

**STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION**

In the Matter of the Application by Bayer CropScience LP, for a Pesticide Special Local Needs Registration for Balance® Pro Herbicide	DOCKET NO. _____ ORDER GRANTING SPECIAL LOCAL NEEDS REGISTRATION SUBJECT TO CONDITIONS
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Based on the attached petition and findings by the Agricultural Resource Management Division, and the attached stipulation between the Applicant and the Division, the Wisconsin Department of Agriculture, Trade and Consumer Protection makes the following findings of fact and conclusions of law, and issues the following order:

FINDINGS OF FACT

(1) Bayer CropScience LP doing business as Aventis CropScience USA LP (“Applicant”) is a Delaware corporation with a mailing address at 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. The Applicant manufactures and labels pesticides and distributes those pesticides in Wisconsin.

(2) The Wisconsin Department of Agriculture, Trade and Consumer Protection (“DATCP”) is a state agency authorized to administer Wisconsin pesticide statutes and rules, including ss. 94.67 through 94.71, Stats., and ch. ATCP 29, Wis. Adm. Code. DATCP’s Division of Agricultural Resource Management (“Division”) administers pesticide laws and rules on behalf of DATCP.

(3) DATCP licenses the Applicant as a pesticide manufacturer and labeler under s. 94.68, Stats., and s. ATCP 29.10, Wis. Adm. Code. The Applicant holds license number 35-010248-000000.

(4) The United States Environmental Protection Agency (“EPA”) has granted the Applicant a conditional federal pesticide registration, under the Federal Insecticide, Fungicide and Rodenticide Act (7 USC 136 et seq.), for Balance® Pro Herbicide (“the pesticide”), containing the active ingredient isoxaflutole, under EPA Registration Number 264-600. The EPA conditional registration authorizes

the Applicant to distribute the pesticide in various states. However, the conditional registration does not authorize the Applicant to distribute the pesticide in Wisconsin.

(5) The Applicant has applied to DATCP for a special local needs registration under s. ATCP 29.72, Wis. Adm. Code, authorizing the Applicant to distribute the pesticide for certain purposes in this state.

(6) DATCP issued a special order, DATCP Docket Number 02-C-38, related to this matter to the Applicant on March 28, 2002.

(7) The Division has petitioned DATCP for this order (see petition attached).

(8) The Division states that it has prepared an environmental impact statement on this matter, and has held public hearings on the environmental impact statement, as provided under s. 1.11, Stats., and ch. ATCP 3, Wis. Adm. Code. A copy of the final environmental impact statement is attached.

(9) The Division states that the proposed special local needs registration complies with s. ATCP 29.72, Wis. Adm. Code. See Division findings attached.

(10) The Division and the Applicant have executed the attached stipulation, in which the Applicant agrees to the entry of this order without further notice or hearing, and without any further adjudication of fact or law.

CONCLUSIONS OF LAW

(1) DATCP has jurisdiction over the subject matter of these proceedings and over the Applicant.

(2) DATCP has complied with applicable requirements under s. 1.11, Stats, and ch. ATCP 3, Wis. Adm. Code.

(3) This special local needs registration complies with s. ATCP 29.72, Wis. Adm. Code.

(4) DATCP may issue the following order granting a special local needs registration subject to conditions, pursuant to s. ATCP 29.72, Wis. Adm. Code, without any further notice or hearing, and without any further adjudication of fact or law.

ORDER

NOW, THEREFORE, IT IS ORDERED that DATCP hereby grants the Applicant a special local needs registration under s. ATCP 29.72, Wis. Adm. Code. Unless suspended or revoked, the special local needs registration expires five years from the date on which this order is signed. The special local needs registration authorizes the Applicant to distribute Balance® Pro Herbicide (“the pesticide”), EPA Reg. No. 264-600, for use in this state, subject to the following conditions:

(1) The pesticide shall bear the supplemental label attached to this order, except that the supplemental label shall be modified to include the following additional statements:

(a) “Do not apply Balance® Pro Herbicide to tile-drained fields.”

(b) “Persons using Balance® Pro Herbicide in Wisconsin must report that use to the Wisconsin Department of Agriculture, Trade and Consumer Protection. Users must report the following information: the name, address and applicator certification number of the person making the application; the name and EPA registration number of the pesticide applied; the name and address of the person contracting for the application; the crop on which the pesticide was applied; the purpose for which the pesticide was applied; the specific location at which the pesticide was applied, including town, range, section and quarter-quarter section; the date and time of the pesticide application; the size of the area treated; and the amount of pesticide applied. Submit this information to DATCP ARM Division, PO box 8911, Madison, Wisconsin 53708-8911 by September 1 of the year in which the pesticide is applied.”

(2) The Applicant shall conduct a 5-year monitoring study to assess the potential impact of isoxaflutole use on Wisconsin surface water and groundwater. The Applicant shall do all the following as part of this study:

(a) The Applicant shall establish 4 surface water monitoring sites, at locations specified by the Division, by April 1, 2004. The Applicant shall collect, or pay for the collection of water samples by Division approved samplers, and analyze water samples from those sites, according to procedures prescribed by the Division. The Applicant shall use site gauging and sampling equipment approved by the Division. The Applicant shall analyze up to 150 surface water samples per year for the duration of the special local needs registration, collected from those sites, and other sites, as determined by the Division. When the study is complete, DATCP shall retain ownership of all installed surface water monitoring equipment that the Applicant uses in the study.

(b) The Applicant shall establish 15 groundwater monitoring sites at locations, approved by the Division, where the pesticide is applied. The following requirements apply to each of these monitoring sites:

1. The Applicant shall provide monitoring equipment, and shall collect and test groundwater samples at each site, as approved by the Division.

2. Each site shall have 4 monitoring wells, including 3 in-field monitoring wells. The 3 in-field monitoring wells may be placed in a line to facilitate cropping activity in the field. The 3 in-field monitoring wells shall be at least 150 feet apart. The fourth monitoring well may be placed on the treated field edge, or in the field, and shall be placed so that the groundwater flow direction and gradient can be determined.

3. Monitoring well sites may not be located in places having impermeable or highly restrictive subsoil layers. The saturated hydraulic conductivity of all materials between the ground surface and monitoring well bottom shall be greater than 10^{-8} m/s.

4. No part of any monitoring well may intersect bedrock.

5. The screen length for each monitoring well shall be 10 feet, unless the Division approves a different length based on the characteristics of a specific site.

6. The area treated with isoxaflutole shall extend at least 300 feet from all 3 in-field monitoring wells. This area shall be treated at the highest isoxaflutole application rate allowed on the pesticide label for the type of application made.

7. Monitored sites shall be treated with isoxaflutole in the first year of the study, in 2 of the first 3 years of the study, and in at least one other year of the study.

8. The Division shall approve the selection and installation of the monitoring wells. The selection and installation may not be inconsistent with the pesticide label.

9. At least 6 of the monitoring wells sites shall have medium-textured surface soils, and shall have a depth to groundwater of less than 25 feet.

10. At least 4 of the monitoring well sites shall have coarse-textured surface soils, and shall have a depth to groundwater of less than 25 feet.

11. At least 2 of the monitoring well sites shall have coarse-textured surface soils, less than 2% organic matter in the upper 12 inches of soil, no finer-grained subsoil layer, and a depth to groundwater greater than 25 feet and less than 50 feet.

(c) The Applicant shall, by December 31, 2002, install at least 10 of the groundwater monitoring sites under par. (b). The remaining groundwater monitoring sites, if any, shall be installed by March 1, 2003.

(d) The Applicant shall collect groundwater samples from all of the wells installed under par. (b) at least once before April 1, 2003, and quarterly thereafter, for a period of 5 years. Quarterly sampling is defined to mean four samples per year collected a minimum of 60 days and a maximum of 120 days apart at a given site.

(e) When the 5-year study period is completed, the Division may require the Applicant to continue collecting and analyzing water samples at any or all of the monitoring sites under par. (a) and (b).

(f) The Applicant shall pay all costs to establish and maintain the monitoring sites, and conduct the monitoring required at those sites, including:

1. The cost of site access.
2. The cost to install and maintain monitoring wells and instruments.
3. The cost to collect and analyze water samples.

IT IS FURTHER ORDERED THAT:

(3) The Division may, at its own cost, install additional monitoring wells or surface water monitoring instrumentation at any of the sites under sub. (2). The Division shall notify the Applicant before installing monitoring wells or instrumentation at any of the sites.

(4) The Division shall have access to, and may collect samples from, any of the monitoring sites under sub. (2) at any time during the 5-year study. The Division may submit samples collected from the monitoring sites to its own laboratory or the Applicant's laboratory, or both.

(5) The Division may submit up to 30 groundwater samples per year, collected from other monitoring, private or public wells, to the Applicant for analysis at no cost to the Department.

(6) Whenever the Applicant receives a water sample for analysis under sub. (2), (4) or (5), the Applicant shall do all the following:

(a) Fully and completely analyze the sample within 60 days after the sample is collected or, in the case of a sample received from the Division, within 60 days after the sample is received. The Applicant shall analyze each sample for isoxaflutole, RPA 202248, and any isoxaflutole degradate that the Applicant, EPA or the Division determines to be of toxicological concern. The limit of detection for isoxaflutole and RPA 202248 shall be no greater than 3 parts per trillion (ppt). The limit of quantification for isoxaflutole and RPA 202248 shall be no greater than 10 ppt.

(b) Report the results of the sample analysis to the Division within 120 days after the sample is analyzed. The Applicant shall provide quarterly reports of sample results to the Division. The Applicant shall also provide, to the Division, an annual report showing that the Applicant's sample collection and analysis comply with applicable EPA good laboratory practices (GLP report).

(c) Do all the following if the analysis finds isoxaflutole, RPA 202248, or any isoxaflutole degradate that the Applicant, EPA or the Division determines to be of toxicological concern, at a level at or above 310 ppt:

1. Report the finding to the Division within 14 days after the sample is analyzed.

2. Collect a confirmation sample from the same site within 21 days after the sample is analyzed. The Applicant shall analyze the confirmation sample and report its findings to the Division within 30 days after the Applicant collects the confirmation sample.

(7) If monitoring wells or surface water monitoring installations under sub. (2) are damaged or lost during the study, DATCP shall consult with an advisory committee and may order the Applicant to install replacement monitoring wells or installations at the Applicant's expense.

(8) The Applicant shall pay all costs associated with the abandonment of the monitoring wells under NR 141.25, Wis. Adm. Code.

(9) The Applicant shall provide the Division with ongoing assistance and standards related to laboratory analysis for isoxaflutole, RPA 202248, and any isoxaflutole degradates that the Applicant, EPA or the Division determine to be of toxicological concern.

(10) The Division shall convene an advisory committee at least annually to review the ongoing results of the study required by this order, and any other information that Division considers relevant to this special local needs registration. The advisory committee shall be composed of representatives from DATCP, the Applicant, the University of Wisconsin System, the Wisconsin Geological and Natural History Survey, the Wisconsin Department of Health and Family Services, the Wisconsin

Department of Natural Resources, corn growers, vegetable growers and environmental groups. The Division shall seek recommendations from the advisory committee on possible changes to this order.

(11) If the Applicant violates any provision of this order, the Division may by written notice summarily suspend the Applicant's special local needs registration under this order.

(12) If the Division determines, based on confirmed test results under this order or other official groundwater test result specified in ATCP 31.01 (8) Wis. Adm. Code, that isoxaflutole, RPA 202248, or any isoxaflutole degradate that the Applicant, EPA or the Division determines to be of toxicological concern is present in Wisconsin groundwater at or above 310 ppt, the Division shall investigate the source of the contamination. If the Division finds that the contamination has resulted from normal use of the pesticide, the Division shall issue a written notice suspending the Applicant's special local needs registration under this order.

(13) The Division may issue a suspension notice under sub. (11) or (12) without prior notice or hearing. A summary suspension notice takes effect when served on the Applicant, unless the notice specifies a later effective date. If the Division issues the suspension under sub. (12), the Division shall consult with the advisory committee under sub. (10) on the appropriate response to the contamination. Applicant may request an informal hearing with the Division. The Division shall hold the informal hearing within 10 days after it receives the request, unless the Applicant agrees to a later date. If the matter is not resolved at the informal hearing, the Applicant may request a contested case hearing before DATCP pursuant to ch. 227, Stats., and ch. ATCP 1, Wis. Adm. Code. The Applicant may ask DATCP to stay the summary suspension pending hearing, but a request for a hearing or stay does not automatically stay a summary suspension.

(14) If the Division suspends the Applicant's special local needs registration under this order, the Applicant shall do all the following:

(a) Halt further sales and distribution of the pesticide in this state, and all further distribution into this state.

(b) Recall and remove the pesticide from this state within 120 days of the suspension date.

This paragraph does not apply to pesticide that has already been delivered to end-users, except as ordered by DATCP.

(15) This order supersedes the DATCP special order, Docket Number 02-C-38, issued on March 28, 2002. That order is hereby withdrawn.

(16) This special local needs registration is issued subject to EPA review. The special local needs registration is issued on the date of this order, but is automatically suspended if EPA denies the special local needs registration.

(17) The Division or the Applicant may, at any time, petition DATCP to modify, suspend or revoke this order. This subsection does not limit the Division's summary suspension authority under subs. (11) to (13).

Signed this _____ day of _____, 2002.

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By _____
James E. Harsdorf, Secretary