HOW TO APPLY FOR A SECTION 18 EMERGENCY EXEMPTION REGISTRATION IN THE STATE OF MONTANA

PESTICIDE REGISTRATION, LICENSING & TRAINING PROGRAM SECTION

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Submission of documents by email (pdf format) is strongly encouraged.

I. BACKGROUND INFORMATION

A. Emergency Pest Problems and the Section 18 Application Process

Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) authorized the U.S. Environmental Protection Agency (EPA) to allow States to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist. Emergency pesticide uses authorized by EPA under Section 18 are commonly referred to as "Section 18s" or "emergency exemptions."

Exemptions: There are four types of emergency exemptions that may be authorized by the EPA under FIFRA Section 18:

- Specific Exemptions
- Quarantine Exemptions
- Public Health Exemptions
- Crisis Exemptions

Most Section 18 exemptions granted by EPA have been specific exemptions that authorize use of pesticides to control emergency pest situations in agricultural crops.

B. When to Consider Applying for an Emergency Exemption

An emergency exemption from registration may be considered for situations in which an emergency condition exists. For a specific exemption, an emergency condition exists only when the situation is urgent and non-routine and all three of the following conditions are met:

1. No effective registered pesticides are available.
2. No economically or environmentally feasible alternative practices are available.
3. The situation will cause significant economic loss; or a significant risk to endangered species, threatened species, beneficial organisms, or the environment.

The EPA has established a 50-day period to review a Section 18 application. MDA also needs time to prepare and apply to EPA.

C. Crisis Exemption

A crisis exemption is an exemption that is reserved for dire situations – those unpredictable emergency situations that seemingly occur overnight; situations where EPA does not have time to complete a full review of a Section 18 application. The very nature of a crisis exemption excludes them from becoming commonplace. Prior to issuing a crisis exemption, MDA must receive verbal approval from EPA. Asking for a crisis exemption because the application was not submitted to MDA in a timely fashion is an unacceptable use of the crisis provision.

II. MDA SECTION 18 APPLICATION CHECKLIST

DOES THE SECTION 18 APPLICATION CONTAIN THE REQUIRED INFORMATION?

Applicants for new Section 18 emergency exemptions, and repeat Section 18 applications not eligible for re-certification, must submit the following information to MDA:

General Information:

1. Type of Application: Specific, Public Health, Quarantine or Crisis.
2. Contact information of petitioner.
3. Description of the pesticide.
4. Description of the proposed use.
5. Alternative methods of control.
6. Efficacy of proposed pesticide – summarize data.
7. Residue data – summarize data, must support the proposed time-limited tolerance.
8. Potential risk information – summarize risks to human health and the environment, list proposed mitigation measures.
9. Acknowledgement of registrant.
10. Previous use under Section 18 [repeat applications only.]
11. Progress towards registration.

Information required for specific exemption, as appropriate:

1. Pest(s) to be controlled.
2. Events which brought about the emergency conditions.
3. Risks to Threatened or Endangered species, beneficial organisms, or environment that are mitigated.
4. Discussion of economic loss – Tier 1, 2, or 3 as appropriate.

Applicants for repeat Section 18 applications eligible for re-certification must submit a letter or email to MDA certifying the following:

1. The emergency condition still exists.
2. The information is still accurate.
3. The conditions of use are identical.
4. Any conditions or limitations from previous exemptions are satisfied.
5. There are no new alternative control measures that are effective.

IS THE SUPPORTING DOCUMENTATION COMPLETE?

1. Letter of support from registrant. [all Section 18 requests.]
2. Draft Section 18 label. [all Section 18 requests.]
3. Current federal label. [all Section 18 requests.]
4. Letter of support from a MDA researcher, extension specialist, or other unaffiliated expert verifying the emergency condition. [new Section 18 requests only.]
5. Residue data – required for food or feed use. Tolerance (or exemption) – 40 CFR 180. [new Section 18 request only, unless additional studies were conducted.]
6. Efficacy data – should be submitted for all uses, required for public health uses. [new Section 18 requests only, unless additional studies were conducted.]
7. Data on risks to human health and the environment. [new Section 18 requests only, unless additional studies were conducted.]
8. Phytotoxicity data – may be required if herbicide or plant growth regulator.
9. Confidential Statement of Formula (CSF) – required if CSF is not already on file with MDA.
10. Letter of authorization from primary registrant – required for supplemental distributor Section 18 registration.
11. Use report. [only for repeat Section 18 requests.]

WHAT IS THE PRODUCT REGISTRATION STATUS?

1. Is the product currently registered with the EPA?
2. Has registration for the proposed use or other uses of product been denied, disapproved, suspended, or cancelled?
3. Is the product under special review at the EPA?
4. Is the pesticide undergoing re-registration?
5. Is the product not unlike any federally registered product?
6. Is the use pattern not unlike any federally registered uses?

III. SECTION 18 LABEL GUIDANCE

1. A statement clearly indicating that the label is a Section 18 label, followed by the statement:
    - "FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF MONTANA"
2. Trade name of the product.
3. The EPA Registration numbers of the product: EPA Registration Number and EPA Section 18 Number: MT-XXXXXX.
4. The signal word (if the pesticide is category 1).
5. Ingredient statement.
6. Indication if the product is a Restricted Use Pesticide.
7. Effective period statement:
    - "This Section 18 specific exemption becomes effective on (date) and expires on (date)."
8. The statements:
    - "This label and the federal label of this product must be in possession of the user at the time of pesticide application."
    - "Follow all applicable directions, restrictions, and precautions on the Section 18 label and the main EPA registered label. It is a violation of federal law to use this product in a manner inconsistent with its labeling."
    - "These directions for use must be in the possession of the user at the time of application."
9. Directions for use:
    - Crop/site, pest(s).
    - Application rate and concentration.
    - Application methods, frequency and timing.
    - Restricted entry interval and pre-harvest interval.
    - Maximum annual application rate.
    - Any other restrictions or precautions that are applicable to the intended use.
    - Include the Agricultural Use Requirements (WPS).
10. Name and address of the Section 18 registrant.
11. Adverse effects statement:
    - "Any adverse effects resulting from the use of (the Brand Name) under this emergency exemption must be immediately reported to the Montana Department of Agriculture."
12. Section 18 labels for unregistered pesticides must contain all label elements required by EPA (such as precautionary statements, first aid, environmental hazards, worker protection, and storage and disposal). If multiple states are requesting the use, then the registrant should prepare a generic container label, and a separate state specific Section 18 label (including complete use directions) for each state that requests the use.

IV. INFORMATION TO SUBMIT TO MDA

Applications for emergency exemptions cannot be submitted by a registrant. Applications for emergency exemptions are normally submitted to MDA by agricultural consultants, State University researchers and extension specialists, and/or commodity organizations. Registrants of pesticide products provide key supporting information for the application, but the emergency must be the result of and driven by actual field conditions.

The following sections coincide with the requirements of federal regulation (40 CFR 166.20) as well as related MDA requirements. Each section contains a detailed description of the information that must be provided. Please submit the information in the following format:

A. GENERAL INFORMATION

1. TYPE OF EXEMPTION: Specific, Public Health, Quarantine or Crisis.
2. CONTACT INFORMATION OF PETIONER: Identify one or more knowledgeable experts who can be contacted for comment on technical and economic aspects of the application. Include name, affiliation, address, telephone number, and e-mail address (if available).
3. DESCRIPTION OF THE PESTICIDE: Identify the active ingredient using the accepted common chemical name.
    a. Federally registered pesticides: Specify the EPA Registration Number, registrant and the name of the product. Provide a copy of the federally registered label and any additional labeling proposed for the emergency exemption use. To minimize processing time, products approved by the EPA should be used whenever possible. If a specific product is not requested, specify the formulation(s) requested and the percent active ingredient.
    b. Any other pesticide products: A CSF or reference to one already submitted to the EPA as part of a previous or pending action for the active ingredient (EPA File Symbol, EUP number, or SLN number), and complete labeling which will be used relating to the proposed exemption use. Include a description of how unused material will be disposed of upon expiration of the emergency exemption.
4. DESCRIPTION OF THE PURPOSED USE: Specify all the following:
    a. Crop(s)/site(s) to be treated and location: Provide the name of the crop(s)/sites(s) to be treated. Specify the geographical location (e.g. counties) where the emergency exists, and applications will occur (if not statewide), giving as much detail as possible (e.g. proximity to water bodies, residences, etc.). To reduce the potential need for an endangered species risk assessment (and mitigation measures), it is important to provide detailed information regarding the location of the application sites, and to only include counties where the use is actually needed.
    b. Method of application: Be as specific as possible, particularly if an innovative method which may reduce exposure will be used.

c. Rate of application: Active ingredient and formulated product.

d. Number of applications: Typical and maximum number of applications.

e. Total acreage (or other appropriate units) expected to be treated under the exemption. This should be the maximum acreage anticipated, but should not be excessive, since risk assessments will be based on maximum acreage.

f. Total amount of pesticide proposed to be used in terms of both active ingredient and formulated product.

g. All applicable restrictions, user precautions, qualifications of applicator and other requirements concerning the proposed use.

h. Use period (or season): State the time period for which use of the pesticide is requested. Be sure to explain if there are anticipated product production or distribution concerns that may delay getting product to the end user. The use period cannot be longer than one year for a specific or public health exemption, or three years for a quarantine exemption.

i. Earliest possible harvest date (food or feed uses).

5. ALTERNATIVE METHODS OF CONTROL: Identify all alternative methods that are available to control the emergency pest situation and provide an explanation of why each is not effective or cannot feasibly be used.

   a. Registered Alternative Pesticides: Identify all pesticides currently registered for use on the crop to control the pest. For each pesticide, provide an explanation of why it is not effective in controlling the emergency. This explanation must be supported by field data that demonstrate the ineffectiveness of the registered pesticides. If such data are not available, provide written statements by qualified agricultural experts, university/extension personnel, or other persons qualified to verify the lack of efficacy.

      If there are specific restrictions or recommendations against using a registered pesticide, such recommendations must be explained. If the product is not available in sufficient quantities to adequately address the emergency, or if specialized equipment required for applying a registered alternative pesticide is not available, such limitations must be explained.

   b. Alternative Control Practices: Alternative practices may include mechanical, biological, and cultural control. Provide a detailed explanation of why alternative practices either would not provide adequate control or would not be economically or environmentally feasible. For each available control measure not considered to be cost effective, appropriate economic cost/benefit information should be supplied to support the claim.

6. EFFICACY OF PROPOSED PESTICIDE: The application must include data, a discussion of field trials, or other evidence (e.g. experimental testing, small plot trials, laboratory

trials, or corroborating evidence from similar uses) which provide the basis for the conclusion that the proposed use will be effective.

7. RESIDUE DATA: If the proposed use is for a food or feed crop or potable water, residue levels must be estimated. Residue levels must be estimated for all the food commodities even if residues in a processed food are expected to be lower than those in the treated commodity. The application must address whether residues are expected in or on food, a list of the food item(s) likely to contain residues, and an estimate of the maximum amount of residues likely to result from the proposed use. If residue levels are expected to be non-detectable, the application should so state and specify the limit of detection.

   The residue data from which the above residue estimate is derived must be provided if not already on file with the EPA. If data are on file with the EPA, please provide the appropriate reference number, such as the tolerance petition number or Master Record Identification (MRID) number.

   If certain potential food/feed items will not be allowed into the marketplace, cite the method(s) for controlling distribution in the marketplace.

8. POTENTIAL RISK INFORMATION: Include a detailed discussion of the potential risks from the proposed use. The discussion must address the potential risk to human health, threatened or endangered species, beneficial organisms, and the environment. A description of the application sites including proximity to aquatic systems, endangered species habitats, residences, etc.., as well as soil type should be provided, along with references to data or other supporting information. Proposals to mitigate risk (protective clothing, setback restrictions, soil type restrictions, etc.) should be listed.

   a. Human Health: The Food Quality Protection Act (FQPA) requires the EPA to consider aggregate exposure from multiple routes (food, water and the environment) when reviewing Section 18 applications. The following information (most of which can be obtained from registrants) must be submitted with all food/feed use Section 18 applications:

      - Groundwater: Include information and available modeling data on the persistence, mobility and chemistry for the product when there is a potential for transfer of residues to drinking water. It should also provide information on any drinking water monitoring program (monitoring, detections and limits of detection) in the state.
      - Residential Use: Include information on residential uses of the chemical.
      - Mode of Action: Include a discussion of whether there are other pesticides with the same mode of action as the active ingredient in the Section 18.
      - Timing of Crop Harvest: A time-limited tolerance must be established for all Section 18 food/feed uses. EPA needs to know the earliest anticipated harvest date so that they can attempt to establish a time-limited tolerance prior to harvest.

- Worker Protection Standard (WPS): Any applicable WPS requirements need to be addressed in the application and on proposed labeling.

b. Environmental Issues: Environmental hazards must be identified. Environmental hazard mitigation statements will be required for pesticides that are toxic to fish or wildlife or have the potential for contaminating groundwater or surface water. These statements should be consistent with standard EPA language, unless MDA determines that more specific restrictions are necessary. Environmental hazards that are adequately mitigated by the Section 3 label do not need to be mitigated on the Section 18 application.

- Ecological Risk & Threatened or Endangered Species: The application must include a list of endangered or threatened species present in the areas to be treated (except for indoor or seed treatment uses) and must include measures to ensure that Threatened and Endangered species will not be adversely affected from the emergency use of a pesticide.

- Beneficial Insects: The application must include measures to ensure that pollinators such as bees will not be adversely affected form the emergency use of a pesticide. A pollinator protection statement is required for insecticides, miticides and fungicides that are toxic to bees, when applied to a crop or site that is attractive to bees.

9. ACKNOWLEDGEMENT OF REGISTRANT: The application must include a letter from the registrant or manufacturer of the pesticide indicating that they support the request. The letter should also include information regarding product availability and progress towards registration of the proposed use.

10. PREVIOUS USE UNDER SECTION 18: If an emergency exemption has previously been granted, an interim report summarizing the results of previously issued exemption(s) must be included. List the year(s) in which previous exemptions(s) were granted. Also include the applications that were submitted to MDA when the exemption was not approved.

- Use Report: Federal regulations (40 CFR 166.32) require that a final report be submitted that summarizes the results of the pesticide use under an emergency exemption. MDA requests submission of a use report be the applicant within 30 days of the report due date in the EPA granting document and/or at least 80 days before the first use date of the next application. The timely delivery of this report to MDA is the responsibility of the person, organization, or commodity group that submitted the Section 18 application. Future applications will not be submitted to the EPA until a use report from Montana is received. The report must include (1) total quantity of pesticide used (2) the rate per acre or other measure, and (3) total number of acres treated. The final report should discuss the effectiveness of the pesticide in dealing with the emergency condition, any adverse effects resulting from the Section 18 use, and any other information requested by EPA.

11. PROGRESS TOWARDS REGISTRATION: Include a discussion of the progress being made toward registration of the proposed use. A summary of deficiencies and data gaps and the registrant's timetable for rectifying the deficiencies must also be included in the discussion.

    If a complete application for federal registration of the proposed use, which has been under an emergency exemption for any three previous years, has not been submitted, the EPA will assume reasonable progress toward registration has not been made. This standard applies to uses which have been applied for during any three previous years, regardless of whether the applications were granted or denied. Uses supported by IR-4 are judged against a 5-year standard.

B. INFORMATION REQUIRED FOR A SPECIFIC EXEMPTION

Applications for Public Health or Quarantine Exemptions Require Different Information Concerning the Nature of the Emergency (refer to 40 CFR 166.20).

1. PEST(S) TO BE CONTROLLED: Include the scientific and common name of the pest or pest complex for which use of the pesticide is sought.
2. EVENTS WHICH BROUGHT ABOUT THE EMERGENCY CONDITIONS: Include <u>detailed</u> discussion of <u>all</u> the events which brought about the emergency (weather conditions, severe pest pressure, resistance development, pesticide cancellations, etc.). Claims of severe pest or disease pressure must be documented with data or written testimony of qualified experts. If the request is being made prior to the existence of an emergency condition, a detailed explanation of why such an emergency condition is expected must be submitted. In addition, a threshold level should be specified, above which an emergency condition would be deemed to exist. Examples of threshold levels include a specified number of pests per plant, some level of rainfall occurring within a specific timeframe, the presence of weeds at a given crop state, or some percentage of crop defoliation due to a pest. Once a pest population or a situation progressed to this threshold level, use under the exemption would be allowed.

    If resistance development, phytotoxicity, or similar claims are the basis for the emergency exemption, the applicant must include evidence (in the form of field or laboratory data) to support the claim. Written testimony from qualified experts may be considered when data are not available.

    If yield loss is being claimed, studies comparing the proposed pesticide with existing registered alternatives must be provided.
3. RISKS TO THREATENED OR ENDANGERED SPECIES, BENEFICIAL ORGANISMS, OR ENVIRONMENTAL THAT ARE MITIGATED: If the emergency exemption is needed to address risks to a Threatened of Endangered species, beneficial organism or the environment, then provide information which demonstrates those risks and how using the pesticide will mitigate the risks.
4. DISCUSSION OF ECONOMIC LOSS: If the emergency exemption is needed to address a significant economic loss (SEL), then discuss the anticipated SEL associated with the

emergency condition and provide data and other information supporting the discussion. EPA considers that a SEL would result from the non-routine condition if the threshold for any of the following tiers is met (per 40 CFR 166.20):

a. Tier 1 – Yield Loss of at Least 20%: Yield loss due to the non-routine condition must be estimated assuming the use of the best available alternative controls.

   - Supporting Data: Comparative efficacy or economic injury studies documenting percentage yield loss (or absolute loss and baseline yield) comparing yields without an emergency with those involving the best available control means (i.e., the registered alternative).

b. Tier 2 – Total Economic Loss of at Least 20% of Gross Revenue: In addition to losses in gross revenues due to yield losses, total economic loss includes other impacts resulting from the non-routine condition, such as quality losses that cause reductions in price and losses owing to increase production costs. Total economic losses will be compared to baseline gross revenues, that is, gross revenues (price times yield) expected in the absence of the non-routine condition.

   - Supporting Data: Data for Tier 1, plus: Data involving baseline yield and price information from the USDA National Agricultural Statistics Service, or other appropriate sources. Quality loss data documenting shift in grade or uses from marketing studies or surveys (e.g. shift in grade or price reduction) from economic injury studies; added production costs (e.g. sorting or repacking costs, additional pest control costs) from marketing studies and surveys, labor demand studies or crop budgets. Like Tier 1, the critical comparison involves revenue without an emergency situation versus projections for losses expected when using the best alternative control.

c. Tier 3 – Total Economic Loss of at Least 50% of Net Operating Revenues: Total economic losses as defined in Tier 2, will be compared to baseline net operating revenues. Net operating revenues are defined as gross revenues less variable operating costs.

   - Supporting Data: Data for Tier 2, plus: Baseline variable production costs from enterprise budgets: Purchased inputs such as pesticides and hired labor and fuel costs should be included. Other items that are relevant to short-term operating costs such as costs for seed, fertilizer, irrigation, labor, and typical pest management costs. However, longer term obligations such as machinery depreciation and costs or other overhead costs should not be included.

   Emergency exemption decisions must be based on reliable data. Applicant should prepare packages that contain the best available information. Typical sources of appropriate data are:

   - Yield loss: economic injury studies or comparative efficacy studies taken to yield, industry field trial experiments.

- Baseline yield and prices: Agricultural statistics (e.g. USDA/NASS data), crop reports, market surveys, futures market.
- Quality (grades, etc.): Marketing studies and surveys.
- Cost increases: Market surveys, labor demand studies, crop budgets (e.g., from university extension programs).
- Operating costs: Crop budgets.

It may be difficult to submit comprehensive data for certain fast-moving and emerging pest problems, or for very minor or new crops. If such data are not available, EPA may consider using qualitative information in making its decision. However, if an exemption is granted based on qualitative data, EPA will require that substantiating data be generated during the first year of use and submitted to support any repeat applications.

d. Other Types of Expected Losses: For any pest activity where EPA determines that the above criteria (Tiers 1-3) would not adequately describe the expected loss: Substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

   For example, an emergency exemption may be justified for a pest problem that adversely affects a perennial crop but does not meet the SEL criteria for yield and/or revenue losses for a single year of production. An emergency exemption may also be justified for pest problems unrelated to agricultural production, such as for protection of structures, museum pieces, or park land. Any non-economic or qualitative information which describes the benefits from using the pesticide will be taken into consideration by the EPA.

V. JUSTIFYING THE EMERGENCY

A. Urgent and Non-Routine

To apply for a Section 18, the emergency must be both urgent and non-routine. To be urgent and non-routine, the situation must require immediate attention and be other than an ordinary one. Chronic or continually occurring pest problems are specifically excluded from the definition of an emergency condition.

The nature of the urgent, non-routine situation determines, in part, how long it would be expected to endure. Emergency situations brought about by unusual environmental conditions would not ordinarily be expected to occur in subsequent years (and therefore EPA would not normally expect repeat applications). Other situations, such as those involving the loss of a registered pesticide, would likely continue until a new pesticide is registered.

It is important that a thorough explanation be provided for all the factors (other than mismanagement) that have caused the urgent and non-routine situation. Unusual weather patterns may be enough alone to justify an emergency; however, if there are other reasons for the emergency those reasons must also be included.

Occasionally there have been applications for multiple pesticides to address a specific emergency pest problem. Though resistance management is an important concern, the EPA does not allow this as justification for requesting multiple pesticides. Therefore, when submitting an application that includes multiple pesticides, it is necessary to thoroughly explain the justification. Essentially, the justification must be that one pesticide alone is not sufficient to control the pest problem, but the reasons for this must be clearly documented.

B. Lack of Effective Control with Registered Pesticides

For each pesticide registered to control the pest problem, the applicant must demonstrate that it is either not effective or not available in adequate supplies. In most situations, efficacy claims must be supported by data; however, in rare cases testimony of qualified experts can be used as a sole support of efficacy claims. Claims of unavailability of registered pesticides must be accompanied by a discussion of the attempts made to obtain adequate supplies.

C. Lack of Effective Control with Alternate Practices

Alternative practices available to control the pest problem must be identified and an explanation of their limitations must be presented. Alternative practices may include such things as mechanical, biological, cultural, and other means of control.

D. Significant Economic Loss

A significant economic loss means that, compared to the situation without the pest emergency and despite the best efforts of the affected persons, the emergency conditions at the specific use site identified in the application are reasonably expected to cause losses meeting any of the following criteria:

(1) For the pest activity that primarily affects the current crop or other output, one or more of the following:

   a. Tier 1 – Yield loss greater than or equal to 20%;

   b. Tier 2 – Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues;

   c. Tier 3 – Economic loss, including revenue losses and cost increases, greater than or equal to 50% of net revenues.

(2) For any pest activity where EPA determines that the above criteria (Tiers 1-3) would not adequately describe the expected loss: Substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

In defining an emergency condition as one that is expected to result in a SEL, the consequences must be more serious than a failure to maximize profits in a growing season. Only those losses caused by the emergency condition are relevant in determining the SEL. Losses due to obvious mismanagement are excluded from the loss estimate. Losses due to an agent other than the target pest problem are also excluded from the SEL.

Another important consideration in presenting economic information is to present data on the specific portion of a crop that is actually affected with the pest problem (and will actually be treated with Section 18 products if approved).

If there are any intangible losses that will be incurred but cannot be quantified, it is helpful to describe these in the narrative. These types of losses may not prove that use of a pesticide under emergency exemption is economically justified, but they can help to bolster the justification. If an emergency exemption application shows that the cost of production per acre exceeded the gross revenue per acre, a detailed explanation is required.

E. Situations that are Not Justified as an Emergency

MDA receives inquiries every year regarding pest problems that do not meet the criteria for an emergency exemption. Usually there is a clear need for a product to address a pest problem, but the pest problem does not meet the urgent and non-routine criteria. Applicants often focus their attention on convincing MDA that the product/use is needed, when in reality the request cannot be submitted to EPA because it does not meet the criteria for an emergency exemption. Often these requests are made for new products that are undergoing the registration process but have not received full registration by the EPA. Requesting Section 18 use for such products attempts to short-cut the registration process. MDA sympathizes with the need but must adhere to federal requirements. This is not to say that none of these requests are legitimate. There are times when the urgent and non-routine nature of a pest emergency can be documented and a new product that is undergoing registration may be a good fit. There are other situations when a new product that is undergoing registration is a more efficacious and/or a less expensive alternative than what is currently registered, but these situations do not meet the urgent and non-routine criteria of a Section 18 emergency exemption.