

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

See reverse side for additional information FORM APPROVED OMB NO. -579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION
**APPLICATION FOR PERMIT OR
COURTESY PERMIT UNDER 7 CFR 340**
(Genetically Engineered Organisms or Products)

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

DAS2K-17

Amended 1

1. NAME AND ADDRESS OF APPLICANT Robert Sibley Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, IN 46268	2. PERMIT REQUESTED ("X" one) <input type="checkbox"/> Limited - Interstate Movement <input type="checkbox"/> Limited - Importation <input checked="" type="checkbox"/> Release into the Environment <input type="checkbox"/> Courtesy Permit	3. THIS REQUEST IS ("X" one) <input checked="" type="checkbox"/> New <input type="checkbox"/> Renewal <input type="checkbox"/> Supplemental
4. TELEPHONE NUMBER Area Code (317) 337-5463	5. MEANS OF MOVEMENT <input checked="" type="checkbox"/> Mail <input checked="" type="checkbox"/> Common Carrier <input checked="" type="checkbox"/> Baggage or Handcarried By whom: <u>Designated Employee</u>	

6. GIVE THE FOLLOWING (IF APPLICABLE OR MORE SPACE IS NEEDED, ATTACH ADDITIONAL SHEETS)

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism:	[]	Plant optimized synthetic genes sourced from mammalian species	CBI
b. Recipient Organism:	<i>Zea Mays</i>	Corn		
c. Vector or Vector Agent:	[]		CBI
d. Regulated Organism or Product:	[Pharmaceutical proteins	CBI
e. If product, list names of constituents:			produced in <i>Zea Mays</i>	


7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS Up to 200 acres at designated locations	8. DATE (or inclusive dates or period) OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE June 15, 2002 to December 31, 2003
9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE HI, IN	10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE [Release:] Yuma, AZ CBI] Corcoran, CA CBI
11. ANY BIOLOGICAL MATERIAL (e.g., culture medium, or host material) ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT Zea Mays plant tissue, defined as leaf, whole immature ears, roots, seeds, pollen, and or stalks.] Cochise, AZ CBI	

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

13. SEE REVERSE SIDE

I hereby certify that the information in the application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than \$10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON 	15. PRINTED NAME AND TITLE Robert Sibley Regulatory Specialist	16. DATE 5-24-02
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State Notification Letter Sent		State Review Received	Permit Issued <input type="checkbox"/> Yes <input type="checkbox"/> No
Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed <input type="checkbox"/> Yes <input type="checkbox"/> No
Signature of BBEP Official		Date	Expiration Date

ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a. Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article.	X	
b. A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the nonmodified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics).	X	
c. A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article.	X	
d. Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced.	X	
e. A detailed description of the purpose of the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f. A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article.	X	
g. A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).	X	
h. A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i. A detailed description of the proposed method of final disposition of the regulated article.	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.



Dow AgroSciences LLC

APHIS FORM 2000 ATTACHMENTS

Permit Summary Statement

Release In Yuma, AZ and Corcoran, CA

This permit involves the release of transgenic corn seeds that contain plant optimized genes that code [] a pharmaceutical protein sourced from mammalian species. The seeds will be transported from [] Molokai, HI to Yuma, AZ and Corcoran, CA. Once transported to the target site, the seeds will be planted in an isolated field for research and trait introgression only. After being harvested and dried, the seed will be transported back to Indianapolis, IN; San Diego, CA; and/or Midland, MI to be used for research purposes []

CBI

The corn will be grown in isolated fields in Yuma, AZ and Corcoran, CA using standard agronomic and containment practices as specified in 7CFR 340. Per USDA's request, three additional isolation conditions will also be followed 1) ensure that no other corn plants are grown within a radius of 0.5 miles of the transgenic plants, at any time during these field tests. 2) plant transgenic corn no less than 21 days before or 21 days after the planting date of any other corn that is growing within a zone extending from 0.5 to 1.0 miles of the transgenic test plants. 3) plant the transgenic corn at sites that are at least 1 mile away from corn seed production. A crop survey and GPS coordinates will verify the isolation distance. At harvest, grain will be collected for further research [] Harvest residues will be destroyed by an approved USDA method.

For interstate movement between HI, AZ, CA, IN and MI seed will be placed in appropriate containers, labeled and securely sealed as specified in 7 CFR 340. Seed for laboratory research and small plot work (<1ac) will be shipped in small lots 20-45 seeds/ bag in approx. 3.5x5 inch manila seed envelopes labeled, sealed, and stapled shut. Seed for larger plot work (1-5 acres) will be shipped in larger sealed paper bags inside sealed thick plastic bags within a shipping crate. Bulk seed from the harvest will be shipped bagged within sealable bulk containers in a closed bed private hire truck. All shipped grain will be labeled with the USDA number and appropriate addresses.

CBI

13a. Names, addresses and telephone numbers of the persons who developed and or supplied the regulated article.

13a.

[

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CBI

13b. A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non modified parental organism, (e.g. morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics).

13b.

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CBI

Selectable marker gene product:

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Statement of Fragment Purification:

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CBI

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CBI

13c. A detailed description of the molecular biology of the system (e.g. donor-recipient-vector) which is or will be used to produce the regulated article.

13c. [

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CBI

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No unusual physiological processes, morphological changes, or byproducts are expected to result in the transgenic corn.

Construct Descriptions:

A. designation of transformed line: Events to be identified in field trial reports

category: OO

phenotype: Pharmaceutical proteins produced [

]CBI

construct: pDAB8505

Genotype:

PDAB8505

Enhancer Elements: [

] from *Nicotiana tabacum* [

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CBI

Promoter: [

] from *Zea mays*

CBI

Leader Sequence: [

] from *Mus musculus* [

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CBI

Gene: [

], synthetically rebuilt to accommodate plant codon usage. [

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CBI

Terminator: [

] from *Zea mays*

CBI



Promoter: [] from *Zea mays* CBI

Leader Sequence: [] from *Mus musculus* [] CBI

Gene: [] synthetically rebuilt to accommodate plant codon usage. [] CBI

Terminator: [] from *Zea mays* CBI

Selectable Marker:

Promoter: [] from *Oryza sativa* [] CBI

Gene: PAT – synthetic, plant-optimized phosphinothricin acetyltransferase coding sequence from *Streptomyces viridochromogenes*

Terminator: [] from *Zea mays* [] CBI

B. designation of transformed line: Events to be identified in field trial reports

category: OO

phenotype: Pharmaceutical proteins produced [] CBI

construct: pDAB1411

Genotype:

PDAB1411

Enhancer Elements: [] from *Nicotiana tabacum*

[] CBI

Promoter: [] from *Zea mays* CBI



Gene: [] synthetically rebuilt to accommodate plant codon usage. [] CBI

Terminator: [] from *Zea mays* CBI

Promoter: [] from *Zea mays* CBI

Leader Sequence: [] from *Mus musculus* [] CBI

Gene: [] synthetically rebuilt to accommodate plant codon usage. [] CBI

Terminator: [] from *Zea mays* CBI

Selectable Marker:
Promoter: [] from *Oryza sativa* [] CBI

Gene: PAT – synthetic, plant-optimized phosphinothricin acetyltransferase coding sequence from *Streptomyces viridochromogenes*

Terminator: [] from *Zea mays* [] CBI



C. designation of transformed line: Events to be identified in field trial reports

category: OO

phenotype: Pharmaceutical proteins produced [.]

CBI
CBI

construct: [] pDAB1413 []

Genotype:

[]

CBI

PDAB1413

Enhancer Elements: [

] from *Nicotiana tabacum*

[

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CBI

Promoter: [

] from *Zea mays*

CBI

Gene: [

] synthetically rebuilt to accommodate plant codon usage. [

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CBI

Terminator: [

] from *Zea mays*

CBI

Promoter: [

] from *Zea mays*

CBI

Leader Sequence: [

] from *Mus musculus* [

]

CBI

Gene: [

] synthetically rebuilt to accommodate plant codon usage. [

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CBI

Terminator: [

] from *Zea mays*

CBI

Selectable Marker: (no selectable marker)



13d. Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced.

13d. [

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CBI

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CBI

13e. A detailed description of the purpose of the introduction of the regulated article including a detailed description of the proposed experiment and/or production design.

13e. [

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CBI

13f. A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the US to prevent contamination, release and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and the regulated article

13f. The corn will be grown in isolated fields in Yuma, AZ and Corcoran, CA using standard agronomic and containment practices as specified in 7CFR 340. Per USDA's request, three additional isolation conditions will also be followed 1) ensure that no other corn plants are grown within a radius of 0.5 miles of the transgenic plants, at any time during these field tests. 2) plant transgenic corn no less than 21 days before or 21 days after the planting date of any other corn that is growing within a zone extending from 0.5 to 1.0 miles of the transgenic test plants. 3) plant the transgenic corn at sites that are at least 1 mile away from corn seed production. A crop survey and GPS coordinates will verify the isolation distance. At harvest, grain will be collected for further research [Harvest residues will be destroyed by an approved USDA method..]

CBI

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CBI

For interstate movement between HI, AZ, CA, IN and MI seed will be placed in appropriate containers, labeled and securely sealed as specified in 7 CFR 340. Seed for laboratory research and small plot work (<1ac) will be shipped in small lots 20-45 seeds/ bag in approx. 3.5x5 inch manila seed envelopes labeled, sealed, and stapled shut. Seed for larger plot work (1-5 acres) will be



shipped in larger sealed paper bags inside sealed thick plastic bags within a shipping crate. Bulk seed from the harvest will be shipped bagged within sealable bulk containers in a closed bed private hire truck. All shipped grain will be labeled with the USDA number and appropriate addresses.

13g. A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location, production, propagation and manufacture location; proposed sale and distribution location).

Release: Planting approximately in June 2002 through December 2003.
Harvesting: approximately in September of 2002 through March of 2003

Introduction:

Release:
NUMBER OF STATES/TERRITORIES AND SITES:
AZ(1) CA(1)

[Yuma, AZ] CBI
[Contact: [] CBI
[] Corcoran, California 93212 CBI
[Contact: [] CBI

13h. A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations

13h. Please refer to Section 13f,g for an explanation of the procedural safeguards and intended movements of the regulated articles.

13i. A detailed description of the proposed method of final distribution of the regulated article.

13i. Seed and plant material will either be replanted as per containment conditions in 13f or shipped to USDA approved lab facilities for further research. Any seed or plant material not used for these purposes will be destroyed by disking under, grinding, burying, burning, or autoclaving.

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