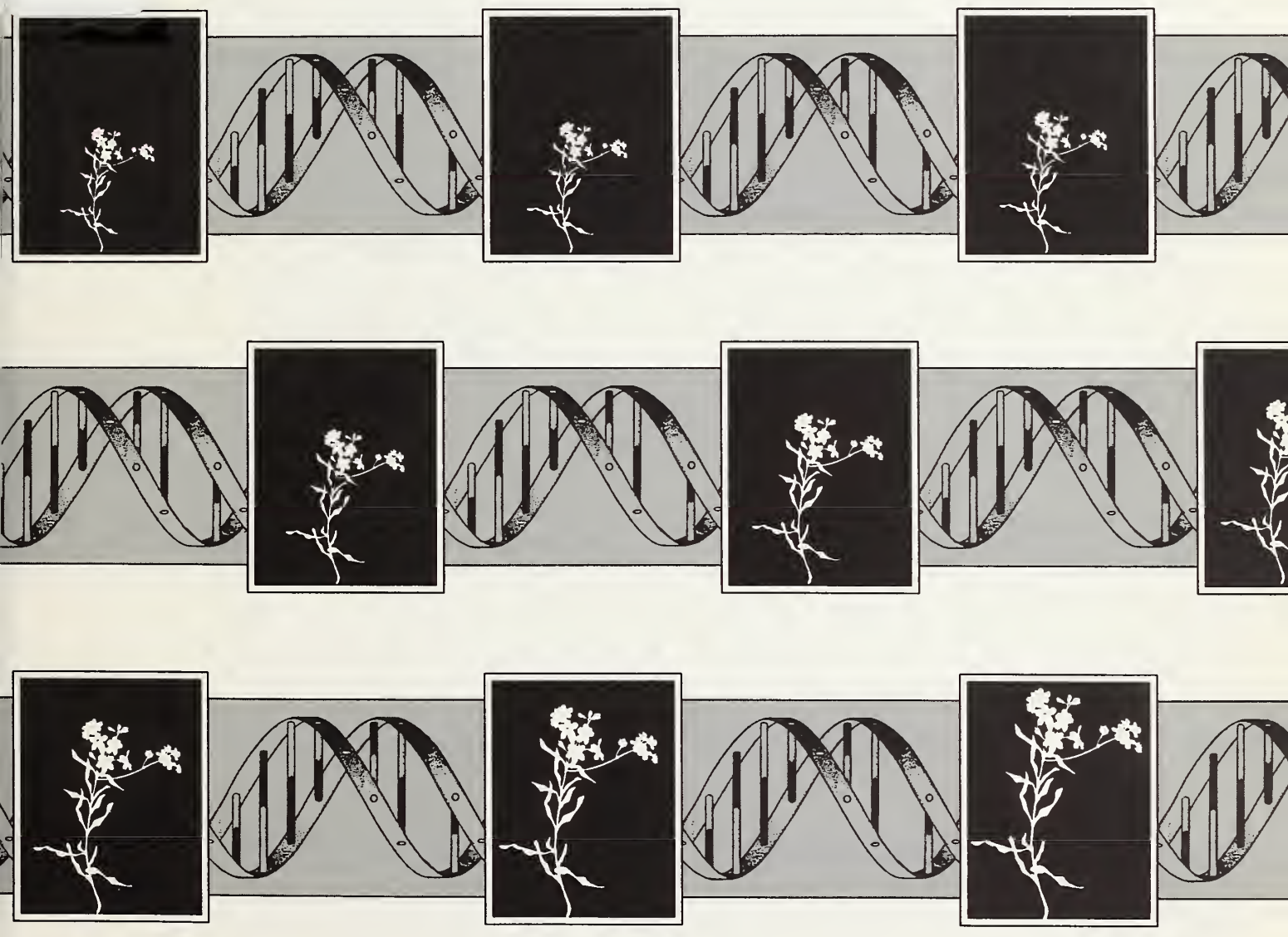
United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

APHIS 21-35-001

Questions and Answers on Biotechnology Permits for Genetically Engineered Plants and Microorganisms

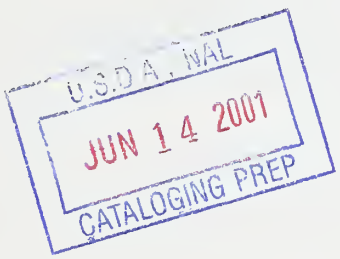


Biotechnology, Biologics, and Environmental Protection
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
6505 Belcrest Road
Hyattsville, MD 20782
Area Code (301) 436-7612
Issued: April 1991

Foreword

This brochure answers questions about permits for the importation, interstate movement, or environmental release of certain genetically engineered plants and microorganisms regulated under 7 CFR Part 340. If you would like additional material or sample applications for movement or release permits, please fill out and return to us the card in this brochure. If you have any questions, please call our Biotechnology Permits staff at Area Code (301) 436-7612.

Terry L. Medley, J.D. , Director
Biotechnology, Biologics,
and Environmental Protection



Questions and Answers on General Regulatory Policy Under 7 CFR 340

1. When is an APHIS permit needed?

A. A permit is required to introduce a regulated article.

2. What is a regulated article?

A. A regulated article is an organism that has been genetically engineered (via recombinant DNA techniques) from a donor organism, recipient organism, vector or vector agent, any of which is a plant pest or contains plant pest components. APHIS regulations in 7 CFR 340.2 list such organisms. Other genetically engineered organisms may be regulated articles if they have been genetically engineered using an unclassified organism or if the Director of Biotechnology, Biologics, and Environmental Protection determines that the genetically engineered organism is a regulated article.

3. Are there classes of microorganisms that are not regulated articles?

A. Yes. Recipient microorganisms that are not plant pests and that result from the addition of genetic material containing only noncoding regulatory regions can be introduced without a permit.

4. What is meant by the term "introduce"?

A. Introduce means to import, move interstate, or release into the environment.

5. What is a plant pest?

A. A plant pest is defined as "any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease in or damage to any plants or parts thereof; or any processed, manufactured, or other products of plants."

6. Whom do I contact if I am uncertain as to whether the organism is a plant pest or a regulated article?

A. Contact the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). Include the following information: geographical source of the organism; whether or not the organism has been genetically engineered; biological, biochemical, molecular, or genetic data that would support the claim of nonplant pest status of the organism (including published or unpublished data); and any additional information that could affect APHIS' decision on the pest status of the organism. Send this information to:

Deputy Director for Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
USDA - APHIS
6505 Belcrest Road, Room 844A
Hyattsville, MD 20782
Area Code (301) 436-7612

7. Do the APHIS regulations apply to an organism if it is genetically engineered but no plant pest component is used in the modification process?

A. No. For APHIS regulations to apply, there must be a plant pest component involved in the modification process, or the organism used in the engineering process must be an unclassified organism, or there must be reason to believe that the resulting organism is or will be a plant pest.

8. Do the APHIS regulations cover the exportation and intrastate movement of a regulated article?

A. The exportation and the **intra**state movement of a regulated article are not covered per se by the APHIS regulations. A permit would be required for the "in transit" movement of a regulated article in the course of the exportation of a regulated article. For example, if in exporting a regulated article to Mexico City, the article were moved via St. Louis and Dallas, an **inter**state movement permit would be required for the movement of the article between St. Louis and Dallas. If the article were exported directly from St. Louis to Mexico City, an intrastate movement permit would not be required.

The USDA's Agricultural Marketing Service regulates the exportation of both genetically engineered and conventionally bred tobacco plants under the Tobacco Plant and Seed Exportation Act. Before exporting these plants, check with the Market Information and Program Analysis Branch of the Tobacco Division of the Agricultural Marketing Service in Washington, DC, at Area Code (202) 447-3489. In addition, the export of certain genetically engineered organisms to specific countries requires a license from the U.S. Department of Commerce, Bureau of Export Administration, Washington, DC, at Area Code (202) 377-5695.

The **intra**state movement of a regulated article may be a matter of State jurisdiction.

9. Is the introduction of an organism regulated if genetic engineering is used in combination with other techniques, such as direct injection, electroporation, embryo rescue, or somaclonal variation?

A. Yes. If during any part of the process genetic engineering is used and a plant pest component is involved, the resulting organism will be regulated.

10. Are subsequent generations of regulated articles regulated?

A. Any subsequent generation of a regulated article is subject to APHIS regulations.

11. Is it possible to have an organism exempted from the regulations? How do I accomplish this?

A. Yes. Use the petition process in APHIS regulations (7 CFR 340.4). Submit data and information to show that the organism in question is not a plant pest. Include copies of scientific literature, unpublished studies, and data from tests performed, even if they are unfavorable. Trade secrets or confidential business information (CBI) should *not* be included.

12. What is the APHIS policy on protecting CBI?

A. APHIS treats CBI as data that may be protected from disclosure under the Freedom of Information Act. CBI includes trade secrets and commercial or financial information found to be confidential. The applicant needs to identify the CBI in the application.

Documents containing trade secrets will be treated as CBI. "Trade secrets" refers to information relating to the production process, such as formulas, quality control tests and data, and research methodology. Such information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.

In addition, documents containing financial or commercial information that the applicant does not want disclosed for competitive reasons are treated confidentially. The applicant needs to submit a detailed statement explaining the potential for competitive harm if this information is disclosed.

13. If I comply with APHIS regulations, do I have to comply with regulations from other Federal agencies?

A. Yes. You must comply with all applicable regulations. Genetically engineered microorganisms may be regulated by the Environmental Protection Agency (EPA), and genetically engineered plants and microorganisms to be used as food may be regulated by the Food and Drug Administration (FDA).

14. How do I apply for approval for importation, interstate movement, or introduction of a regulated article?

A. You must submit an application form (APHIS Form 2000) to the Biotechnology Permits unit of Biotechnology, Biologics, and Environmental Protection. Form 2000 is used to apply for a permit to import a regulated article, to move it interstate, to release it into the environment, or to request a courtesy permit.

15. Can an application be modified once the APHIS review process has started?

A. Yes. However, proposed modifications should be brought to the attention of the Biotechnology Permits unit as early as possible so that the review process can be completed on time.

16. What recourse do I have if a permit is denied or revoked?

A. You can appeal the decision. The procedures are found in the APHIS regulations.

17. Are there any regulated articles for which interstate movement permits are not required?

A. Yes. Two types of regulated articles do not require a permit for interstate movement:
1) strains of *Escherichia coli* (K12 and its derivatives) that contain genetic material derived from a plant pest and
2) plants or plant parts of *Arabidopsis thaliana* containing genetic material derived from a plant pest stably integrated into the plant genome.

These exemptions from permitting requirements for interstate movement are dependent upon certain conditions for biological and physical containment as specified in 7 CFR 340.2(b) of the regulations.

18. If I plan to move interstate or to import a conventional plant pest that has *not* been modified by genetic engineering but that I plan to modify by genetic engineering techniques, do I need to apply for a permit on Form 2000?

A. No. However, to so move or import a nonindigenous, nongenetically engineered plant pest, a permit is required. To obtain this permit (PPQ Form 526) and additional information, write to:

Biological Assessment and Technical Support Staff
USDA - APHIS - Plant Protection and Quarantine
6505 Belcrest Road, Room 625
Hyattsville, MD 20782

19. Is the movement of disarmed strains of *Agrobacterium tumefaciens* or other disarmed plant pests regulated?

A. Yes. A permit is a certification that the organism has been disarmed and does not present a risk of plant pest introduction.

20. How soon can I get a permit?

A. Interstate movement, importation, or courtesy permits are issued within 60 days of APHIS' receipt of your application.

21. After my movement permit application is received by your office, what happens next?

A. The application is reviewed, a preliminary pest risk analysis is made, and a letter requesting review is sent to the State regulatory official. If APHIS and State officials have not inspected the receiving facility, they will arrange for an inspection. You will receive written notification of approval or denial.

22. Why do facilities need to be inspected?

A. The inspections verify that the facility is adequate to prevent release of a regulated article into the environment.

23. What will the inspectors look for during laboratory, growth chamber, and greenhouse inspections?

A. The inspector will review the facilities, personnel, physical security, and operational procedures and determine if National Institutes of Health guidelines for good laboratory, growth chamber, and greenhouse practices are being followed.

24. What events require mandatory reporting to APHIS after a movement or importation permit is used?

A. If an accidental or unauthorized release of a regulated article occurs, you must orally notify the Biotechnology Permits unit immediately and send written notification within 24 hours.

25. Do permits need to be renewed?

A. Permits are valid for 1 year from the date of issuance. A renewal is required if additional material is to be moved after this period.

26. Can a regulated article be given to another person in my lab?

A. Yes. When a permit is issued, one person must maintain control of the regulated article to make sure all permit conditions are met. However, this "responsible person" may give the regulated article to another person if the former agrees to maintain control of the regulated article and comply with all permit conditions.

27. Who should be the responsible person for a movement permit—the shipper or recipient of the regulated article?

A. The responsible person may be either the shipper or the recipient, but that person must ensure that all permit conditions are met. If the responsible person is the shipper, the shipper must make sure that the recipient is aware of all permit conditions.

28. If my laboratory moves, do I need to submit a new permit application for all regulated articles?

A. Yes. Because the permit is issued for work in a specific facility, moving your laboratory would require an inspection of the new facility. Contact the Biotechnology Permits unit for guidance (address and phone number are on the inside cover.)

29. Do I need a separate permit for each importation or interstate movement of a regulated article?

A. A separate permit must be requested for each importation of a regulated article. However, a permit may be issued for the importation of multiple regulated articles in the course of a single importation. APHIS may grant a single permit that is valid for multiple interstate movements of a regulated article or for the interstate movement of multiple regulated articles.

30. What is the purpose of a courtesy permit, and under what circumstances should it be requested?

A. The purpose of a courtesy permit is to facilitate the movement or the release into the environment of genetically modified organisms that are *not* regulated articles.

31. How long does it take to obtain a permit for release of a regulated article into the environment?

A. Release permits are issued within 120 days of APHIS' receipt of your application.

32. After my permit application is received, what happens next, and whom do I contact during the review process?

A. After receipt of the application, APHIS personnel review the CBI copy and the nonconfidential business information copy for completeness. If complete, the permit application is given an application number and assigned to a scientific reviewer, the responsible person is notified, and the 120-day review period begins. If the permit application is not complete, the responsible person is notified. During the review period, all correspondence (which must contain the application number) should be directed to the Deputy Director of the Biotechnology Permits unit. Notification of approval or denial will be in writing.

33. Must I notify the authorities in the State where an introduction is proposed?

A. No. Federal regulations require APHIS to notify appropriate State officials before the final decision is made on an application.

34. What is an environmental assessment, and under what law is it prepared?

A. An Environmental Assessment (EA) is a document that analyzes the environmental impacts associated with an environmental release permit. EA's are prepared in accordance with the National Environmental Policy Act (NEPA), Council on Environmental Quality regulations, and the USDA's NEPA procedures.

35. Can I use one permit application to support field tests in more than one State?

A. Yes.

36. Do field trials have any limits in size?

A. No, but APHIS officials take into consideration the size of the field trial when they determine the significance of the impact on the environment.

37. When will USDA inspect the field test site?

A. An APHIS representative will inspect the site either at or near the beginning of the field test, possibly during the course of the trials, and shortly after the harvest.

38. Does a permit for release into the environment have an expiration date?

A. The experiment must be started within 1 year from the date the permit is issued.

39. Is there a maximum time limit on field tests?

A. No, but periodic status reports will be required if the field test exceeds 1 year.

40. What events require mandatory reporting to APHIS after a release permit has been issued?

A. If an accidental or unauthorized release of a regulated article occurs, you must orally notify the Biotechnology Permits unit immediately and send written notification within 24 hours. APHIS must be notified in writing within 5 days if the regulated article or associated host organisms are found to have characteristics substantially different from those listed in the permit application or if they have an unanticipated effect on nontarget organisms.

41. What conditions must be met for a subsequent application to be considered a renewal?

A. (1) The field trial must occur in the same county as the previous trial.

(2) The field trial must be essentially the same as the one previously approved.

(3) A new APHIS Form 2000, indicating the application is for a renewal, must be submitted with a photocopy of the previous submission. Include a statement indicating what changes in the field test design, if any, are planned.

42. How can I obtain a copy of an applicant's submission?

A. A submission can be obtained by sending a written request to:

Freedom of Information Act Coordinator
USDA, APHIS, LPA, PI
6505 Belcrest Road, Room 600 FB
Hyattsville, MD 20782

Include the APHIS application number or the Federal Register Notice citation, the applicant's name, name of the engineered organism, and the location and date of the test.

43. How may I obtain copies of completed environmental assessments?

A. Submit a written request to the Biotechnology Permits unit. Include the APHIS application number or the Federal Register Notice citation, the applicant's name, name of the engineered organism, and the location and date of the test.

Notes

I would like the following material/information:

- ☐ APHIS Form 2000 (APHIS Form 2000 is used to apply for interstate movement, importation, release into the environment, and courtesy permits.)
- ☐ Sample applications for interstate movement, importation, and courtesy permits
- ☐ Sample application for release into the environment
- ☐ Regulations for genetically engineered plants and microorganisms (7 CFR Part 340)
- ☐ Confidential business information - instructions and policy statement

Name and Address: _____

_____

_____

_____

Phone: _____ Fax: _____

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