

Balance Revisited

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Background

BALANCE Herbicide (Isoxaflutole) is a pre-emergent herbicide for the control of grass and broad-leaf weed species in corn. This product was first conditionally registered in September 1998, which allowed commercial introduction for the 1999-growing season. As a condition of the registration, the US Environmental Protection Agency (EPA) required the registrant, AVENTIS, to conduct studies to better define the risks posed by isoxaflutole to non-target plants and crops. The primary concern is the phyto-toxicity of isoxaflutole and its degradate (RPA 202248) and potential contamination of water resources. Data from these studies were used by EPA to render a registration decision in November 2001. Based on the information at hand, EPA decided in November 2001 to extend the conditional registration of isoxaflutole for an additional 3 years to allow additional time for review.

Because of concerns about groundwater contamination and subsequent damage to irrigated vegetable crops, the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) has requested and received from EPA an exclusion from the list of labeled states from 1999 through the 2002-growing season. Therefore, BALANCE Herbicide can not be used in Wisconsin. For similar reasons, BALANCE Herbicide can not be used in Minnesota or Michigan through 2002.

Interest on the part of grower groups to register BALANCE in Wisconsin for the 2003-growing season has prompted WDATCP to pursue the steps necessary to consider such a decision. The major steps required before a decision could be made include the development of an agreement with the registrant of BALANCE on Wisconsin specific restrictions to protect water resources, implementation of appropriate stewardship activities, and conduct of monitoring activities. Additionally, an Environmental Impact Statement (EIS) would be required with mandatory public hearings.

Process to consider the use of BALANCE Herbicide (Isoxaflutole) in Wisconsin under a section 24c label (Special Local Need)

To permit use of BALANCE in Wisconsin, a section 24c label, must be developed by WDATCP and submitted to EPA. The label must include all product restrictions that WDATCP requires. Before taking such action, WDATCP would have to develop an Environmental Assessment or an Environmental Impact Statement (ATCP 3.02(1)(b) *Pesticide Permits* and ATCP 3.03(1) Actions requiring an environmental impact statement.) Assuming that the decision to allow use of BALANCE in Wisconsin is considered a major action an EIS would be required. The decision to allow use through a

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24c label cannot be made until the environmental impact statement, which includes a public hearing, is completed. The following outlines the procedure and timeframe to develop a 24c request. The label would be effective for 5 years assuming continuing Federal registration.

Procedure	Timeframe
Develop an agreement with Aventis regarding product restrictions that would be required on the label, as well as stewardship and monitoring responsibilities.	30 days
Develop a special order to implement the agreement.	30 days
A Environmental Assessment is required under ATCP 3.02(b) Environmental Assessments; <i>Permits</i> . An Environmental Assessment would likely conclude that granting the permit would constitute a major action, potentially affecting the quality of the human environment, thus requiring the development of an Environmental Impact Statement . Note that DATCP shall make no final decision to proceed with the action until the EIS is completed.	45 days
A draft of the EIS must be distributed for comment for a specified period (routinely 45 days).	45 days
Final EIS shall be prepared following receipt of comments.	15 days
DATCP is required to hold public hearings on the action prior to making its final decision to proceed.	5 days
DATCP makes final decision on section 24c for Balance use in Wisconsin and if appropriate submits request to EPA. No final decision on the action may be made earlier than 30 days after the issuance of the final EIS or 90 days after the issuance of the draft EIS whichever is later.	30 days minimum
Total:	200 days

Summary

Assuming that the first stage in the process (an agreement between Aventis and WDATCP on label restrictions, stewardship, and monitoring) can be achieved during January 2002, a decision regarding the use of BALANCE in Wisconsin for the 2003-growing season could be reached in late summer of 2002. This further assumes that no other step in the process is delayed in a serious way. Ultimately, WDATCP would weigh the EIS and comments received at the public hearings to make a final decision on BALANCE use in Wisconsin for 2003.