

US EPA ARCHIVE DOCUMENT

JUN 24 2003

Dr. Penny Hunst
Regulatory Manager
Mycogen Seeds
c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054

Dear Dr. Hunst:

Subject: *Bacillus thuringiensis* Cry34/34Ab1 Proteins and the Genetic Material Necessary for their Production (From the Insert of Plasmid PHP17662) in Corn / Your January 15, 2003 Revised Application; January 21, 2003 Revised Experimental Program Section G; June 18, 2003 Letter, Updated Confidential Statement of Formula, and Label; and Your June 19, 2003 Letter and Updated Label; June 23, 2003 Letter and Updated Label
EPA Experimental Use Permit No. 68467-EUP-7
Effective Dates: Plantings Through May 1, 2004 and Associated Activities Such as Collection of Field Data; Harvesting & Processing of Seed After Last Planting; and Containment Activities Such as Destruction of Volunteer Corn Plants

On the basis of the information furnished by the applicant and the annexed program, an experimental use permit under § 5 of the Federal Insecticide, Fungicide, and Rodenticide Act is hereby issued for *Bacillus thuringiensis* Cry34/34Ab1 proteins and the genetic material necessary for their production (from the insert of plasmid PHP17662) in corn. A temporary tolerance exemption being issued under 40 CFR §180.1242 is associated with this experimental use permit.

Prior to shipment and/or use of the subject corn, you must consult with the pesticide regulatory officials and, if applicable, the biotechnology regulatory officials of the State(s) in which your experimental program will be conducted, and obtain a State permit or license if such is required. (Note Hawaii's reporting requirement for genetically modified organisms under section 321-11.6 of the Hawaii revised statutes.) Issuance of this Federal permit does not negate the need for permission from individual States. Prior to initiating this experimental program in any State, you are to notify the lead Agency of the State(s) in which your experimental program will be conducted of the specific testing program (when, where, how much, etc.). Failure to do so may result in revocation or modification of this EUP. You must comply with all requirements of the USDA/APHIS as they apply to the proposed testing.

You must provide notice to the State pesticide regulatory Agency at least 72 hours before

you begin to apply the experimental use product. You must also provide a copy of this authorization letter and stamped label, as well as the non-confidential portion of the Section G (the January 21, 2003 version of your section G with a modified last planting date of May 1, 2004) to all cooperators, participants, and users prior to the initial pesticide application made in accordance with the EUP. The Agency is also notifying the relevant EPA Region(s), by sending them copies of this EUP.

Conditions under which the EUP is being issued are as follows.

1. The total amount of construct 17662 corn seed to be used will not exceed the quantity authorized by the EUP.

2. The permittee will immediately notify the Environmental Protection Agency of any findings from the experimental uses that have a bearing on safety (*i.e.*, reporting to the Agency of any adverse effects from the use of, or exposure to, the pesticide is required). The permittee will also keep records of production, distribution and performance, and, on request, make the records available to any authorized officer or employee of the Environmental Protection Agency.

3. You must provide a final report within 180 days of the expiration of the permit. The final report must include all of the items set forth in 40 CFR § 172.8(b). We note that the acreage listed in your experimental program did not include isolation distances or non-construct 17662 plants receiving construct 17662 pollen. Future experimental use permit application requests and the final report for this permit must include or report on the area of the field planted to construct 17662 corn and any plants intended to receive pollen from construct 17662 corn plants through cross pollination. A perimeter drawn around the circumference of such a plot will serve as the defining measure of what is contained within the experimental plot. This must include border row plantings where required. The disposition of all planted construct 17662 corn and any plants intended to receive pollen from construct 17662 corn plants must also be reported.

4. Per 40 CFR §174.4(b)(v), you must provide the name and street address of all cooperators as soon as available and prior to planting.

5. The labeling submitted in connection with your application is acceptable and must be used for all shipments of seed subsequent to receiving this approval and be in possession of the user under this EUP. A stamped copy of the label which contains the correct EUP number, 68467-EUP-7, is enclosed for your records.

6. This experimental use permit is not a limited seed increase registration under § 3 of FIFRA and plantings solely for commercial seed increase are prohibited

Based upon the submitted experimental program, the subject corn seed may be shipped for

use under this permit to the following State(s) and be planted on the following acreage and crops, provided that the States agree to the trials and all other requirements of the USDA/APHIS have been met as they apply to the testing:

<u>STATE or COMMONWEALTH</u>	<u>ACREAGE</u>
Colorado	5
Hawaii	104
Illinois	53
Indiana	43
Iowa	46.5
Kansas	6
Michigan	5
Minnesota	31
Missouri	12
Nebraska	27
North Dakota	6
Ohio	6
Puerto Rico	14
South Dakota	9
Texas	1
<u>Wisconsin</u>	<u>26</u>
Total	394.5

Sincerely,

/s/ Phil Hutton for/

Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division (7511C)

Enclosure