

US EPA ARCHIVE DOCUMENT

9

EFFICACY REVIEW

DATE: IN 2- 3-93 OUT 5- 4-93

FILE OR REG. NO. _____

PETITION OR EXP. PERMIT NO. 66736-EUP-R

DATE DIV. RECEIVED January 19, 1993

DATE OF SUBMISSION January 13, 1993

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): (I,)D, H, F, N, R, S Transgenic Biological

DATA ACCESSION NO(S). 426362-04;D187402;S434296;Case#008236;AC:720

PRODUCT MGR. NO. 18-Hutton/Mendelsohn

PRODUCT NAME(S) Insect Resistant Corn Seed

COMPANY NAME CIBA-Geigy Corporation, Seed Division ("CIBA Seeds")

SUBMISSION PURPOSE Original application for permit to ship & use transgenic seed for European corn borer control evaluation, plant breeding & research purposes.

CHEMICAL & FORMULATION Bacillus thuringiensis var.kurstaki δ -endo-toxin as produced in corn by a CryIA(b) gene & its controlling sequences as found on plasmid vector pCIB44_ (=18 or 31) 00.01%

CONCLUSIONS & RECOMMENDATIONS The proposed program appears acceptable from the standpoint of supervision, size and number of test plots, types of evaluations, geographic distribution of pests, application equipment (planters), planting rate (standard for corn), and planting dates (appropriate for areas). This complex evaluation of transgenic corn to control European corn borer and other lepidopterous pests of corn is well designed to accomplish a number of objectives simultaneously: gene efficacy evaluations, resistance management experiments, insect susceptibility studies, breeding, seed increases, yield evaluations and insect population dynamics studies. Each one of these objectives is discussed in sufficient detail in the administrative materials accompanying the application to account for all the acreages and amounts requested and to ensure that the experimental material will be properly utilized. The data presented in EPA Accession (MRID) No. 426362-04, having been obtained from small plot field testing meeting requirements of 95-2(b)(2)(i)(B) on p. 235 of the Product Performance Guidelines, are adequate to demonstrate the efficacy of the CryIA(b) gene produced in several elite lines of corn by means of event number 171 (involving cryIA(b), selectable marker gene bar and scorable marker gene GUS under control of CaMV 35S promoters) and by means of event number 176 (involving cryIA(b), (continued)

PEPC and pollen promoters and selectable marker gene bar under control of a CaMV 35S promoter as a selectable marker for PPT resistance) against European corn borer, Ostrinia nubilalis, 1st and 2nd generation larvae at population levels many times in excess of those encountered in the highest natural infestations in the field. These populations were produced by artificial means using corn borer egg masses. It is significant to note that this almost total control of corn borer damage was produced by a concentration of B.t.k. protein only 1/320th that in currently available commercial products! Thus the importance of the current research on amounts of pesticide required to grow borer-free corn in the future can scarcely be overemphasized. It is our recommendation that the program be approved as soon as possible.

RL Vern L. McFarland, IRB