

The collection of this information is authorized by the Plant Protection Act of 2000. The information will be used to determine eligibility to receive all types of permits. No permit will be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICE
APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340
(Genetically Engineered Organisms or Products)

1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT Name: (b)(6) Position: Organization: Applied Biotechnology Institute Organization Unique ID: Address: California Polytechnic State University, Bldg. (b)(6) San Luis Obispo, CA 94307 County/Province: Township/Island: Day Telephone: (b)(6) FAX: Alternate: Email 1: (b)(6) Email 2:	2. INTRODUCTION TYPE <input type="checkbox"/> Importation <input type="checkbox"/> Interstate Movement <input type="checkbox"/> Interstate Movement and Release <input checked="" type="checkbox"/> Release	3. PERMIT TYPE <input checked="" type="checkbox"/> Standard Permit <input type="checkbox"/> Courtesy Permit
4. PURPOSE OF PERMIT <input type="checkbox"/> Industrial Product <input checked="" type="checkbox"/> Pharmaceutical Product <input type="checkbox"/> Phytoremediation <input type="checkbox"/> Traditional		

5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)

Does this application contain CBI? Yes No

CBI Justification:

The information designated CBI in this submission is information that relates to processes and research data that have been maintained in secrecy by the Applied Biotechnology Institute, because its disclosure will jeopardize patent applications currently being prepared, and it will reveal critical information on confidential production processes used by ABI in its business operations. Based on previous destruction of transgenic plants by anti-GMO groups, we are also concerned about vandalism at the location of the field trial. It would be easy to identify the test plants in an area that has relatively few plots of corn grown therefore, we have kept the location confidential. Disclosure of such information will cause financial damage to ABI because it will result in the loss of its competitive position.

6. REQUEST TYPE

New Amendment Renewal Variance Amendment, Renewal and/or Variance

Amendment/Renewal Description:

Amend SOP No. RGP-10, Pre-Harvest and Harvest, by adding the following section:

4.5a Contingency Plan in the Event Harvested Seed Are Not Dry Enough to Shell

Prior to shelling, inspect ears for dryness. Those ears not dry enough to shell should be separated and bagged for transport. The ears should be placed in plastic bags with ties and these bags placed in labeled cardboard boxes. Use the same plastic bags indicated in SOP No. RGP-06, Seed Packaging and Shipment. The boxes should be labeled consistent with SOP No. RGP-05, ABI Seed Coding System. Seal the boxes with packing tape and place in an enclosed vehicle.

The boxed ears should be transported to our dedicated and locked storage shed (see SOP No. 14, Seed Storage, Section 5.4, first storage facility) for temporary storage. The transport vehicle should be cleaned according to SOP RGP-13, Seed Transport, and Form 13, Vehicle Cleanout Verification, should be completed. Move the boxes into one of two ABI greenhouses, approximately 10 and 50 feet from the storage shed. These greenhouses have been inspected by USDA and approved for the growing of transgenic plants. The greenhouses are locked and entry restricted to authorized personnel only. Place the ears in mesh bags and allow to air dry in the greenhouse. When the ears are dry enough to shell, shell by hand or use our dedicated sheller inside the greenhouse. Clean the sheller and any other equipment used inside the greenhouse as instructed in SOP No. RGP-12, Field Equipment Cleanout and complete Form 12, Field Equipment Cleanout Verification. The greenhouse should be cleaned by thoroughly sweeping the concrete floor with a dedicated greenhouse broom. Any loose seed should be collected and devitalized by autoclaving as instructed in SOP No. RGP-15, Seed Devitalization and Disposal, and Form 15, Seed Disposal Verification, completed.

WARNING: Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

Previous Permit Number(s): 08-337-106r

7. MEANS OF MOVEMENT

Seed for the trial will be moved from the ABI laboratory at California Polytechnic University (Cal Poly) in San Luis Obispo, California, to the test site in containers in a closed vehicle.

8. VARIANCE VERIFICATION

Have you previously applied for variance(s) that you wish to apply to this permit? Yes No

Variance Number(s): 08-004

If so, describe in a brief summary how the variance will be applied:

This variance is for packaging and shipping seed. We will package the harvested seed as described in this variance for the future shipment of seed. There will be a separate request for a movement permit for the future shipment at a later date.

9. REGULATED ARTICLE

Scientific Name: *Zea mays*

Common Name:

Any biological material (e.g., culture medium, or host material) accompanying the regulated Article during movement:

none

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

The transgenic corn plants were developed in College Station, Texas. The regulated material was transported to California under a USDA movement permit (06-059-02m). Some of the seeds were grown in San Luis Obispo, California in a greenhouse inspected by USDA to generate the seeds planned for the field planting.

Processes, Procedures, and Safeguards Description:

Donor organisms: All components of donor organisms are cloned DNA fragments contained in plasmids of *E. coli* or *Agrobacterium tumefaciens*, and maintained in the laboratories of Applied Biotechnology Institute under BL1 containment conditions.

Recipient organism: Non-transformed *Zea mays* has been cultivated in the field and propagated in the laboratory under standard good agricultural or laboratory practices.

Vector and vector agent: *Agrobacterium tumefaciens* has been maintained in the laboratory under BL1 containment conditions.

Regulated article: Transformed *Zea mays* has been maintained in the laboratory and greenhouse under BL1P containment conditions.

10. ARTICLE SUPPLIER AND/OR DEVELOPER

Name	Location	Contact Information
(b)(6)	Applied Biotechnology Institute California Polytechnic State University, Bldg. (b)(6) San Luis Obispo, CA 93407	Day Telephone: (b)(6) FAX: Email: (b)(6)

11. PHENOTYPES/GENOTYPE

1) Phenotypic Designation Name:	Other--00
Identifying Line(s):	[]
Construct(s):	[]
Mode of Transformation:	<i>Agrobacterium tumefaciens</i> , disarmed
Phenotype Description:	The construct used to generate the transgenic plants contains two plant transcription units for protein products. The first is the product from the selectable marker encoded by the PAT gene. This is isolated from <i>Streptomyces viridochromogenes</i> which produces the enzyme phosphinothricin N-acetyltransferase. This enzyme is used to confer resistance to the commercial herbicide Finale from Bayer and related compounds. This gene is constitutively expressed throughout the plant and is the same gene used for many transgenic plants including commercialized corn plants used in crop improvement. The second transgenic product is that of the surface antigen from the hepatitis 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 non-modified parental organism.	

virus (HepBSAg). This is a structural protein and has no enzymatic or toxic activity. This protein is currently used to make the commercial vaccine for hepatitis B (e.g. Recombivax HB by Merck) and millions of people have been injected with this protein. A promoter which has been shown to provide expression specific to the embryo of maize (Belanger and Kriz, Plant Physiol. 91:636, 1989) is used to drive the expression of this protein. [

] Both of these proteins are unique to the corn plant and are not present in wild type plants. The only observed change in phenotype is herbicide resistance attributed to the PAT gene and the HebBSAg protein that can be only be detected by biochemical assays.

Phenotype(s)

OO - Pharmaceutical Protein

Genotype(s)

Gene(s) of Interest

Promoter: globulin-1 **from** Zea mays - Promoter from the Zea mays globulin-1 gene

Enhancer: alpha amylase signal sequence **from** Hordeum vulgare - Hordeum vulgare alpha amylase signal sequence, serving as an enhancer and targeting sequence

Gene: Hepatitis B virus surface antigen **from** Hepatitis virus B - Hepatitis B virus surface antigen codon optimized for Zea mays

Terminator: proteinase inhibitorII **from** Solanum tuberosum - Terminator from Solanum tuberosum proteinase inhibitor II gene

Selectable Marker

Promoter: 35S **from** Cauliflower mosaic caulimovirus - Cauliflower mosaic caulimovirus 35S promoter

Gene: phosphinothricin N-acetyltransferase **from** Streptomyces viridochromogenes - Streptomyces viridochromogenes phosphinothricin N-acetyltransferase codon optimized for Zea mays

Terminator: 35S **from** Cauliflower mosaic caulimovirus - Cauliflower mosaic caulimovirus 35S terminator

12. INTRODUCTION

Release Site

<u>Location Name & Description</u>	<u>Location Address</u>	<u>Contact(s)</u>
1) ABI site 2008-1	[CA Proposed Release Start Date: 5/20/2009 Proposed Release End Date: 11/17/2009 No. of Releases: 1 Quantity: 0.5 acres Comments: []	1) (b)(6) Day Telephone: (b)(6) Email 1: (b)(6)

Location Unique ID:	ABI08337106dr
Location GPS Coordinates:	[], [] [], [] [], [] [], []
Release Site History:	The site and area to be monitored has been under managed agricultural production

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The site and area to be monitored has been under managed agricultural production for the past several years. There have only been forage crops, cover crops and grapes grown on the site and area to be monitored.

Critical Habitat Involved?: Yes No

13. DESIGN PROTOCOLS

Production Design

A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:

Purpose of Introduction and Intended Use:

[

Description of the Field Plot Design:

Description of the Field

Description of the Field Plot Design:

1. Field Site Location:

[

]

2. Distance to Reproductively Compatible Plants:

Adjacent fields are used for cultivation of forage grasses and grapes. [

] pollen flow will be controlled by placing bags around the corn tassels and pollination will be done by hand. In addition, the transgenic corn will be planted no less than 28 days before or 28 days after any corn growing in a zone extending from 2,640 to 5,280 feet from the field test site.

[

]

3. Field Trial Supervisor:

(b)(6) will act as the field trial supervisor

Office (b)(6)
 Mobile (b)(6)

Destination or Release Description

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):

[

] This is the final destination of the regulated seed where it will be devitalized by grinding followed by selected processing applications including degermination, defatting, flour preparation and extrusion. The devitalized processed grain will then be used in laboratory analysis to determine the stability of the transgenic protein under various conditions. Some of the processed material will also be used in experiments to [

]

Confinement Protocols

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:

[

]

Final Disposition Method:

Destruction/Devitalization Other Storage in Contained Facility

Final Disposition Description:

[

] This is the final destination of the regulated seed where it will be devitalized by grinding followed by selected processing applications including degermination, defatting, flour preparation and extrusion. The devitalized processed grain will then be used in laboratory analysis to determine the stability of the transgenic protein under various conditions. Some of the processed material will also be used in experiments to [

] The remainder of the seed will be stored in a locked storage container at an ABI-dedicated and locked storage area. ABI will use the material for further analysis of protein integrity as well as for growing seeds in the greenhouse to improve agronomic characteristics of the plants.

14. ATTACHMENTS**Attachments**

ABI SOPs_CBI-deleted (11/2/2009 @ 09:39 PM)
Data 4-10-09_CBI deleted (11/2/2009 @ 09:39 PM)
Letter of Completeness CBI-deleted (11/2/2009 @ 09:39 PM)
Requested Pictures CBI deleted (11/2/2009 @ 09:39 PM)
Response to Aphis CBI deleted (11/2/2009 @ 09:39 PM)

15. ADDITIONAL INFORMATION

16. COURTESY JUSTIFICATION

I, (b)(6) hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

I will not introduce the regulated articles described in this application until APHIS has deemed the application complete and has granted the permit. By signing this permit, I agree to comply with any and all state, local, and tribal laws and regulations that may apply to the introduction of the articles described in this applications.

If there are any changes to the information disclosed in this application, I will contact APHIS.

17. SIGNATURE OF RESPONSIBLE PERSON

(b)(6)

18. DATE

November 2, 2009