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

MEMORANDUM

SUBJECT: Review of Information submitted from D.A. Vlachos to P. Hutton on April 8, 1993, concerning "Amendments to 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.'" Ciba Seeds-Biotechnology Research, Ciba-Geigy Corporation, P.O. Box 12257, Research Triangle Park, North Carolina 27709-2257. Case 008236. Submission S438792. Chemical 006430. ID# 066736-EUP-R. Action Type 724. DP Barcode D190253. EFGWB #93-0609.

TO: Phillip Hutton, PM18

DATE: April 30, 1993

THRU: Robert W. Pilsucki, Ph.D. 
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and

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FROM: Leo LaSota, Ph.D. 
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EFGWB has reviewed the information submitted by Ciba Seeds to amend their application for EUP permit Number 66737-EUP-R. Based on the data submitted EFGWB believes that these proposed changes do not present any additional risk of unplanned exposure to the transgenic plant pesticide. The proposed changes include:

Gene Efficacy Evaluation:

(1). An additional treatment has been added to the original study design. This new treatment consists of application of first and second brood European corn borer larvae. No insecticide treatment will be applied to the infested plants. (2). Efforts will be made at all six Gene Efficacy Evaluation locations to monitor, characterize and compare the natural insect populations on transgenic and nontransgenic plants. Sweep samples will be taken for insects at least three times during the 1993 growing season.

Insect Susceptibility Study:

The descriptions for Test Site, Experimental Design and Activities, Plot Design, Schedule and Gene Containment have been changed. (1). **Test Site:** A second site in addition to the one originally scheduled for Research Triangle Park has been added. The additional test plot will be at the Breeding Nursery located in Bloomington, Illinois. No additional acreage of transgenic plants will be required than previously described for Breeding activities at the Bloomington site. The space and plant requirements of the breeding plots will be reduced commensurate with the space and plant requirements of the insect susceptibility study. (2). **Experimental Design and Activities:** Non-segregating seed (from parents homozygous with respect to the presence or absence of the cryIA(b) gene) may be available. If so, this would preclude the necessity of germinating seeds in the greenhouse to screen for insecticidal activity. **The planned infestations with southwestern corn borer have been eliminated.** Other treatments have been redesigned to reduce the number of experimental variables. Three subplots will be used, each containing CryIA(b)-producing (Bt+) and CryIA(b)-negative (Bt-) plants. Subplot 1: Plants will be infested with larvae of fall armyworm and one or more insect species known to parasitize fall army worm. Subplot 2: Plants will be infested with European corn borer (the target pest), aphids (a nontarget pest) and ladybird beetles (a predatory beneficial insect). Subplot 3: Plants will be infested with either or both European corn borer and fall army worm at regular intervals. All subplots: Any plants producing silks will be infested with corn ear worm. This part of the study involving corn earworm infestations will be conducted only at the Research Triangle Site and not at the Bloomington, IL site. (3). **Plot design:** The plot design has been modified such that subplots 1 and 2 will each measure approximately 70' X 25' and each contain four blocks of Bt- plants, arranged in a random block design. Each block will consist of three rows of 10 plants each, and will be separated from adjacent blocks by space

and border rows of untreated, nontransgenic corn. The size of subplot 3 will be approximately 37' X 50'. Each block will consist of two rows of seven plants each, and will be separated from adjacent blocks by space and/or border rows. (4). **Schedule:** The estimated planting date for both the North Carolina and Illinois site are between April 15 and May 15, 1993. (5). **Gene Containment:** Gene containment at the Illinois site will be changed to that described for Breeding on page 43 of the Administrative Materials of the original EUP submission. This change will include covering tassels of transgenic plants prior to pollen shed, surrounding the plot by at least 15 feet of nontransgenic corn, and "isolated spatially or temporally from and other corn fields."

Test Sites: Illinois

The location for the second Gene Efficacy site at Bloomington has been changed from the Ciba Seeds Agronomic Research Center farm on Highway 51 to the following location: Ciba Seeds Agronomic Center farm, McClean County Road 36, Bloomington (McClean County), Illinois.

These proposed amendments do not alter the EFGWB recommendations for this EUP which are that the applicant provide the following additional information concerning the proposed field tests:

1. The minimum isolation distance from any other corn plants for the proposed insect susceptibility study at Research Park Triangle Park, North Carolina. The application merely states "No concerns for pollen escape exist for this location, as there are no other corn plants in the vicinity..."
2. The expected maximum period of receptive pistil exposure for nontransgenic corn plants in proximal fields temporally isolated from the proposed field trials. Given the diverse lines being tested, and possible differential degree day effects, how will temporal shifts in planting guarantee a poor nick, and a consequent limit to pollen exposure to receptive pistils of offsite, nontransgenic corn?

EFGWB has also already recommended that the applicant make the following changes in the proposed experimental protocols:

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.
2. The applicant should also consider temporal shifts in planting for the breeding/seed increase sites as an additional, but not sole, limit to pollen movement to non-target corn (Schoultz 1985). The efficacy of this shift in producing an effective barrier to gene flow could be documented during the conduct of the 1993-94 trials.