

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.

| | | |
|---|---|--|
| 1. NAME AND ADDRESS OF APPLICANT | 2. PERMIT REQUESTED ("X" one) <input type="checkbox"/> Limited - Interstate Movement <input type="checkbox"/> Limited - Importation <input type="checkbox"/> Release into the Environment <input type="checkbox"/> Courtesy Permit | 3. THIS REQUEST IS ("X" one) <input type="checkbox"/> New <input type="checkbox"/> Renewal <input type="checkbox"/> Supplemental |
| 4. TELEPHONE NUMBER Area Code () | 5. MEANS OF MOVEMENT <input type="checkbox"/> Mail <input type="checkbox"/> Common Carrier <input type="checkbox"/> Baggage or Handcarried By whom _____ | |

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

| | <u>Scientific Name</u> | <u>Common Name</u> | <u>Trade Name</u> | <u>Other Designation</u> |
|--|------------------------|--------------------|-------------------|--------------------------|
| a. Donor Organism: | | | | |
| b. Recipient Organism: | | | | |
| c. Vector or Vector Agent: | | | | |
| d. Regulated Organism or Product: | | | | |
| e. If product, list names of constituents: | | | | |

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| 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 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 | 16. DATE |
|--|-----------------------------------|-----------------|

| FOR APHIS USE ONLY | | | |
|--------------------------------|-----------------------|---|--|
| 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. | | |
| 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). | | |
| 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 of 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. | | |

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.