of meeting that condition:

(A) The state in which the registration is sought provides assurance through some regulatory process that the seed crop will not be diverted to food or feed. This assurance must include all crop parts that could be consumed by humans or livestock. Crops of special concern are alfalfa, clover, and grass, which may be cut for hay or whose seed screenings may end up as animal feed. The first example of a state using this procedure was Washington for registration of pesticides on alfalfa grown for seed.

(B) Cultural practices information is submitted showing how the seed crop may be distinguished from the corresponding food crop and how the seed crop is not commercially viable as a food crop. Examples of such cultural practices might be smaller crop spacing preventing adequate root formation or planting in a different season to encourage bolting versus head formation.

Some general statements can be made at a crop grouping level with regard to the chances of the first condition being met. Most cole crops, leafy vegetables, and root crops grown for seed have a good chance of meeting this requirement. On the other hand, crops where the seeds themselves are major raw agricultural commodities such as grains, beans, and peas have very little chance of non-food registrations. Cucurbits and fruiting vegetables are probably not eligible for non-food uses since the fruit is still edible at the stage when the seeds have formed. Now we will address the second condition to be met for a non-food use: "There is no likelihood of residues in crops grown from the harvested seed." In many cases this condition may be met without actual residue data on the harvested seed or the crop grown from that seed. The registrant and/or state should consider data or information on the following factors when calculating a theoretical residue in the crop grown from the harvested seeds.

- Weight of seed
- Weight of edible portion of following crop
- Total weight of following crop

(The above weights could be expressed in terms of an individual seed/plant or on a per acre basis. In either case the figures would allow an estimate of the dilution of residues due to growth of the plant.)

- Tolerances on other crops with similar rate and preharvest interval

- Information as to whether the seeds are directly exposed to the pesticide spray

(The above two factors can be used to estimate maximum likely residues on the harvested seeds.)

- Seed treatment data for the pesticide on other crops
- Degree to which the pesticide translocates (how systemic?)
- Half-life of the pesticide on other crops

(The above three factors can be used to estimate how much pesticide might move from seed to the growing crop.)

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If a calculation using reasonable assumptions and taking into account the above factors indicates residues in the raw agricultural commodity grown from the harvested seeds will be well below (for example, one order of magnitude) the detection limit of the analytical method, then condition two would be met. On the other hand, if the calculation shows residues close to or above the detection limit, actual residue data on the harvested seeds and/or following crop will be required to show that the use can be considered non-food.

Third Party Registrants

28. Issue: Can EPA help the states develop a standard and effective liability disclaimer for third party registrants?

Response: While EPA might assist the states in developing acceptable disclaimer language for third party §24(c) registrations, whether such disclaimers would be effective in court is a matter of individual state tort law, and is therefore, beyond the control of EPA.

29. Issue: How will the agency address third party applications that do not have the support of the basic producer?

Response: The Agency expects the state to make every effort to ensure that the 24(c) issuance is agreed to by the registrant. The Agency believes that FIFRA and EPA regulations do not prevent the state from issuing a registration to a third party applicant even if the registration does not have the support of the basic registrant. In such instances, the third party registrant would actually become the registrant and would be responsible for maintenance fees, any data to support the 24(c) product, the addition of required label language for worker protection standard, endangered species etc, and all other obligations of a registrant under FIFRA.

Communication

30. Issue: How can a state find out what EPA's response to a §24(c) registration would be prior to actually submitting the registration?

Response: The state should contact the appropriate Product Manager with specifics on the proposed 24(c) registration. If the state does not know who the

appropriate Product Manager is, the state should contact the appropriate Branch Chief in the Registration Division who can indicate which PM to contact.

31. Issue: Could states be given a list of product managers by active ingredient? States need a list of people they can call on for a given registration to ask about special requests [i.e., residue data requirements on seed crops, environmental fate questions, residue data comprehensiveness questions, labeling format, precautionary statements on a §24(c) registration].

Response: The current PM/a.i. list is over one hundred pages long and is being updated. It changes frequently due to new active ingredients and switches between PM. It is our hope that the recently established Information Management Strategy Group (which includes the states) will be able to make available an electronic list in the near future. We have included in this document a one-page summary listing the Product Managers and the types of products they manage.

32. Issue: Should EPA make available a listing of issued §24(c) registrations to all states? If so, what method would be preferable?

Response: The states should seek this information through the Information Management Strategy Group. Questions may be directed to Branch Chief, Systems Branch at 703-305-5484.

33. Issue: How can states find out if EPA canceled the special local need; for instance, for failure to pay maintenance fees?

Response: The states should seek this information through the Information Management Strategy Group. Questions may be directed to [Tawanda Maignan](mailto:Tawanda.Maignan@epa.gov) (maignan.tawanda@epa.gov), Section 18 Team Leader at (703)308-8050.

34. Issue: Whom should states call with questions about interpretations of §24(c) regulations?

Response: Specific questions about a specific §24(c) registration may be directed to the Product Manager. General questions may be referred to the §24(c) Coordinator [Tawanda Maignan](mailto:Tawanda.Maignan@epa.gov) (maignan.tawanda@epa.gov), Section 18 Team Leader at (703)308-8050.

Fees

35. Issue: Can §24(c) registrations can be exempted from maintenance fees?

Response: Maintenance fees can be reduced or waived for minor agricultural uses when the Agency determines that the fee would be likely to cause significant impact on the availability of the pesticide. If a state believes a use qualifies, it may contact the maintenance fee information line at 1-800-444-7255 for specific instructions.

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Proposed Monitoring of the 24(c) Program

To ensure the 24(c) program is being implemented in accordance with these requirements, as well as best utilize resources, we plan to put into place a program to monitor the 24(c)s.

The objectives of the monitoring program will be to:

- 1) Evaluate the states performance in exercising control over their registrations and,
- 2) Evaluate the performance of OPP in overseeing the 24(c) program.
- 3) Monitor for the possible circumvention of §3 registration through the use of 24(c)s.

EPA plans to monitor the performance of the 24(c) program by reviewing a small selected sampling of previous 24(c) reviews and decisions. EPA will monitor for unreasonable adverse effects problems, tolerance problems, patterns in rejection rates, and consistency in reviews. EPA will monitor the number of 24(c) registrations being issued for individual products and use sites to monitor compliance with the provisions outlined in issue 8.

24 (c) Addendum

This Question & Answer document is an addendum to EPA's guidance to states regarding the issuance of special local needs registrations under section 24(c) of FIFRA.

Question: May an applicant include on proposed 24(c) labeling a provision that requires a grower, as a condition of lawful use of a product, to waive any right he or she may have to bring a civil action against the applicant? If the answer is no, what sort of labeling statements may the applicant make with regard to the existence of private liability agreements or to disclaim liability generally?

Answer: 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 reference 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.

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