OMB APPROVED
0579-0085

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICE

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

INSTRUCTIONS: PLEASE TYPE OR PRINT CLEARLY. PERMITS ARE NOT ISSUED TO P.O. BOXES. READ THE ENTIRE APPLICATION BEFORE COMPLETING. ENCLOSE THE SUPPORTING MATERIALS LISTED ON PAGE 2. SEE PAGE 3 FOR DETAILED INSTRUCTIONS. ATTACH ADDITIONAL SHEETS OF PAPER IF MORE SPACE IS NEEDED.

1. NAME, ADDRESS, OF APPLICANT

2. PERMIT REQUESTED *("X" one)*

- ☐ Limited - Interstate Movement
- ☐ Limited - Importation
- ☐ Release into the Environment
- ☐ Courtesy Permit

3. THIS REQUEST IS *("X" one)*

- ☐ New
- ☐ Renewal
- ☐ Supplemental

4. TELEPHONE NUMBER

Area Code ( )

5. MEANS OF MOVEMENT

- ☐ Mail
- ☐ Baggage or Hand-carried
- ☐ Common Carrier
- By whom_____

6. GIVE THE FOLLOWING (If applicable)	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism				
b. Recipient Organism				
c. Vector or Vector Agent				
d. Regulated Organism or Product				
e. If product, list names of constituents				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

8. DATE *(or inclusive dates of period)* OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT

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

13. SEE PAGE 2

WARNING: Any alteration, forgery, or unauthorized use of this document is subject to civil penalties of up to $250,000 (7 U.S.C. s7734(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. s1001).

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

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE

FOR APHIS USE ONLY

State Notification Sent		State Review Received	Permit Issued Yes No
Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed Yes No
Signature of BRS 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.		
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 (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).		
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.		
d. Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced.		
e. A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.		
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.		
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).		
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.		
i. A detailed description of the proposed method of final disposition of the regulated article.		

INSTRUCTIONS - APHIS FORM 2000

This application form may be used to apply for a limited permit for interstate movement or importation; a permit for release into the environment; or a courtesy permit.

Two copies of this application must be submitted to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, BRS, Unit 147, 4700 River Road, Riverdale, MD 20737.

Each copy of the application must be signed by the "responsible person." The responsible person is the person who has control and will maintain control over the introduction of the regulated article and ensure that all conditions contained in the permit and regulations in 7 CFR Part 340 are complied with. A responsible person must be a resident of the United States or designate an agent who is a resident of the United States.

Confidential Business Information

If there are portions of the application deemed to contain trade secret or confidential business information (CBI), each page of the application containing such information should be marked "CBI Copy." In addition, those portions of the application which are deemed "CBI" will be so designated. The second copy will have all such CBI deleted and will be marked on each page of the application where CBI was deleted "CBI Deleted." If an application does not contain CBI, the first page of both copies will be marked "No CBI."

Limited Permit for Interstate Movement or Importation

The responsible person seeking a limited permit for interstate movement or importation must complete all items on the application EXCEPT 12, 13(a), (b), (e), and (f).

a. Interstate Movement - The responsible person may apply for a single limited permit for the interstate movement of multiple regulated articles in lieu of submitting an application for each individual interstate movement. Each limited permit issued will be valid for 1 year from the date of issuance. If a permit is sought for multiple interstate movements between contained facilities, the responsible person will specify in the permit application all the regulated articles to be moved interstate; the origins and destinations of all proposed shipments; a detailed description of all the destinations (contained facilities) where regulated articles will be utilized; and a description of the containers that will be used to transport the regulated articles. A limited permit for interstate movement of a regulated article will only be valid for the movement of those regulated articles moving between those locations specified in the application. If a person seeks to move regulated articles other than those specified in the application, or to locations other than those listed in the application, a supplemental application will be submitted to BRS. No person will move a regulated article interstate unless the number of the limited permit appears on the outside of the shipping container. The responsible person who ships a regulated article interstate will keep records for 1 year to demonstrate that the regulated article arrived at its intended destination.

b. Importation - The responsible person seeking a limited permit for the importation of a regulated article will submit an application for a permit prior to the importation of EACH shipment of regulated articles. The responsible person importing a regulated article will keep records for 1 year demonstrating that the regulated article arrived at its intended destination.

Permit for Release into the Environment

The responsible person seeking a permit for release into the environment of a regulated article should complete this form in its entirety by submitting data called for by items (1) - (16).

Courtesy Permit

The responsible person seeking a courtesy permit for the introduction (importation, interstate movement, or release into the environment) of genetically engineered organisms not subject to regulation under Part 340 must complete items (1) through (4), (6), (9), (12), (13(b)), and (14) through (16).

Standard Permit Conditions
For the Introduction of a
Regulated Article
(7 CFR 340.4(f))

Permit Conditions: A person who is issued a permit and his/her employees or agents shall comply with the following conditions , and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit.

(4) The regulated article shall be maintained only in areas and premises specified in the permit.

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article.

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation.

(7) The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article.

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Administrator to be necessary to prevent spread of plant pests.

(9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment.

(10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);

(ii) Notify APHIS promptly upon arrival of any regulated article at a port of entry, or its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with 7 CFR 340.7.