(d) *Duration.* State experimental use permits shall be issued for a specified period of time, not to exceed three years, depending upon the nature of the pest problem and the requirements of the testing program submitted. The designated State agency may renew, extend or amend the stated duration of a permit, if circumstances warrant.

(e) *Limitations.* The designated State agency shall impose such limitations in the permit as are necessary to protect health and the environment, including limitations on quantity, sites, area, disposal, and other aspects of pesticide use.

(f) *Program surveillance and reporting of data.* (1) The permittee shall supervise the test program and evaluate the results of testing at each site of application. The designated State agency shall require the permittee to report to it immediately any adverse effects resulting from use of, or exposure to, the pesticide.

(2) During the course of the program, the designated State agency shall require the permittee to submit such reports (both special and periodic) as are necessary to supervise effectively the progress of the program to prevent unreasonable adverse effects on man or the environment. The designated State agency shall also require the permittee to submit a final report at the conclusion of the program. Where applicable, such reports shall also be made available to the U.S. Department of Agriculture, Food Service and Quality Service (FSQS), as required by §172.8(c).

(g) *Disposal.* All pesticides and pesticide containers, whether disposed of during the course of a State permit or remaining at the termination of a permit, must either be:

(1) Disposed of in accordance with a disposal plan approved as part of the experimental program; or

(2) Returned to the permittee for storage or disposal in accordance with the requirements of RCRA and rules there under; or

(3) If the product is currently registered, used in accordance with the registered label.

[44 FR 41787, July 18, 1979, as amended at 60 FR 32097, June 19, 1995]

§172.26 EPA review of permits.

(a) *Notification of State action.* (1) Within 10 days after the issuance of an experimental use permit, the designated State agency shall notifiy EPA of the action by forwarding to the appropriate EPA Regional Office a copy of the permit, a description of the experimental program to be conducted under the terms of the permit, a copy of the approved labeling, and a copy of the confidential statement of formula for any new product.

(2) Within 10 days after amendment or revocation of an experimental use permit by a State, the designated State agency shall notify the appropriate EPA Regional Office in writing of the amendment or revocation. The notice shall include a brief explanation of the reason for the amendment or revocation. If amendments to permits include changes in the approved labeling, the designated State agency shall also forward a copy of the amended labeling.

(3) EPA shall give notice in the FEDERAL REGISTER of State issuance of experimental use permits.

(b) *Reports.* The designated State agency shall submit the following reports to EPA:

(1) An annual report covering the number of permits issued, the names and addresses of permittees, the names of the products covered by permits, and the State permit numbers issued;

(2) Reports, as requested by EPA, containing any information that EPA may determine necessary to ensure that a State has acted in compliance with provisions of FIFRA and this subpart; and

(3) Reports of any serious adverse effect(s), as soon thereafter as possible, from use of, or exposure to, a pesticide used pursuant to an experimental use permit.

(c) *Revocation by EPA.* (1) The Administrator may revoke an experimental use permit issued under this subpart if he finds:

(i) That its terms and conditions are being violated;

(ii) That its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment;

(iii) That new evidence demonstrates that any tolerance or food additive regulation upon which the permit is based

will be inadequate to protect the public health, or that any exemption from the requirement for a tolerance or food additive regulation is no longer appropriate; or

(iv) That a failure by the permittee to meet any other provisions of FIFRA or this subpart has occurred.

(2) The Administrator shall, prior to revoking a State experimental use permit, consult with the State agency which issued the permit, except in cases where continued use of the pesticide under the permit would create an imminent hazard to man or the environment.

(3) The Administrator shall notify the designated State agency, in writing, of the revocation, and the State agency shall notify the permittee, also in writing, of the revocation.

(4) The permittee shall notify all participants of the revocation within 10 days after he receives notice of revocation.

(5) The revocation of a permit shall not preclude the Administrator from initiating civil or criminal sanctions for violations of the permit conditions or other violations, as authorized by law.

(6) If a permittee wishes to contest the revocation of a State experimental use permit, he shall, within 30 days after receipt of notice of such revocation, file with the Administrator a written request for an opportunity to confer with the Administrator or his designee. The revocation of the permit shall remain effective pending the outcome of any conference requested under this paragraph.

(7) If a permittee requests a conference under paragraph (c)(6) of this section, the Administrator shall provide the permittee:

(i) With information as to the time, place and nature of the conference, and of the matters of fact and law asserted by the Agency as grounds for the revocation action;

(ii) An opportunity to offer a written statement of facts, explanations, and arguments relevant to the revocation action;

(iii) All other procedural opportunities to which the permittee may be entitled by law.

(8) The Administrator shall notify the affected permittee and State Agency, in writing, of his final decision on the revocation matter as expeditiously as possible and shall attempt to do so within 30 days after the conclusion of a conference conducted under paragraph (c)(7). The Administrator shall also provide the permittee and the State agency with a written statement of the reasons for his decision, which shall take into account the evidence presented pursuant to paragraph (c)(7)(ii) of this section.

(9) A decision to revoke a permit under paragraph (c)(8) of this section is a final Agency action subject to judicial review as provided by law.

Subpart C—Notification for Certain Genetically Modified Microbial Pesticides

SOURCE: 59 FR 45612, Sept. 1, 1994, unless otherwise noted.

§ 172.43 Definitions.

Terms used in this subpart shall, with the exception of those defined below, have the meaning set forth in the Act and in § 172.1.

Containment and inactivation controls means any combination of mechanical, procedural, or biological controls designed and operated to restrict environmental release of viable microorganisms from a facility.

Deliberately modified means the directed addition, rearrangement, or removal of nucleotide sequences to or from genetic material.

Introduction of genetic material means the movement of nucleotide sequences into a microorganism, regardless of the technique used.

Inversions of genetic material means the replacement of an internal section of a chromosome in the reverse orientation.

Microbial pesticide means any pesticide whose active ingredient is a microorganism intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant.