

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 17 1993

MEMORANDUM:

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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SUBJECT: Review of Amendment to EUP Application No. 66737-EUP-R

"Request for Field Testing of Bacillus thuringiensis var. kurstaki CrylA(b) Insect Control Protein as

Expressed in Corn Plants".

TO: Phil Hutton (PM 18)

Registration Division

FROM: Anthony F. Maciorowski, Chief

Ecological Effects Branch

Environmental Fate and Effects Division (H7507C)

EBB has reviewed the changes proposed by Ciba Seeds in their EUP submission. The original study design for the Gene Efficacy Evaluation has been modified to include an additional treatment of applying first and second brood European corn borer larvae to the transgenic corn plants. Changes in nontarget insect populations will be monitored by taking sweep samples of selected test plots.

The Insect Susceptibility Study will be duplicated at a second location, Bloomington (McClean County), Illinois and the seed will most likely be directly seeded into the plots instead of germinated in the greenhouse. The infestation of the test plots by the southwestern corn borer has been eliminated due to a concern of releasing this pest into the environment. The treatments have been modified to reduce the number of experimental variables and as in the above study, the seed will most likely be directly planted into the field. The plot design has been modified so that the subplots (70'x25') will contain four replicate blocks of Bt+ and Bt- plants (with 3 rows of 10 plants each), arranged in a random block. The third subplot will contain two rows of seven plants each.

The planting dates for the North Carolina test site have been changed due to the weather, with planting estimated to start between April 15 and May 15, 1993. For the Bloomington site, gene containment procedures will be increased and strengthened because of the presence of other corn fields in the vicinity of the site.

The site of the second Gene Efficacy test has been changed to another location on the Ciba Seed Agronomic Center farm in Bloomington because the original field was not large enough to accommodate the test plot. In addition, efforts will be made to

monitor the natural insect populations in the test plots at all six test locations.

The above changes were minor and should not affect the risk assessment for the original EUP submission. Specifically, the small changes in experimental design and site location will not significantly increase the risk to nontarget organisms. Therefore, these changes can be made without any additional submissions or changes in the EUP already issued for these experiments.