

Department of Agriculture, Trade and Consumer Protection Secretary Randy Romanski

Application for a Pesticide Special Local Need Registration (FIFRA Section 24c) in Wisconsin

Introduction

Normally, pesticides are federally registered with the U.S. Environmental Protection Agency (EPA). However, the Department of Agriculture, Trade and Consumer Protection (DATCP) may register, **on a time-limited basis**, either a new end-use pesticide product which is not federally registered with EPA or a new use for a pesticide product that is currently registered with EPA in order to meet a special local need (SLN) in Wisconsin. A special local need is a current or imminent pest problem in Wisconsin that cannot be adequately controlled by the use of any available federally-registered pesticide product.

Visit <u>http://datcp.wi.gov/Plants/Pesticides/Special_Registrations/index.aspx</u> for a list of existing SLN/Section 24(c) registrations authorized for Wisconsin. Examples of new uses could include: new method or timing of application, new crop/new site/new pest, changed rate, application in particular soil type, new product/different formulation, or products useful in managing pesticide resistance in a particular crop.

Registration by DATCP as an SLN under ATCP 29.72, Wis. Adm. Code and Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) has the same effect as registration under Section 3 of FIFRA, unless EPA disapproves the registration. To reference our administrative code, ATCP 29 – Pesticide Use and Control, visit <u>http://docs.legis.wisconsin.gov/code/admin_code/atcp/29.pdf</u>. To reference EPA's regulations, 40 CFR Part 162 – State Registration of Pesticide Products, visit <u>http://ecfr.gpoaccess.gov</u>.

Process overview

The request for an SLN registration involves two or three groups – the company that registers the product ("registrant"), a technical expert, and often a commodity group. After analysis of the problem and examination of current pest management strategies, the registrant prepares a detailed application and submits it to DATCP. The application includes a description of the problem, valid evidence to support the request including an analysis explaining why existing available pesticides are insufficient, a risk benefit analysis, and other relevant information. Following review, the department may request revisions to the application, or grant the request or deny the request. DATCP has up to 180 business days to grant or deny a complete application so plan your application submittal accordingly. (More details below.)

Who may apply

Applicants must be licensed in Wisconsin as a pesticide manufacturer and labeler under ATCP 29.10, Wis. Adm. Code. Applicants typically are either the primary registrant or a supplemental distributor for the requested product. DATCP can only issue an SLN registration to a primary registrant; if a supplemental distributor intends to market its product under the registration, the applicant must specify this in the application and submit proposed labeling for both products. Applicants collaborate with a pest management expert, typically a University of Wisconsin extension researcher, to prepare a complete application.

Initiating the SLN registration process for first-time requests

- 1. **Problem Identification:** Either individuals (e.g. crop producers) or an organization (e.g. Wisconsin crop association) identifies a pest problem they cannot sufficiently manage using existing control methods.
- 2. **Technical Advice:** The individuals or organization contact their technical expert for pest management (typically a University of Wisconsin extension faculty member specializing in the crop/pest).



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- 3. **Evaluation:** The expert evaluates existing pest management options, including currently registered pesticide products.
 - a. If the expert determines existing management options are insufficient to meet the local need and identifies a viable pesticide candidate, the expert initiates the SLN application process by contacting the applicant (typically the pesticide registrant or supplemental registrant).
 - b. The applicant, with assistance from the expert, completes the process outlined below.

Application timing considerations

Technical experts and applicants will need to consider both the timing needs of the pesticide users and the DATCP review timeline in order to determine when to initiate the SLN process and to best submit a complete application. DATCP may receive multiple SLN applications, and other special use requests including Section 18 emergency exemptions and experimental use permits, in any given year.

- Under ATCP 29.72, Wis. Adm. Code, DATCP has up to **180 business days** (over 6 months) to grant or deny a <u>complete</u> application. The timeline begins once DATCP receives a complete application.
- Applications will be screened for completeness within 10 business days of submittal and incomplete applications will be returned to the applicant.
- The process includes: package review, development of an environmental assessment (see Ch. ATCP 3 <u>http://docs.legis.wisconsin.gov/code/admin_code/atcp/3.pdf</u>), signature process, and public comment.
- DATCP cannot guarantee timely completion of the review process if an applicant submits a complete application less than 180 business days prior to the time the users need to use the pesticide.
- Accordingly, applicants should submit complete applications as far in advance of the needed use dates as possible.

Application instructions

All applicants for an SLN registration must complete the following steps, in order.

- 1. Contact Alyssa Foss, Environmental Analysis and Pesticide Review Specialist, (608) 224-4547, prior to developing and submitting a special local needs application.
- 2. Complete the DATCP SLN Application Outline below, with assistance from the technical expert.
- 3. Submit the application fee and a cover letter by mail (details provided in the application outline).
- 4. Electronically submit the remainder of the application including the Application Outline, letters of support, and other attachments as one package to Alyssa Foss at <u>alyssa.foss@wisconsin.gov</u>. If you believe your application materials will exceed 10 MB, submit clearly identified separate e-mails with smaller attachments. DATCP will only review complete applications.

Registration standards, conditions for registration, and duration of registration

DATCP may issue an SLN registration if all registration standards are met. See ATCP 29.72(3) at http://docs.legis.wisconsin.gov/code/admin_code/atcp/29.pdf for the list of standards. If approved, DATCP may establish conditions to the registration, including restricting use of the product to certified applicators. Any conditions will be part of the permit issuance. If approved, the registration will be valid for no more than 5 years following the date of registration. The department may issue the registration for less than 5 years.

Suspension or revocation of registration

Under ATCP 29.72(10), DATCP may summarily suspend or revoke an SLN registration if the department finds:

- information contained in the registration application is false or misleading,
- registration conditions have been violated,



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- a registered use poses an unreasonable risk to persons, property or the environment,
- the special local need no longer exists, or
- the registration is suspended or disapproved by the federal environmental protection agency.

"Renewal" requests

DATCP may renew an SLN registration for up to 5 years, but the applicant must submit an entirely new application.

- The initiation and application processes, and application requirements, are the same as for first-time registration requests.
- The application will be evaluated as a new registration and, accordingly, the application must include updated information. Examples of updated information include, but are not limited to, the status of the pest situation and a new evaluation of existing pest control methods, including pesticides.

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Wisconsin Special Local Need (SLN) Registration (Section 24c) Application Outline

A A	Applicants must complete and submit this outline as part of a complete SLN application. Enter all information in this outline in bold font.
A A	A complete application will include all applicable items below <u>and</u> completed check boxes in the outline. Do <u>not</u> submit Wisconsin Manufacturer and Labeler License application materials with this submission.
1)	Application fee submitted [ATCP 29.72(4)(b)] Submit the following items <u>via mail</u> to: Alyssa Foss, WDATCP, 2811 Agriculture Drive, PO Box 8911, Madison, WI, 53708-8911
	a check, in the amount of \$250 and made payable to WDATCP
	 a brief cover letter that clearly identifies your electronic application package attach the check via paperclip to the top of the cover letter
2)	Basic applicant information [ATCP 29.72(4)(a)]
	Applicant Address:
3)	Basic product information [ATCP 29.72(4)(d) and (e)] The name of the pesticide product:
	The EPA registration number of the pesticide product:
	Note: If the pesticide product is not federally registered, you must include the complete product formula. If you are required to submit the product formula, label it as "Attachment 3 ".
4)	A complete description of the special local need requiring registration [ATCP 29.72(4)(c)] A special local need is a current or imminent pest problem in this state that cannot be adequately controlled by the use of any available federally registered pesticide product. A pest problem that exists on a nationwide or multi-state regional basis may not be considered a special local need. [ATCP 29.72(3)(a)]
	The description of the special local need must include a detailed and clear description of the events which led to the special local need request, including:
	 Name and description of the crop(s) or other site(s) of application Scientific and common name(s) of the pest(s)
	 A detailed description of the pest problem A description of whether the pest problem is localized in Wisconsin, regional, or nationwide.
	 Specify which other states have requested or been granted this request. A brief description summarizing the lack of sufficient pesticides. <i>Evidence must be provided in Item 7 of this outline</i>.
	A description of the proposed pesticide use (e.g. higher application rate, new use site)



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☐ The timing needs of pesticide users (e.g. producers need to use the proposed pesticide from May through August)

Is the letter of support from the technical expert intended to meet this requirement? us us on the support from the technical expert intended to meet this requirement?

- If you selected "yes", refer to the directions for cover letters in Item 9.
- If you selected "no", attach the complete description of the SLN as a separate attachment and label it as "Attachment 4".

5) Copy of the proposed pesticide product labeling [ATCP 29.72(4)(f)]

The proposed pesticide labeling must comply with ATCP 29 and federal regulations and warrants that the product is effective for the requested uses. It is the applicant's responsibility to ensure the labeling meets the complete requirements under ATCP 29; Ch. 94, Wis. Stats; and federal regulations.

The proposed labeling must:

- Be in searchable pdf format (created as a pdf file and not scanned in)
- Comply with federal labeling requirements as specified in 40 CFR 162.153(e)
- Comply with ATCP 29.06

Comply with ATCP 29.72(8) by including:

- A statement indicating that the SLN registration is only valid in Wisconsin
- A placeholder for the SLN registration number to be assigned by DATCP
- The following text as a placeholder for the expiration date to be assigned by DATCP: This label expires and must not be distributed or used in accordance with this SLN registration after ______.
- ☐ The following text regarding endangered species:

It is a violation of federal law to harm an endangered species. Use of this product may be in counties which have endangered and threatened species present; therefore, applicators should evaluate the areas to be treated and take necessary precautions to avoid harming endangered species or their habitat/environment. Growers who are uncertain of the presence of a protected species should contact the Wisconsin Department of Agriculture, Trade and Consumer Protection at 608-224-4547.

Specify the special local needs registration labeling must be in the possession of the user at the time of pesticide application

Include directions that are applicable to Wisconsin crop production practices or to other use sites

Comply with acceptable waiver of liability language ("warranty statements"), if such language is included. For example, written waivers are not allowed through labeling. See EPA's guidance at http://www.epa.gov/pesticides/regulating/labels/pdf/warranty.pdf.

Attach the proposed pesticide product labeling and label it as "Attachment 5."

6) Valid <u>scientific evidence</u> demonstrating that the product is effective for the proposed use [ATCP 29.72(4)(g)]

Examples of scientific evidence include efficacy trials conducted by researchers or the registrant, either independently or as part of an experimental use permit issued by DATCP or EPA.

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Attach the following information and label it as "Attachment 6":

- Results of testing for efficacy of the proposed product against the pest(s) of concern, including information on application rates, methods, and sites.
- Comparative data in possession for testing of the proposed product's efficacy against that of any other products already registered for the proposed use.
- Brief statement of test methodology for the above information.
- 7) <u>Evidence</u> showing that pest control methods <u>and</u> federally registered pesticides are not adequate to meet the special local need [ATCP 29.72(4)(h)]

 \Box 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:
 - Product name
 - EPA registration number
 - Active ingredient(s)
 - Explanation of why each product will not sufficiently control the pest problem or is not sufficiently available

Applicants (or technical experts) can generate this list by searching the Kelly Registration Systems database at <u>http://kellysolutions.com/wi/pesticideindex.asp</u> for the appropriate type of EPA-registered pesticide products currently listed with DATCP for sale/distribution in Wisconsin that include the proposed use site(s) [e.g. insecticides registered for use on corn (seed treatment), fungicides registered for use on cherries (foliar treatment)].

• For assistance with searching this database, contact Alyssa Foss (608-224-4547).

Label any tables and other supporting documentation as "Attachment 7".

8) A <u>description and analysis</u> of the potential <u>benefits and risks</u> associated with the proposed pesticide use. Demonstrate that the potential benefits to be derived from the proposed pesticide use exceed the potential adverse effects and will not have unreasonable adverse effects on persons, property, or the environment when used according to label directions. [ATCP 29.72(4)(i), (j), (k), (L)]

- Benefits described and analyzed could include, but are not limited to, improved crop yield/quality, economic gain, and control of invasive species. Applicants <u>may not</u> cite lower cost of product as the sole benefit.
- Risks described and analyzed could include, but are not limited to, risks posed to applicators, bystanders, target site of application (e.g. phytotoxicity), endangered and threatened species, other non-target species including pollinators, groundwater, and surface water.
 - Demonstration of adverse effects could include, but is not limited to, phytotoxicity data.
 - The description and analysis should be sufficiently detailed so that DATCP can clearly identify the potential benefits and risks and determine whether the benefits exceed the risks.



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9)	Other relevant information required by the departmen	t.
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Submit the following:

Properly completed EPA Form 8570-25 <u>http://www.epa.gov/opprd001/forms/8570-25.pdf</u>
The department has noted errors with the following items:

- \circ $\;$ Item 1: $\;$ Only enter the name and address of the primary registrant.
- \circ $\:$ Item 2: $\:$ Only enter the EPA registration number for the primary registrant.
- \circ $\;$ Item 6b: If option 6 selected, enter the required information in Item 13.
- \circ $\;$ Item 10: Select the appropriate boxes and list the names of states in Item 13.
- \circ $\;$ Item 11: Enter the required information in Item 13 or on a separate page.
- Item 13: Ensure the responses for Items 6b (option 6), 10, and 11 are entered here, when applicable.

Letter(s) of support for use of the product (from the primary registrant and, if applicable, the supplemental distributor); label each as "**Attachment 9-A**"

Include a statement regarding federal registration and labeling goals for the requested use, including a timeline of application submission and expected registration decision

Letter(s) of support (technical expert); label as "Attachment 9-B"

Letter(s) of support (representative of the organization representing the crop/site; or, in the absence of such an organization, at least one letter from a grower/applicator); label as "Attachment 9-C"

Copy of the current Section 3 specimen label for the proposed product, if the product is federally registered; label as "Attachment 9-D"

- Copy of the current MSDS for the proposed product; label as "Attachment 9-E"
- For proposed uses on a food or feed crop:
 - Provide the appropriate Code of Federal Regulations (CFR) citation(s) for established tolerances, or exemption from tolerances, for the proposed use.
 - Describe how the treated items will be marketed (processed, fresh, or both) and what will happen to byproducts of the produced item (e.g. consumption by livestock).
 - Provide data showing that the proposed use will not result in residues that exceed established tolerances; label as "**Attachment 9-F**".