



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

6-14-93

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Information submitted from D.M. Vlachos, Manager, Biotechnology Product Development, Ciba Seeds, to P.O. Hutton (PM 18) on June 4, 1993 concerning the "Pending EUP application No. 66737-EUP-R, 'Request for Field Testing of *Bacillus thuringiensis* var. *kurstaki* CryIA(b) Insect Control Protein as Expressed in Corn Plants.'" USDA Aphis Permit #92-363-05. DP Barcode D191971. EFGWB # 93-0794.

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TO: Phillip Hutton, PM18

DATE: June 10, 1993

THRU: Robert W. Pilsucki, Ph.D.
Microbiologist
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

and

Henry Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

FROM: Leo LaSota, Ph.D.
Biologist
Environmental Fate and Ground Water Branch
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EFGWB has reviewed the information submitted by Ciba Seeds, Agricultural Biotechnology, Ciba-Geigy Corporation, addressing two issues raised by EFGWB in their April 5, 1993 review of the EUP submission (DP Barcode 187336; EFGWB # 93-0364). The issues raised and the Ciba-Geigy responses are as follows:

Issue

EFGWB recommends that the applicant provide the following information



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concerning the proposed field tests: (1) The minimum isolation distance from any other corn plants for the proposed insect susceptibility study at Research Triangle Park, North Carolina. The applicant merely states "No concerns for pollen escape exist for this location, as there are no other corn plants in the vicinity..."

Response

"The test plot is surrounded on two sides by mixed pine forest, and on the other two sides by Ciba building structures and grassy areas, beyond which is a mixed pine forest. The nearest other corn plants are at least one mile, and most likely several miles, from the test plot."

EFGWB Evaluation of the Response

Based on the data submitted and a review of the scientific literature, EFGWB believes that an isolation distance of one mile or more, and the presence of the buffer afforded by buildings and a pine forest, will restrict the limit the risk of outcrossing to nontransgenic corn plants not a part of the field test at least as effectively as will the combination of a 660-foot isolation distance and a 15 foot border of nontransgenic corn recommended in the EFGWB evaluation of the protocols originally submitted by the applicant for this EUP.

Issue

EFGWB recommends that the applicant make the following changes to the experimental protocol: (1) Employ a 15-foot border of nontransgenic corn **and** an isolation distance of at least 660 feet from other corn for the resistance management and seed increase/hybrid production sites.

Response

"The resistance management test plot (Johnson County, NC) and one of the seed increase plots at Molokai, Hi have already been planted (under USDA-APHIS permits). Although 15 foot borders of nontransgenic corn were not used on all sides of these test plots, the minimum isolation distance of 660 feet from other corn was greatly exceeded. (Specific details of these plantings are provided below.) When considered together with additional features of these test plantings, the level of transgenic pollen containment is expected to meet or exceed the intent of the EFED recommendation.

The transgenic corn for the resistance management experiment was planted by our cooperator on May 24. The nearest other corn is at least 1200 feet away. The test plot is bordered on two sides by at least 15 feet of

nontransgenic corn, and on the other two sides by at least seven feet of nontransgenic corn. Adjacent to the plot are woods on one side and non-corn crops on the other three sides.

A seed increase trial was planted at Molokai, HI on May 21. The test plot (see attached map) is surrounded on the northeast and southwest sides by five foot borders of nontransgenic corn, beyond which is planted a 15-20 foot high windbreak of *Erythrina variegata* ("willi-willi"), a dense perennial woody shrub which will be a barrier to pollen outflow. The northwest and southeast sides of the plot are bordered by 15 feet of nontransgenic corn. The nearest corn is at least 2000 feet to the south of the test plot, and was planted on April 22. The one-month difference in planting dates will provide effective temporal isolation. A large portion of the area between the two corn plantings consists of uncleared brush and a gulch, which will form an additional barrier to pollen escape."

EFGWB Evaluation of the Response

The insect susceptibility study is limited to one site not to exceed 0.2 acre. Based on the data submitted and a review of the scientific literature, EFGWB believes that, at the Research Triangle Park site, an isolation distance of at least 1200 feet, a 15 foot buffer of nontransgenic corn on two sides and a 7 foot border of nontransgenic corn on the other two sides will limit the risk of outcrossing to nontransgenic corn plants not a part of the field test at least as effectively as will the combination of a 660-foot isolation distance and a 15 foot border of nontransgenic corn recommended in the EFGWB evaluation of the protocols originally submitted by the applicant.

Based on the data submitted and a review of the scientific literature, EFGWB believes that, at the Molokai site, the isolation distance of at least 2000 feet, the 5 foot buffer of nontransgenic corn on two sides surrounded by a 15-20 foot high *Erythrina variegata* windbreak, the 15 buffer of nontransgenic corn on the other two sides, and the one-month temporal shift in planting dates from the nearest corn not a part of this test will collectively limit the risk of outcrossing to nontransgenic corn plants not a part of the field test at least as effectively as will the combination of a 660-foot isolation distance and a 15 foot border of nontransgenic corn recommended in the EFGWB evaluation of the protocols originally submitted by the applicant.

The applicant also proposes to use either a temporal shift of one month and a border of at least 15 feet of nontransgenic corn or an isolation distance of 660 feet and a border of at least 15 feet of nontransgenic corn for future seed increase/hybrid productions described in this EUP. EFGWB recommends that the applicant validate the efficacy of the temporal shift for the Hawaii site by documenting the extent of overlap (if any) between the release

of transgenic pollen and the pistil receptivity of the nearest non-test corn during the conduct of the field test planted on May 21. At the present time, EFGWB further recommends that the use of a gene containment strategy for future seed increase/hybrid production plantings for this EUP consisting exclusively of at least a one-month temporal shift and a nontransgenic corn border of 15 feet be restricted to areas where no corn grown for seed is within 660 feet of the test site.