

Special Registration Technical and Supplemental Information

Information also covered in MDA Webinar 11/5/2020:

Special Pesticide Registrations in Minnesota –Section 18 emergency exemptions, Section 24(c) special local need registrations, and experimental uses

<https://www.mda.state.mn.us/pesticide-product-registration>

Types of Special Pesticide Registrations

[Experimental Use Permits \(EUP\)](#)

- Testing would take place within the state of Minnesota
- Product is not yet registered for uses being tested
- EUP is required with the EPA

[Section 18 Emergency Exemption](#)

- Pesticide is either already registered within the state with a section 3 registration or has not yet been approved for section 3 registration with EPA
- The state of Minnesota and the EPA determine a specific, quarantine, public health, or crisis emergency condition exists

[Section 24\(c\) Special Local Need](#)

- Pesticide is either already registered within the state with a section 3 registration or, less commonly, has not yet been approved for section 3 registration with EPA
- An existing or imminent pest problem exists within Minnesota

Experimental Use Permits (EUP)

Under [Section 5](#) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the United States Environmental Protection Agency (EPA) will allow manufacturers to field test pesticides under development.

Manufacturers of conventional pesticides must obtain Experimental Use Permits (EUPs) before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or 1 acre or more of water.

To determine whether a Minnesota experimental use pesticide product registration is required, you first need to determine whether an EPA-issued EUP is required. Visit EPA's [Pesticide Registration Manual](#) for more information on EPA requirements and exemption criteria.

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If it has been determined that an EPA permit is required, and once the federal permit has been granted, an application for a [Minnesota Experimental Use Permit](#) must be submitted.

EUPs are issued for:

- Pesticides containing any chemical or combination of chemicals that have not been included in any previously registered pesticide; and
- Registered pesticides for which a use, e.g., application to a particular crop, is not registered with the EPA.

Certain tests and circumstances are exempt from the requirements of an EUP because they are presumed not to involve unreasonable adverse effects:

- Laboratory or Greenhouse Tests
 - Involving fewer than 10 acres per pest for terrestrial tests or less than one acre per pest for aquatic tests
- Limited Replicated Field Trials
 - *Land*: Testing on plots of land 10 acres or less in size.
 - *Aquatic Uses*: Testing on water bodies one surface acre or less in size
- Animal Treatment Uses
 - Where experimental animals will not be used for food or feed unless a tolerance or exemption from tolerance exists

Section 18 Emergency Exemptions

Emergency Exemptions can be requested by State or Federal agencies when an emergency condition (e.g., serious pest problem) jeopardizes production of agricultural goods, the environment, or public health, but there are inadequate tools (including pesticide registrations) to address the situation.

Any emergency condition exists only when the situation is **urgent and non-routine**¹ and all three conditions are met:

1. No effective registered pesticides are available.
2. No feasible alternative control practices are available.
3. The situation:
 - a. Involves the introduction or spread of a new pest,
 - b. Will present significant risks to human health or the environment, or
 - c. Will cause significant economic loss.

¹The status quo has changed in an unusual way that was unforeseen by the grower and immediate action requiring the use of a pesticide is needed

Examples of situations that would be both urgent and non-routine

1. The loss of a pesticide to pest resistance or regulatory action, where there are no other effective control methods available for an important pest.
2. The introduction of a new pest that has expanded beyond its typical range or one that has invaded from some other location.
3. Or, unusual weather or environmental conditions that cause a problem that a pesticide could alleviate.

Types of Emergency Exemptions:

Specific

- Majority of emergency exemption requests are for Specific Exemptions.
- Requested when an emergency condition exists, in order to avert a significant economic loss, or a significant risk to the environment, which may include risks to endangered or threatened species and beneficial organisms.
- Typically the type to be used for pest problems in crops.
- May be authorized for up to one year.

Quarantine

- Requested to control the introduction or spread of an invasive pest species not previously known to occur in the United States and its territories.
- "Emergency" based on the need to prevent the introduction or spread of a harmful invasive species.
- More likely to be used by the DNR.
- May be authorized for up to three years.

Public Health

- Requested to control a pest that will cause a significant risk to human health.
- Emergency is based upon the risk to human health presented by the pest.
- Covid-19 is an example of a situation that may qualify for a public health emergency exemption.
- May be authorized for up to one year.

Crisis

- Requested when there is an immediate need for a Specific, Quarantine, or Public Health Exemption.
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- A Crisis Exemption may be “stand-alone” or may be allowed in conjunction with a full request for a Specific, Quarantine, or Public Health Emergency Exemption
- This is considered a last resort and is rarely ever used.

Section 24(c) Special Local Need

Registered pesticides might not always be able to address persistent pest problems. Special local need (SLN) registrations allow states to address these localized pest problems before these problems result in significant damage or expand throughout the state.

Special local need means an existing or imminent pest problem within Minnesota for which the MDA has determined that an appropriate federally registered pesticide product is not sufficiently available.

- Section 24(c) SLN labels are valid only in the state of issue. Persons must have in their possession a valid Minnesota SLN label when using a pesticide pursuant to a section 24(c) SLN registration.
- “**...existing or imminent pest problem...**” means a problem which already exists or is likely to exist.
- “**...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.

Examples of SLN Label Changes-

SLN registrations can be granted to products that do not currently have a section 3 registration with the EPA, but most commonly SLN registrations will alter requirements from the original section 3 product label of a pesticide found to be of interest to treat a localized pest problem.

Examples:

1. A new method or timing of application
 - Example: Sec. 3 label only allows for pre-plant application, 24(c) requests post-plant application
 2. New crop/new site
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- Example: Sec. 3 label doesn't allow for use on sugar beets, 24(c) label requests the products use be expanded to include sugar beets
 - Example: Sec. 3 label allows for only foliar treatment on sugar beets, 24(c) label requests soil applications for sugar beets
3. Changed rate
 - Example: Sec. 3 label has a stated application rate or time frame, 24(c) requests more frequent or higher rates of application
 4. Application in particular soil type
 5. Products useful in managing pesticide resistance in a particular crop
 - 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:
 1. 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.
 2. If there are currently registered pesticides, there is only one effective mode of action remaining.
 3. 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.
 4. The currently registered pesticide has a history of resistance which is documented through field studies or references to field studies.
 5. 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.
 6. A brief description of the implementation plan for resistance management and how the use under the 24(c) will fit into the plan.
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Section 18 and Section 24(c) Comparison

	Section 18: Emergency Exemption	Section 24(c): Special Local Need
Pest situation	urgent and non-routine <ul style="list-style-type: none"> The introduction or spread of a new pest Significant risks to human health/ environment Will cause significant economic loss 	non-urgent and/or routine <ul style="list-style-type: none"> Insufficient registered pesticides available.
Tolerance	EPA establishes time-limited tolerances if needed	Use must be covered by (or not need) existing tolerances
Applicants	Technical Expert (University staff)	Pesticide Manufacturer
Issuer	EPA	MDA issues the registration. EPA reviews it
Timeline	<ul style="list-style-type: none"> Growers identify a problem and contact their technical expert at the University. The technical expert contacts the registrant of the requested pesticide to determine if the registrant supports a Section 18. The technical expert should contact MDA at this point, prior to submitting an application. The earlier this process is started, the better 	<ul style="list-style-type: none"> Commodity groups, technical experts, and the registrant, should begin work on an application as far in advance as possible. New and renewal applications should be submitted in full, no later than 2 months prior to the initial use date. The earlier this process is started, the better
Requirements	Technical expert prepares an application	Registrant assembles application package.
Registration length	<ul style="list-style-type: none"> <u>Specific and Public Health</u>- up to 1 year <u>Quarantine</u>- up to 3 years <u>Crisis</u>- up to 15 days <ul style="list-style-type: none"> Or If such a full request is submitted, use is allowed to continue under the Crisis Exemption until EPA makes a decision on the request for a Specific, Quarantine, or Public Health Exemption 	Up to 5 years

Sec. 18 Minnesota Application Process & Requirements

EPA Authority:

[Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\)](#) authorizes the U.S. Environmental Protection Agency (EPA) to allow Emergency Exemptions for unregistered uses of pesticides to address emergency pest conditions.

Under such an exemption, EPA allows use of a pesticide in Minnesota for a limited period of time once EPA confirms that the situation meets the statutory definition of "emergency condition."

Sec. 18 Application Package Requirements:

A completed "Application for Pesticide Special Registration"

- A technical expert prepares an application by Copying and pasting the outline from [Title 40 of the Code of Federal Regulations, part 166](#) and filling it out accordingly.
 - Description of the pesticide
 - Description of the proposed use
 - Alternative methods of control
 - Repeated use
 - Effectiveness of proposed use
 - Discussion of residues for food uses
 - Discussion of risk information
 - Coordination with other affected State/ Federal agencies
 - Acknowledgment by registrant
 - Description of proposed enforcement program.
 - Additional information dependent on exemption type
 - Example: Specific Exemption
 - Discussion on the anticipated significant economic loss
 - Entire module on how to do this in the FIFRA Section 18 Training resource discussed below.
- Formatting of the outline should match that found in Title 40 of the Code of Federal Regulations, part 166.

It is strongly recommended that the technical expert reference the [FIFRA Section 18 Emergency Exemption Program Information and Training Resource](#) before beginning any Sec. 18 application.

- Available in both a "live" training version and a [textual pdf version](#).
 - This resource will help you to determine if you really qualify for a sec. 18 exemption.
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Sec 18 Application Review Process:

MDA Process

1. The MDA reviews the application package for completeness and makes a preliminary determination if it meets federal requirements.
2. The MDA may request additional information or provide recommendations.
3. MDA review staff present their findings to management.
4. The decision to send the application to the EPA is made by the MDA commissioner.
5. If the application is approved by the Commissioner, it is then sent to EPA for review.

EPA Process

6. EPA conducts a multi-disciplinary evaluation, comprised of the following assessments:
 - Validity of the emergency claim (including economic loss, if reason for request).
 - Risks to human health through dietary and non-dietary (e.g., inhalation, dermal, etc.) exposures.
 - Risks to workers through occupational exposures.
 - Ecological risks through environmental exposures.
 - Progress toward registration of the use (Specific and Public Health Exemption requests only).
7. EPA then makes the final decision on registration typically within 50 days.

24(c) Minnesota Application Process & Requirements

EPA Authority:

[Section 24\(c\)](#) of the Federal Insecticide Fungicide, and Rodenticide Act (FIFRA), allows for registration of a pesticide product as a Special Local Need (SLN).

EPA reviews these registrations, and may disapprove the state registration if:

- The use is not covered by necessary tolerances
 - 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.
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States' Responsibilities:

Minnesota may register a new end use product for any use, or an additional use of a federally registered pesticide product, if the Commissioner determines that:

1. The pesticide's composition warrants the proposed claims for the pesticide;
2. The pesticide's label and other material required to be submitted comply with this chapter;
3. The pesticide will perform its intended function without unreasonable adverse effect on the environment;
4. The pesticide will not generally cause unreasonable adverse effects on the environment when used in accordance with label directions; and
5. A special local need for the pesticide exists.

In addition to these general conditions, states must assure that their 24(c) registrations are properly issued and reported to EPA

24(c) Application Submission Expectations:

- Grower groups and technical experts from the university should be working in conjunction with the registrant to complete an application as soon as pest problem is recognized.
- The MDA expects new and renewal applications to be submitted by the registrant, in full, no later than **2 months** prior to the initial use date.
- Registrants submit the application fee via mail to the address designated on the MDA application form.
- Registrants submit the completed application package via email to Haley Bloomquist at haley.Bloomquist@state.mn.us with subject line: [PRODUCT NAME] 24c Application.

*****Applications will not be reviewed until the entire packet is submitted.

24(c) Application Components:

1. [Application for Pesticide Special Registration \(PDF\)](#)
 2. Application fee of \$150/product (payable only by check)
 3. Registrant letter of support
 4. Efficacy and/or residue data
 - Residue data- products classified for food or feed use.
 - Efficacy data- products classified for public health use.
 5. Letter of support from a qualified knowledgeable expert
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6. Letter of support from commodity group
7. EPA [Application for Notification of State Registration](#) form No. 8570-25
8. A draft SLN label
9. The current Section 3 container label

Qualified Expert Support Letter Expectations:

1. The anticipated use dates for the product. (For example: June 1 through August 31.)
2. A description of the pest problem.
 - Name and description of the crop(s) or other site(s) of application
 - Scientific and common name(s) of the pest(s)
 - A description of whether the pest problem is localized in Minnesota, regional, or nationwide. Specify which other states have requested or been granted this request.
 - A description of the proposed pesticide use (e.g. higher application rate, new use site)
3. A summary of which existing pesticide and non-pesticide options/methods are available for managing the pest, and why they are insufficient.
 - Document the lack of sufficient non-chemical pest control methods for the pest(s) of concern.
 - Document the lack of sufficient EPA-registered pesticides by providing a list of the available pesticides currently registered for the proposed use including:
 - Active ingredient(s)
 - Explanation of why each pesticide will not sufficiently control the pest problem or is not sufficiently available.
4. A discussion covering how the proposed use would not result in unreasonable adverse effects on people or the environment.
5. Field studies if available.
6. Send directly to the registrant.

Commodity Group Support Letter Expectations:

1. A description of the pest problem.
 2. A summary of which existing pesticide and non-pesticide options/methods are available for managing the pest, and why they are insufficient.
 3. The anticipated use dates for the product. (For example: June 1 through August 31.)
 4. Send directly to the registrant
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24(c) Application Review Process:

Upon receiving a completed 24(c) product registration packet for an EPA registered product the State of Minnesota can begin the registration process. The MDA reviews the application package to ensure it is complete and meets both state and federal requirements:

- State:
 1. the pesticide's composition warrants the proposed claims for the pesticide;
 2. the pesticide's label and other material required to be submitted comply with this chapter;
 3. the pesticide will perform its intended function without unreasonable adverse effect on the environment;
 4. the pesticide will not generally cause unreasonable adverse effects on the environment when used in accordance with label directions; and
 5. a special local need for the pesticide exists.
 - Federal:
 1. Special Local Need
 2. The additional use is covered by necessary tolerances or other clearances under the Federal Food, Drug, and Cosmetic Act (FFDCA).
 3. Registration for the same use has not previously been denied, disapproved, suspended, or canceled by the Administrator, or voluntarily canceled by the registrant
 4. The state has determined that it will not cause unreasonable adverse effects on man or the environment
 - The MDA may request additional information or provide recommendations.
 - MDA review staff present their findings to management.
 - The final decision may be made by the MDA commissioner.
 - After issuing a SLN registration, the MDA is then required by federal regulations to notify the EPA. EPA has 90 days from the effective date to disapprove the SLN registration (the SLN registration is valid during the 90-day EPA review period).
 - SLN registrations and labels are given an expiration date typically one growing season in length up to 5 years from the approval date.
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24(c) Maintenance

Once a 24(c) is within **6 months** from its expiration date, the registrant is responsible for notifying the State of Minnesota if they want to request an extension to the expiration date or let the registration expire.

- Technical experts and commodity groups should keep track of expiration dates and inform the registrant of the need for renewal.
- If there is still a need, new support letters should be drafted addressing any new alternative products.

In order to request an extension past the label expiration date, the registrant will need to submit a new 24(c) registration packet in full, restarting the process from the beginning.

- This is to ensure a special local need still exists and a registration is still warranted.
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