

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the microorganism will not present an unreasonable risk of injury to health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law, for the microorganism that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received MCANs for some or all of the activities designated as significant new uses of the microorganism and, after reviewing such MCANs, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) For a microorganism added to subpart M of this part under § 725.980, EPA has examined new information, or has reexamined the test data or other information supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act and has concluded that a rational basis no longer exists for the findings that activities involving the microorganism

may present an unreasonable risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act.

(5) For a microorganism added to subpart M of this part under § 725.980, certain activities involving the microorganism have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) Procedures for limitation or revocation. Modification or revocation of significant new use notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in § 725.980 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in § 725.980 by writing to the Director, or a designee, and stating the basis for such request. The request must be accompanied by

information sufficient to support the request. All requests should be sent to the TSCA Document Processing Center (7407), Room L-100, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, ATTN: Request to amend SNUR.

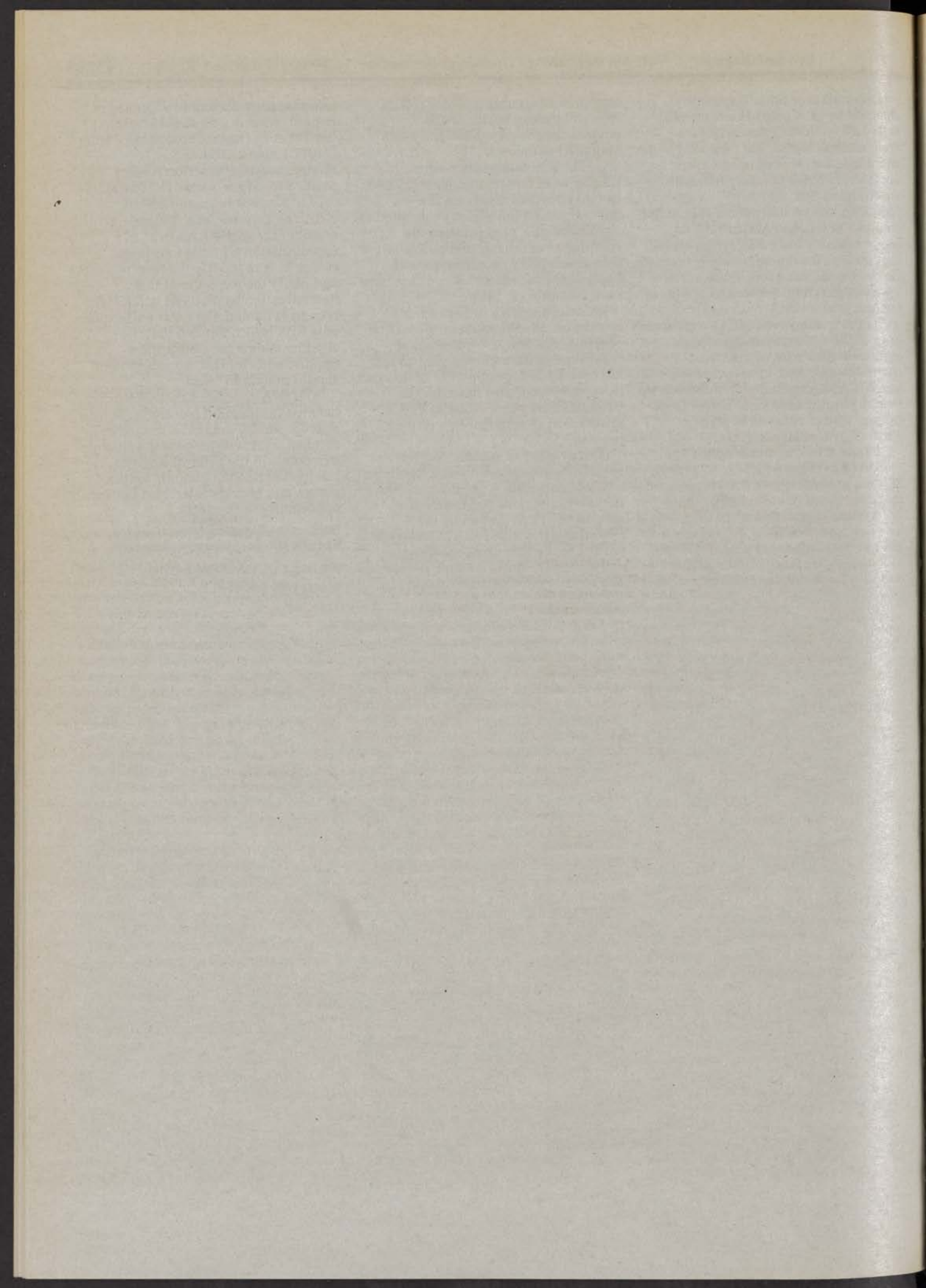
(2) The Director, or a designee, will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that microorganism should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a microorganism should be limited or revoked, EPA will propose the changes in a notice in the **Federal Register**, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

Subpart M—Significant New Uses for Specific Microorganisms—[Reserved]

[FR Doc. 94-21359 Filed 8-31-94; 8:45 am]

BILLING CODE 6560-50-F



Federal Register

Thursday
September 1, 1994

Part IV

**Department of the
Interior**

Fish and Wildlife Service

50 CFR Part 20

**Migratory Bird Hunting: Seasons, Limits,
and Shooting Hours; Establishment, Etc.:
Final Rule**

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR PART 20

RIN 1018-AA24

Migratory Bird Hunting; Early Seasons and Bag and Possession Limits for Certain Migratory Game Birds in the Contiguous United States, Alaska, Hawaii, Puerto Rico, and the Virgin Islands

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This rule prescribes the hunting seasons, hours, areas, and daily bag and possession limits of mourning, white-winged, and white-tipped doves; band-tailed pigeons; rails; moorhens and gallinules; woodcock; common snipe; sandhill cranes; sea ducks; early (September) waterfowl seasons; migratory game birds in Alaska, Hawaii, Puerto Rico, and the Virgin Islands; and some extended falconry seasons. Taking of migratory birds is prohibited unless specifically provided for by annual regulations. This rule will permit taking of designated species during the 1994-95 season.

EFFECTIVE DATE: September 1, 1994.

FOR FURTHER INFORMATION CONTACT: Paul R. Schmidt, Chief, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, ms 634-ARLSQ, 1849 C Street, NW, Washington, DC 20240 (703) 358-1714.

SUPPLEMENTARY INFORMATION:

Regulations Schedule for 1994

On April 7, 1994, the Service published for public comment in the *Federal Register* (59 FR 16762) a proposal to amend 50 CFR part 20, with comment periods ending July 21, 1994, for early-season proposals and September 2, 1994, for late-season proposals. On June 8, 1994, the Service published for public comment a second document (59 FR 29700) which provided supplemental proposals for early- and late-season migratory bird hunting regulations frameworks. On June 23, 1994, a public hearing was held in Washington, DC, as announced in the April 7 and June 8 *Federal Registers* to review the status of migratory shore and upland game birds. Proposed hunting regulations were discussed for these species and for other early seasons. On July 12, 1994, the Service published in the *Federal Register* (59 FR 35566) a third document in the series of

proposed, supplemental, and final rulemaking documents which dealt specifically with proposed early-season frameworks for the 1994-95 season. On August 4, 1994, a public hearing was held in Washington, DC, as announced in the April 7, June 8, and July 12 *Federal Register*, to review the status of waterfowl. Proposed hunting regulations were discussed for these late seasons. On August 17, 1994, the Service published a fourth document (59 FR 42474) containing final frameworks for early migratory bird hunting seasons from which wildlife conservation agency officials from the States, Puerto Rico, and the Virgin Islands selected early-season hunting dates, hours, areas, and limits. The fifth document in the series, published August 24, 1994 (59 FR 43684), dealt specifically with proposed frameworks for the 1994-95 late-season migratory bird hunting regulations. The final rule described here is the sixth in the series of proposed, supplemental, and final rulemaking documents for migratory game bird hunting regulations and deals specifically with amending subpart K of 50 CFR 20 to set hunting seasons, hours, areas, and limits for mourning, white-winged, and white-tipped doves; band-tailed pigeons; rails; moorhens and gallinules; woodcock; common snipe; sandhill cranes; sea ducks; early (September) waterfowl seasons; mourning doves in Hawaii; migratory game birds in Alaska, Puerto Rico, and the Virgin Islands; and some extended falconry seasons.

NEPA Consideration

NEPA considerations are covered by the programmatic document, "Final Supplemental Environmental Impact Statement: Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (SEIS 88-14)," filed with EPA on June 9, 1988. Notice of Availability was published in the *Federal Register* on June 16, 1988 (53 FR 22582). The Service's Record of Decision was published on August 18, 1988 (53 FR 31341). Copies of these documents are available from the Service at the address indicated under the caption ADDRESSES.

Endangered Species Act Consideration

In August 1994, the Division of Endangered Species concluded that the proposed action is not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of their critical habitats. Hunting regulations are designed, among other things, to remove or alleviate chances of conflict between seasons for migratory

game birds and the protection and conservation of endangered and threatened species and their habitats. The Service's biological opinions resulting from its consultation under Section 7 are considered public documents and are available for inspection in the Division of Endangered Species and the Office of Migratory Bird Management.

Regulatory Flexibility Act; Executive Order 12866 and the Paperwork Reduction Act

In the *Federal Register* dated April 7, 1994 (59 FR 16762), the Service reported measures it had undertaken to comply with requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq) and Executive Order 12866. These included preparing an Analysis of Regulatory Effects, preparing a Small Entity Flexibility Analysis under the Regulatory Flexibility Act, and publishing a summary of the latter. This action was not subject to review by the Office of Management and Budget under Executive Order 12866. This rule does not contain any information collection requiring approval by the Office of Management and Budget under 44 U.S.C. 3504.

Regulations Promulgation

The rulemaking process for migratory game bird hunting must, by its nature, operate under severe time constraints. However, the Service intends that the public be given the greatest possible opportunity to comment on the regulations. Thus, when the preliminary proposed rulemaking was published, the Service established what it believed were the longest periods possible for public comment. In doing this, the Service recognized that when the comment period closed time would be of the essence. That is, if there were a delay in the effective date of these regulations after this final rulemaking, the States and Territories would have insufficient time to establish and publicize the necessary regulations and procedures to implement their decisions. The Service therefore finds that "good cause" exists, within the terms of 5 U.S.C. 553(d)(3) of the Administrative Procedure Act, and these regulations will, therefore, take effect immediately upon publication.

Accordingly, with each conservation agency having had an opportunity to participate in selecting the hunting seasons desired for its State or Territory on those species of migratory birds for which open seasons are now to be prescribed, and consideration having been given to all other relevant matters

presented, certain sections of title 50, chapter I, subchapter B, part 20, subpart K, are hereby amended as set forth below.

Authorship

The primary author of this rule is Robert J. Blohm of the Office of Migratory Bird Management.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Dated: August 25, 1994.

George T. Frampton, Jr.,

Assistant Secretary for Fish and Wildlife and Parks.

For the reasons set out in the preamble, title 50, chapter I, subchapter

B, part 20, subpart K is amended as follows.

PART 20—[AMENDED]

1. The authority citation for part 20 is revised to read as follows:

Authority: Migratory Bird Treaty Act (July 3, 1918), as amended (16 U.S.C. 701-711); the Fish and Wildlife Improvement Act of 1978 (November 8, 1978); as amended, (16 U.S.C. 712); and the Fish and Wildlife Act of 1956 (August 8, 1956), as amended, (16 U.S.C. 742 a-d and e-j).

Note.—The following annual hunting regulations provided for by §§ 20.101 through 20.106 and 20.109 of 50 CFR 20 will not appear in the Code of Federal Regulations because of their seasonal nature.

2. Section 20.101 is revised to read as follows:

§ 20.101 Seasons, limits, and shooting hours for Puerto Rico and the Virgin Islands.

Subject to the applicable provisions of the preceding sections of this part, areas open to hunting, respective open seasons (dates inclusive), shooting and hawking hours, and daily bag and possession limits for the species designated in this section are prescribed as follows:

Shooting and hawking hours are one-half hour before sunrise until sunset.

Check commonwealth regulations for additional restrictions, including area descriptions.

(a) Puerto Rico:

	Season dates	Limits	
		Bag	Possession
Doves and Pigeons:			
Zenaida, white-winged, and mourning doves	Sept. 3-Oct. 31	10	10
Scaly-naped pigeons	Sept. 3-Oct. 31	5	5
Ducks	Nov. 5-Dec. 19 & Jan. 14-Jan. 23	3	6
Common Moorhens	Nov. 5-Dec. 19 & Jan. 14-Jan. 23	3	6
Common Snipe	Nov. 5-Dec. 19 & Jan. 14-Jan. 23	6	12
		6	12
		6	12
		6	12

Restrictions: In Puerto Rico, the season is closed on the ruddy duck, white-cheeked pintail, West Indian whistling duck, fulvous whistling duck, masked duck, purple gallinule, American coot, and Caribbean coot.

Closed areas: Closed areas are described in the August 17, 1994, Federal Register (59 FR 42474).

(b) Virgin Islands:

	Season dates	Limits	
		Bag	Possession
Zenaida doves	Sept. 1-Sept. 30	10	10
Ducks	Jan. 1-Jan. 31	3	6

Restrictions: In the Virgin Islands, the seasons are closed for ground or quail doves, pigeons, ruddy duck, white-cheeked pintail, West Indian whistling duck, fulvous whistling duck, masked duck, and purple gallinule.

Closed areas: Ruth Cay, just south of St. Croix, is closed to the hunting of migratory game birds.

3. Section 20.102 is to read as follows:

§ 20.102 Seasons, limits, and shooting hours for Alaska.

Subject to the applicable provisions of the preceding sections of this part, areas open to hunting, respective open seasons (dates inclusive), shooting and hawking hours, and daily bag and possession limits for the species designated in this section are prescribed as follows:

Shooting and hawking hours are one-half hour before sunrise until sunset. Area descriptions were published in the

August 17, 1994, Federal Register (59 FR 42474).

Check state regulations for additional restrictions, including area descriptions.

Area seasons	Dates
North Zone	Sept. 1-Dec. 16.
Gulf Coast Zone	Sept. 1-Dec. 16.
Southeast Zone	Sept. 1-Dec. 16.
Pribilof & Aleutian Islands Zone	Oct. 8-Jan. 22.
Kodiak Zone	Oct. 8-Jan. 22.

DAILY BAG AND POSSESSION LIMITS

Area	Ducks ¹	Geese ²	Brant	Common snipe	Sandhill cranes ³
North Zone	8-24	6-12	2-4	8-16	3-6
Gulf Coast Zone	6-18	6-12	2-4	8-16	2-4

DAILY BAG AND POSSESSION LIMITS—Continued

Area	Ducks ¹	Geese ²	Brant	Common snipe	Sandhill cranes ³
Southeast Zone	5-15	6-12	2-4	8-16	2-4
Pribilof and Aleutian Islands Zone	5-15	6-12	2-4	8-16	2-4
Kodiak Zone	5-15	6-12	2-4	8-16	2-4

¹ In State Game Management Units (Units) 1-26 (Statewide), the basic bag limits may include not more than 2 pintails daily, 6 in possession, and 1 canvasbacks daily, 3 in possession. In addition to the basic daily bag and possession limits, a daily bag limit of 15 and a possession limit of 30 is permitted singly or in the aggregate of the following species: scoter, king and common eider, oldsquaw, harlequin ducks, and common and red-breasted mergansers. The season is closed for Steller's and spectacled eiders. In Units 6(D) and 7, the season for harlequin ducks will be October 1 through December 16.

² No more than 4 daily, 8 in possession, may be any combination of Canada and/or white-fronted geese, except in Units 9E and 18 the bag limits for Canada geese are 1 daily and 2 in possession. In Units 5 and 6, the taking of Canada geese is only permitted from September 21 through December 16. In Units 8 and 10 (except Unimak Island), the taking of Canada geese is prohibited. In Unit 1(C), the taking of snow geese is prohibited. In Units 1-26 (Statewide), the taking of Aleutian Canada geese and emperor geese is prohibited.

³ In Unit 17, the daily bag limit for sandhill cranes is 2 and the possession limit is 4.

Falconry: The total combined bag and possession limit for migratory game birds taken with the use of a falcon under a falconry permit is 3 per day, 6 in possession, and may not exceed a more restrictive limit for any species listed in this subsection.

Special Tundra Swan Season: In Unit 22, there will be a tundra swan season from September 1 through October 30 with a season limit of 1 tundra swan per hunter. This season is by registration permit only. Up to 300 permits may be issued. In Unit 18, there will be a tundra swan season from September 1 through

October 31 with a limit of 1 tundra swan per permit. More than 1 permit per season may be issued to a hunter, with issuance one at a time upon filing a harvest report. Up to 500 permits may be issued.

4. Section 20.103 is revised to read as follows:

§ 20.103 Seasons, limits, and shooting hours for doves and pigeons.

Subject to the applicable provisions of the preceding sections of this part, areas open to hunting, respective open seasons (dates inclusive), shooting and hawking hours, and daily bag and

possession limits for the species designated in this section are prescribed as follows:

Shooting and hawking hours are one-half hour before sunrise until sunset except as otherwise noted. Area descriptions were published in the August 17, 1994, *Federal Register* (59 FR 42474).

Check state regulations for additional restrictions, including area descriptions.

(a) Doves:

Note.—Unless otherwise specified, the seasons listed below are for mourning doves only.

	Season dates	Limits	
		Bag	Possession
Eastern Management Unit			
Alabama:			
North Zone:			
12 noon to sunset	Sept. 17-Oct. 30 & Dec. 26-Jan. 10	15	15
South Zone:			
12 noon to sunset	Oct. 8-Nov. 25 & Dec. 26-Jan. 15	12	12
Delaware:			
12 noon to sunset	Sept. 3-Sept. 24	12	24
1/2 hour before sunrise to sunset	Oct. 17-Oct. 29 & Dec. 12-Jan. 14	12	24
Florida: ¹			
Northwest Zone:			
12 noon to sunset	Sept. 17-Oct. 10	12	24
1/2 hour before sunrise to sunset	Nov. 12-Nov. 27 & Dec. 10-Jan. 8	12	24
South Zone:			
12 noon to sunset	Oct. 1-Oct. 24	12	24
1/2 hour before sunrise to sunset	Nov. 12-Nov. 27 & Dec. 10-Jan. 8	12	24
Georgia:			
Zone 1:			
12 noon to sunset	Sept. 3	12	24
1/2 hour before sunrise to sunset	Sept. 4-Oct. 2 & Nov. 24-Nov. 26 & Dec. 10-Jan. 15 ..	12	24
Zone 2:			
12 noon to sunset	Sept. 24	12	24
1/2 hour before sunrise to sunset	Sept. 25-Oct. 23 & Nov. 24-Nov. 26 & Dec. 10-Jan. 15	12	24
Illinois:			
Sunrise to sunset	Sept. 1-Oct. 30	15	30
Indiana	Sept. 1-Oct. 16 & Nov. 4-Nov. 13 & Nov. 24-Nov. 27 ..	15	30
Kentucky:			
11 a.m. to sunset	Sept. 1-Sept. 30 & Oct. 8-Oct. 31	15	30
Sunrise to sunset	Dec. 3-Dec. 8	15	30
Louisiana:			
12 noon to sunset	Sept. 3-Sept. 4 & Oct. 15-Oct. 16 & Dec. 10-Dec. 11 ..	15	30
1/2 hour before sunrise to sunset	Sept. 5-Sept. 11 & Oct. 17-Nov. 6 & Dec. 12-Jan. 6	15	30

	Season dates	Limits	
		Bag	Possession
Maryland:			
12 noon to sunset	Sept. 1-Oct. 22	12	24
1/2 hour before sunrise to sunset	Nov. 21-Nov. 25 & Dec. 26-Jan. 7	12	24
Mississippi:			
North Zone	Sept. 3-Sept. 25 & Oct. 15-Nov. 13 & Dec. 26-Jan. 1 ..	15	30
South Zone	Sept. 24-Oct. 9 & Nov. 19-Dec. 10 & Dec. 24-Jan. 14 ..	15	30
North Carolina:			
12 noon to sunset	Sept. 3-Sept. 10	12	24
1/2 hour before sunrise to sunset	Sept. 11-Oct. 1 & Nov. 21-Nov. 26 & Dec. 12-Jan. 14 ..	12	24
Pennsylvania:			
12 noon to sunset	Sept. 1-Oct. 8	12	24
1/2 hour before sunrise to sunset	Oct. 29-Nov. 26	12	24
Rhode Island:			
12 noon to sunset	Sept. 19-Oct. 2	12	24
1/2 hour before sunrise to sunset	Oct. 15-Nov. 20 & Dec. 26-Jan. 11	12	24
South Carolina:			
12 noon to sunset	Sept. 3-Sept. 5	12	24
1/2 hour before sunrise to sunset	Sept. 6-Oct. 8 & Nov. 19-Nov. 26 & Dec. 20-Jan. 14 ...	12	24
Tennessee:			
12 noon to sunset	Sept. 1	15	30
1/2 hour before sunrise to sunset	Sept. 2-Sept. 27 & Oct. 8-Oct. 22 & Dec. 23-Jan. 9	15	30
Virginia:			
12 noon to sunset	Sept. 3-Sept. 30	12	24
1/2 hour before sunrise to sunset	Oct. 1-Oct. 29 & Dec. 26-Jan. 7	12	24
West Virginia:			
12 noon to sunset	Sept. 1	12	24
1/2 hour before sunrise to sunset	Sept. 2-Oct. 8 & Oct. 24-Nov. 5 & Dec. 20-Jan. 7	12	24

Central Management Unit

Arkansas	Sept. 3-Sept. 25 & Oct. 1-Oct. 16 & Dec. 10-Dec. 30 ..	15	30
Colorado	Sept. 1-Oct. 30	15	30
Kansas	Sept. 1-Oct. 30	15	30
Missouri	Sept. 1-Oct. 30	15	30
Montana	Sept. 1-Oct. 30	15	30
Nebraska	Sept. 1-Oct. 30	15	30
New Mexico ²	Sept. 1-Oct. 30	15	30
North Dakota	Sept. 1-Sept. 30 & Dec. 1-Dec. 30	15	30
Oklahoma	Sept. 1-Oct. 30	15	30
South Dakota ³	Sept. 1-Oct. 30	15	30
Texas: ⁴			
North Zone	Sept. 1-Oct. 30	15	30
Central Zone	Sept. 1-Oct. 15 & Dec. 26-Jan. 8	15	30
South Zone:			
Special Area	Sept. 23-Nov. 2 & Dec. 26-Jan. 9	15	30
[Special season]	Sept. 3-Sept. 4 & Sept. 10-Sept. 11	10	20
Remainder of the South Zone	Sept. 23-Nov. 6 & Dec. 26-Jan. 9	15	30
Wyoming	Sept. 1-Oct. 15	15	30

Western Management Unit

Arizona ⁵	Sept. 1-Sept. 11 & Nov. 21-Jan. 8	10	20
California ⁶	Sept. 1-Sept. 15 & Nov. 14-Dec. 26	10	20
Idaho	Sept. 1-Sept. 30	10	20
Nevada ⁶	Sept. 1-Sept. 30	10	20
Oregon	Sept. 1-Sept. 30	10	20
Utah	Sept. 1-Sept. 30	10	20
Washington	Sept. 1-Sept. 15	10	20

Other Populations

Hawaii ⁷	Nov. 5-Jan. 1 & Jan. 7-Jan. 15	10	10
---------------------------	--------------------------------------	----	----

¹ In Florida, the daily bag limit is 12 mourning and white-winged doves in the aggregate, of which not more than 4 may be white-winged doves. The possession limit is twice the daily bag limit.

² In New Mexico, the daily bag limit is 15 and the possession limit is 30 mourning and white-winged doves in the aggregate.

³ In South Dakota, shooting hours are from sunrise to sunset.

⁴ In Texas, the daily bag limit is 15 mourning, white-winged, and white-tipped doves in the aggregate, of which no more than 6 may be white-winged doves and 2 may be white-tipped doves. Possession limits are twice the daily bag limit.

During the special season in the Special White-winged Dove Area of the South Zone, the daily bag limit is 10 mourning, white-winged, and white-tipped doves in the aggregate, of which no more than 5 may be mourning doves and 2 may be white-tipped doves. Possession limits are twice the daily bag limit.

⁵ In Arizona, during September 1 through 11, the daily bag limit is 10 mourning and white-winged doves in the aggregate, of which no more than 6 may be white-winged doves. During November 21 through January 8, the daily bag limit is 10 mourning doves. The possession limit is twice the daily bag limit. See State regulations for restrictive shooting hours in certain areas.

⁶ In the areas of California and Nevada open to white-winged dove hunting, the daily bag limit is 10 and the possession limit is 20 mourning and white-winged doves in the aggregate.

⁷ In Hawaii, the season is only open on the island of Hawaii. The daily bag and possession limits are 10 mourning and laced doves in the aggregate. Shooting hours are from one-half hour before sunrise through one-half hour after sunset. Hunting is only permitted on weekends and holidays.

(b) Band-tailed Pigeons:

	Season dates	Limits	
		Bag	Possession
Arizona ¹	Oct. 12–Oct. 21	5	10
California:			
North Zone	Sept. 17–Sept. 25	2	2
South Zone	Dec. 17–Dec. 25	2	2
Colorado ¹	Sept. 1–Sept. 30	5	10
New Mexico: ¹			
North Zone	Sept. 1–Sept. 20	5	10
South Zone	Oct. 1–Oct. 20	5	10
Oregon ¹	Sept. 15–Sept. 23	2	2
Utah ¹	Sept. 1–Sept. 30	5	10

¹ Each band-tailed pigeon hunter must have either a band-tailed pigeon hunting permit or a special bird permit stamp issued by the respective State.

5. Section 20.104 is revised to read as follows:

§ 20.104 Seasons, limits, and shooting hours for rails, woodcock, and common snipe.

Subject to the applicable provisions of the preceding sections of this part, areas open to hunting, respective open

seasons (dates inclusive), shooting and hawking hours, and daily bag and possession limits for the species designated in this section are prescribed as follows:

Shooting and hawking hours are one-half hour before sunrise until sunset except as otherwise noted. Area descriptions were published in the

August 17, 1994, **Federal Register** (59 FR 42474).

Check state regulations for additional restrictions, including area descriptions.

Note.—States with deferred seasons may select those seasons at the same time they select waterfowl seasons in August. Consult late-season regulations for further information.

	Sora and Virginia Rails	Clapper and King Rails	Woodcock	Common Snipe
Daily bag limit	25 ¹	15 ²	5 ³	8
Possession limit	25 ¹	30 ²	10 ³	16

Atlantic Flyway

Connecticut ⁴	Sept. 1–Nov. 9	Sept. 1–Nov. 9	Oct. 15–Nov. 28	Oct. 15–Nov. 28.
Delaware	Sept. 1–Nov. 9	Sept. 1–Nov. 9	Oct. 17–Nov. 5 & Nov. 21–Dec. 15.	Nov. 21–Jan. 31.
Florida	Sept. 1–Nov. 9	Sept. 1–Nov. 9	Dec. 10–Jan. 23	Nov. 1–Feb. 15.
Georgia	Sept. 7–Nov. 15	Sept. 7–Nov. 15	Dec. 10–Jan. 23	Nov. 16–Feb. 28.
Maine	Sept. 1–Nov. 9	Closed	Oct. 1–Nov. 14	Sept. 1–Dec. 16.
Maryland	Sept. 1–Nov. 9	Sept. 1–Nov. 9	Oct. 24–Nov. 25 & Dec. 12–Dec. 23.	Sept. 20–Nov. 25 & Dec. 12–Jan. 20.
Massachusetts ⁵	Sept. 1–Nov. 9	Closed	Deferred	Sept. 1–Dec. 16.
New Hampshire	Closed	Closed	Oct. 1–Nov. 14	Sept. 25–Nov. 30.
New Jersey: ⁶				
North Zone	Sept. 1–Nov. 9	Sept. 1–Nov. 9	Oct. 15–Nov. 18	Oct. 1–Jan. 15.
South Zone	Sept. 1–Nov. 9	Sept. 1–Nov. 9	Nov. 7–Dec. 3 & Dec. 17–Dec. 24.	Oct. 1–Jan. 15.
New York ⁷	Sept. 1–Nov. 9	Closed	Oct. 1–Nov. 14	Sept. 1–Dec. 16.
North Carolina	Sept. 1–Nov. 9	Sept. 1–Nov. 9	Dec. 8–Jan. 21	Nov. 14–Feb. 28.
Pennsylvania	Sept. 1–Nov. 5	Closed	Oct. 22–Nov. 5	Oct. 22–Nov. 26.
Rhode Island	Sept. 12–Nov. 20	Sept. 12–Nov. 20	Oct. 15–Nov. 28	Sept. 12–Dec. 2 & Dec. 12–Jan. 5.
South Carolina	Sept. 7–Oct. 10 & Nov. 1–Dec. 6.	Sept. 7–Oct. 10 & Nov. 1–Dec. 6.	Nov. 23–Dec. 10 & Dec. 26–Jan. 21.	Nov. 11–Feb. 25.
Vermont	Closed	Closed	Oct. 1–Nov. 14	Sept. 24–Dec. 2.
Virginia	Sept. 12–Nov. 20	Sept. 12–Nov. 20	Oct. 31–Nov. 26 & Dec. 21–Jan. 7.	Oct. 17–Jan. 31.
West Virginia	Sept. 1–Nov. 9	Closed	Oct. 15–Nov. 28	Sept. 1–Dec. 16.

	Sora and Virginia Rails	Clapper and King Rails	Woodcock	Common Snipe
Mississippi Flyway				
Alabama ⁸	Sept. 10-Sept. 18 & Nov. 21-Jan. 20.	Sept. 10-Sept. 18 & Nov. 21-Jan. 20.	Nov. 26-Jan. 29	Nov. 14-Feb. 28.
Arkansas	Sept. 1-Nov. 9	Closed	Nov. 5-Dec. 11 & Dec. 31-Jan. 27.	Nov. 12-Feb. 26.
Illinois	Sept. 10-Nov. 18	Closed	Oct. 1-Dec. 4	Sept. 10-Dec. 25
Indiana ⁹	Sept. 1-Nov. 9	Closed	Sept. 24-Nov. 27	Sept. 1-Dec. 16.
Iowa ¹⁰	Sept. 3-Nov. 11	Closed	Sept. 27-Nov. 20	Sept. 3-Nov. 11.
Kentucky	Sept. 1-Nov. 9	Closed	Oct. 15-Dec. 18	Sept. 14-Oct. 28 & Nov. 24-Jan. 24.
Louisiana	Sept. 17-Sept. 25 & Nov. 12-Jan. 11.	Sept. 17-Sept. 25 & Nov. 12-Jan. 11.	Nov. 28-Jan. 31	Nov. 5-Feb. 19.
Michigan ¹¹	Sept. 15-Nov. 4	Closed	Sept. 15-Nov. 14	Sept. 15-Nov. 14.
Minnesota	Sept. 1-Nov. 4	Closed	Sept. 1-Nov. 4	Sept. 1-Nov. 4.
Mississippi	Oct. 15-Dec. 23	Oct. 25-Dec. 23	Nov. 28-Jan. 31	Nov. 14-Feb. 28.
Missouri	Sept. 1-Nov. 9	Closed	Oct. 15-Dec. 18	Sept. 1-Dec. 16.
Ohio	Sept. 1-Nov. 9	Closed	Sept. 23-Nov. 26	Sept. 1-Nov. 26 & Dec. 5-Dec. 24.
Tennessee	Deferred	Closed	Oct. 8-Dec. 11	Nov. 14-Feb. 28.
Wisconsin	Deferred	Closed	Sept. 27-Nov. 20	Deferred.
Central Flyway				
Colorado	Sept. 1-Nov. 9	Closed	Closed	Sept. 1-Dec. 16.
Kansas	Sept. 1-Nov. 9	Closed	Oct. 8-Dec. 11	Sept. 1-Dec. 16.
Montana	Closed	Closed	Closed	Sept. 1-Dec. 16.
Nebraska ¹²	Sept. 1-Nov. 9	Closed	Sept. 15-Nov. 18	Sept. 1-Dec. 16.
New Mexico	Deferred	Deferred	Deferred	Deferred.
North Dakota ¹³	Closed	Closed	Closed	Oct. 1-Nov. 6 & Nov. 12-Nov. 13 & Dec. 10-Dec. 21.
Oklahoma	Sept. 1-Nov. 9	Closed	Nov. 1-Jan. 4	Oct. 1-Jan. 15.
South Dakota ¹⁴	Closed	Closed	Closed	Sept. 1-Oct. 31.
Texas	Sept. 1-Nov. 9	Sept. 1-Nov. 9	Deferred	Deferred.
Wyoming	Sept. 10-Nov. 18	Closed	Closed	Sept. 10-Dec. 13.
Pacific Flyway				
Colorado	Sept. 1-Nov. 9	Closed	Closed	Sept. 1-Dec. 16.
Idaho ¹⁵	Closed	Closed	Closed	Sept. 17-Jan. 1.
Montana	Closed	Closed	Closed	Sept. 1-Dec. 16.
New Mexico	Deferred	Deferred	Deferred	Deferred.
Wyoming	Sept. 10-Nov. 18	Closed	Closed	Sept. 10-Dec. 13.

Note: For all other States in the Pacific Flyway, snipe seasons have been deferred and no seasons are prescribed for woodcock and rails.

¹ The bag and possession limits for sora and Virginia rails apply singly or in the aggregate of these species.

² All bag and possession limits for clapper and king rails apply singly or in the aggregate of the two species and, unless otherwise specified, the limits are in addition to the limits on sora and Virginia rails in all States. In Connecticut, Delaware, Maryland, New Jersey, and Rhode Island, the limits for clapper and king rails are 10 daily and 20 in possession.

³ In States of the Atlantic Flyway, the woodcock bag limit is 3 daily and 6 in possession.

⁴ In Connecticut, the daily bag and possession limits may not contain more than 1 king rail.

⁵ In Massachusetts, the sora bag limit is 5 daily and 10 in possession; the Virginia rail bag limit is 10 daily and 20 in possession.

⁶ In New Jersey, the season for king rails is closed by State regulation.

⁷ In New York, seasons for sora and Virginia rails and common snipe are closed on Long Island.

⁸ In Alabama, the rail limits are 15 daily and 15 in possession, singly or in the aggregate.

⁹ In Indiana, the sora and Virginia rail limits are 15 daily and 15 in possession, singly or in the aggregate.

¹⁰ In Iowa, the limits for sora and Virginia rails are 12 daily and 24 in possession.

¹¹ In Michigan, the season opens concurrently with the duck season in certain areas.

¹² In Nebraska, the rail limits are 10 daily and 20 in possession.

¹³ In North Dakota, the snipe season dates of December 10 through December 21 only applies to the High Plains Unit.

¹⁴ In South Dakota, the snipe limits are 5 daily and 15 in possession.

¹⁵ In Idaho, in Zone 5, the snipe season in October 22, through December 19.

6. Section 20.105 is amended by revising paragraphs (a) through (d) to read as follows:

§ 20.105 Seasons, limits, and shooting hours for waterfowl, coots, and gallinules.

Subject to the applicable provisions of the preceding sections of this part, areas open to hunting, respective open

seasons (dates inclusive), shooting and hawking hours, and daily bag and possession limits for the species designated in this section are prescribed as follows:

Shooting and hawking hours are one-half hour before sunrise until sunset, except as otherwise noted. Area descriptions were published in the

August 17, 1994, **Federal Register** (59 FR 42474).

Note.—States with deferred seasons may select those seasons at the same time they select waterfowl seasons in August. Consult late-seasons regulations for further information.

(a) Common Moorhens and Purple Gallinules:

	Season dates	Limits	
		Bag	Possession
Atlantic Flyway			
Delaware	Sept. 1–Nov. 9	15	30
Florida ¹	Sept. 1–Nov. 9	15	30
Georgia	Deferred		
Maine	Sept. 1–Nov. 9	15	30
New Jersey	Sept. 1–Nov. 9	15	30
New York:			
Long Island	Closed		
Remainder of State	Sept. 1–Nov. 9	15	30
North Carolina	Sept. 1–Nov. 9	15	30
Pennsylvania	Sept. 1–Nov. 5	15	30
Rhode Island	Oct. 7–Oct. 9 & Nov. 23–Jan. 7	15	30
South Carolina	Sept. 7–Oct. 10 & Nov. 1–Dec. 6	15	30
Virginia	Deferred		
West Virginia	Deferred		
Mississippi Flyway			
Alabama	Sept. 10–Sept. 18 & Nov. 21–Jan. 20	15	15
Arkansas	Sept. 1–Nov. 9	15	30
Indiana	Sept. 1–Nov. 9	10	20
Kentucky	Sept. 1–Nov. 9	15	30
Louisiana	Sept. 17–Sept. 25 & Nov. 12–Jan. 11	15	30
Michigan	Deferred		
Minnesota	Deferred		
Mississippi	Oct. 15–Dec. 23	15	30
Ohio	Sept. 1–Nov. 9	15	30
Tennessee	Deferred		
Wisconsin	Deferred		
Central Flyway			
Colorado	Deferred		
New Mexico	Deferred		
Oklahoma	Sept. 1–Nov. 9	15	30
Texas	Sept. 1–Nov. 9	15	30
Wyoming	Deferred		
Pacific Flyway			
All States	Deferred		

¹ The season applies to common moorhens only.

(b) *Sea Ducks* (scoter, eider, and oldsquaw ducks in Atlantic Flyway).

Within the special sea duck areas, the daily bag limit is 7 scoter, eider, and oldsquaw ducks, singly or in the aggregate, of which no more than 4 may be scoters. Possession limits are twice the daily bag limit. These limits may be in addition to regular duck bag limits only during the regular duck season in the special sea duck hunting areas.

	Season dates	Limits	
		Bag	Possession
Connecticut	Deferred		
Delaware	Sept. 24–Jan. 7	7	14
Georgia	Deferred		
Maine	Deferred		
Maryland	Deferred		
Massachusetts	Deferred		
New Hampshire	Sept. 15–Dec. 30	7	14
New Jersey	Oct. 1–Jan. 15	7	14
New York	Oct. 6–Jan. 20	7	14
North Carolina	Deferred		
Rhode Island	Oct. 1–Jan. 15	7	14
South Carolina	Deferred		
Virginia	Deferred		

Note: Notwithstanding the provisions of this Part 20, the shooting of crippled waterfowl from a motorboat under power will be permitted in Maine, Massachusetts, New Hampshire, Rhode Island, Connecticut, New York, Delaware, Virginia and Maryland in those areas described, delineated, and designated in their respective hunting regulations as special sea duck hunting areas.

(c) Early (September) Duck Seasons:

Note.—Unless otherwise specified, the seasons listed below are for teal only.

	Season dates	Limits	
		Bag	Possession
Atlantic Flyway			
Florida ¹	Sept. 24–Sept. 28	4	8
Mississippi Flyway			
Alabama	Sept. 10–Sept. 18	4	8
Arkansas ²	Sept. 17–Sept. 25	4	8
Illinois ²	Sept. 10–Sept. 18	4	8
Indiana ²	Sept. 1–Sept. 9	4	8
Iowa ³		4	8
North Zone	Sept. 17–Sept. 19		
South Zone	Closed		
Kentucky ⁴	Sept. 14–Sept. 18		
Louisiana	Sept. 17–Sept. 25	4	8
Mississippi	Sept. 17–Sept. 25	4	8
Missouri ²	Sept. 10–Sept. 18	4	8
Ohio ²	Sept. 3–Sept. 11	4	8
Tennessee ⁴	Sept. 10–Sept. 14	4	8
		4	8
Central Flyway			
Colorado	Sept. 3–Sept. 11	4	8
Kansas	Sept. 10–Sept. 18	4	8
New Mexico	Sept. 10–Sept. 18	4	8
Oklahoma	Sept. 10–Sept. 18	4	8
Texas	Sept. 17–Sept. 25	4	8

¹ In Florida, the daily bag limit is 4 wood ducks and teal in the aggregate. The possession limit is twice the daily bag limit.

² Shooting hours are from sunrise to sunset.

³ In Iowa, the September season is part of the regular season, and limits will conform to those set for the regular season.

⁴ In Kentucky and Tennessee, the daily bag limit is 4 wood ducks and teal in the aggregate, of which no more than 2 may be wood ducks. The possession limit is twice the daily bag limit.

(d) Special Early Canada Goose Seasons:

	Season dates	Limits	
		Bag	Possession
Atlantic Flyway			
Maryland	Sept. 6–Sept. 15	3	6
Massachusetts ¹	Sept. 6–Sept. 15	5	10
New Jersey	Sept. 7–Sept. 15	5	10
New York:			
Northern	Sept. 6–Sept. 15	3	6
Western	Sept. 6–Sept. 15	3	6
Southeastern	Sept. 6–Sept. 15	3	6
North Carolina ¹	Sept. 16–Sept. 30	3	6
Pennsylvania:			
Northwestern Counties	Sept. 1–Sept. 10	3	6
Southeastern Counties	Sept. 1–Sept. 15	5	10
Virginia	Sept. 6–Sept. 15	5	10
West Virginia	Sept. 1–Sept. 15	3	6
Mississippi Flyway			
Indiana ¹	Sept. 1–Sept. 15	5	10
Michigan:			
Upper Peninsula Zone	Sept. 1–Sept. 10	5	10
Northern Lower Peninsula Zone	Sept. 1–Sept. 10	5	10
Southern Lower Peninsula Zone	Sept. 1–Sept. 15	5	10
Minnesota ²	Sept. 3–Sept. 12	5	10
Ohio	Sept. 3–Sept. 15	4	8
		3	6

	Season dates	Limits	
		Bag	Possession
Tennessee	Sept. 10-Sept. 19	2	4
Wisconsin	Sept. 1-Sept. 2 & Sept. 6-Sept. 10	5	10

Pacific Flyway

Oregon: ¹			
Lower Columbia River Zone	Sept. 1-Sept. 12	2	4
Northwestern Zone	Sept. 1-Sept. 12	2	4
Washington	Sept. 1-Sept. 12	3	6
Wyoming ¹	Sept. 3-Sept. 5	(³)	

¹ State permit required.² In Minnesota, the bag and possession limits for Canada geese will be 2 and 4, respectively, in the Fergus Falls/Benson Zone and Southwest Zone.³ 2 per season.

(e) Regular Goose Seasons:

Note. Bag and possession limits will conform to those set for the remainder of the regular season.

	Zone ¹	Season dates
Mississippi Flyway		
Michigan	North	Sept. 24-Sept. 30.
Wisconsin	Horicon, Collins	Sept. 24-Sept. 30 & Sept. 24-Sept. 30.

¹ Consult State regulations for zone descriptions.

7. Section 20.106 is revised to read as follows:

§ 20.106 Seasons, limits, and shooting hours for sandhill cranes.

Subject to the applicable provisions of the preceding sections of this part, areas open to hunting, respective open seasons (dates inclusive), shooting and

hawking hours, and daily bag and possession limits on the species designated in this section are as follows: Shooting and Hawking hours are one-half hour before sunrise until sunset, except as otherwise noted. Area descriptions were published in the August 17, 1994 Federal Register (59 FR 42474).

CHECK STATE REGULATIONS FOR ADDITIONAL RESTRICTIONS, INCLUDING AREA DESCRIPTIONS

Note. States with deferred seasons may select those seasons at the same time they select waterfowl seasons in August. Consult late-season regulations for further information.

	Season dates	Limits	
		Bag	Possession
Central Flyway			
Colorado ¹	Oct. 1–Nov. 27	3	6
Kansas ^{1,2}	Nov. 5–Jan. 1	2	4
Montana:			
Regular season ¹	Sept. 24–Nov. 20	3	6
New Mexico:			
Regular season ¹	Oct. 15–Jan. 15	3	6
Middle Rio Grande Valley Area ^{3,4,5}	Oct. 29–Oct. 30 & Dec. 10–Dec. 11 & Jan. 7–Jan. 8 & Jan. 21–Jan. 22.	2	4
Southwest Area ^{3,4,5}	Dec. 17–Dec. 18 & Jan. 14–Jan. 15	2	4
North Dakota ¹	Sept. 10–Nov. 6	3	6
Oklahoma ¹	Deferred		
South Dakota ¹	Sept. 24–Oct. 30	3	6
Texas ¹	Deferred		
Wyoming:			
Regular Season ¹	Sept. 14–Nov. 10	3	6
Riverton-Boysen Unit ³	Sept. 24–Sept. 29	2 per season	

	Season dates	Limits	
		Bag	Possession
Montana:			
Special-season Area ³	Sept. 10–Sept. 11 & Sept. 17–Sept. 18	1 per season	
Utah ^{3,5,6}	Sept. 3–Sept. 4 & Sept. 10–Sept. 11	1 per season	
Wyoming:			
Bear River Area ³	Sept. 3–Sept. 5	2 per season	
Salt River Area ³	Sept. 3–Sept. 5	2 per season	
Eden-Farson Area ³	Sept. 3–Sept. 5	2 per season	

¹ Each hunter participating in a regular sandhill crane hunting season must obtain and carry in his possession while hunting sandhill cranes a valid Federal sandhill crane hunting permit available without cost from conservation agencies in the States where crane hunting seasons are allowed. The permit must be displayed to any authorized law enforcement official upon request.

² Shooting hours are sunrise to 2:00 p.m.

³ Hunting is by State permit only.

⁴ The seasonal bag limit is 4.

⁵ Shooting hours are sunrise to sunset.

⁶ In Utah, the season is open in Rich County only.

8. Section 20.109 is revised to read as follows:

§20.109 Extended seasons, limits, and hours for taking migratory game birds by falconry.

Subject to the applicable provisions of the preceding sections of this part, areas open to hunting, respective open seasons (dates inclusive), hawking hours, and daily bag and possession limits for the species designated in this section are prescribed as follows:

Hawking hours are one-half hour before sunrise until sunset except as otherwise noted. Area descriptions were published in the August 17, 1994, **Federal Register** (59 FR 42474).

CHECK STATE REGULATIONS FOR ADDITIONAL RESTRICTIONS, INCLUDING AREA DESCRIPTIONS.

Daily bag limit

3 migratory birds, singly or in the aggregate.

Possession limit

6 migratory birds, singly or in the aggregate.

These limits apply to falconry during both regular hunting seasons and extended falconry seasons—unless further restricted by State regulations. The falconry bag and possession limits are not in addition to regular season limits. Unless otherwise specified, extended falconry for ducks does not include sea ducks within the special sea duck areas. Only extended falconry seasons are shown below. Many States permit falconry during the gun seasons. Please consult State regulations for details.

For ducks, mergansers, coots, geese, and some moorhen seasons; additional season days occurring after September 30 will be published with the late-season selections. Some States have deferred selections. Consult late-season regulations for further information.

	Extended falconry dates		Extended falconry dates
Atlantic Flyway			
Florida:		Michigan:	
Mourning and white-winged doves:		Rails, snipe, and woodcock.	Sept. 7–Sept. 14 & Nov. 15–Dec. 22.
Northwest Zone	Oct. 18–Nov. 11 & Nov. 28–Dec. 9.	Ducks, mergansers, coots, and moorhens ¹ .	Sept. 7–Sept. 30.
South Zone	Oct. 25–Nov. 11 & Nov. 28–Dec. 9 & Jan. 9–Jan. 15.	Minnesota:	
Rails and common moorhens.	Nov. 10–Dec. 16.	Rails, snipe, and woodcock.	Nov. 5–Dec. 16.
Woodcock	Nov. 24–Dec. 9 & Jan. 24–Mar. 10.	Ducks, mergansers, coots, and moorhens ¹ .	Sept. 1–Sept. 30.
Maryland:		Missouri:	
Mourning doves	Oct. 23–Nov. 20 & Dec. 18–Dec. 25.	Mourning doves	Oct. 31–Dec. 16.
Rails	Nov. 10–Dec. 16.	Wisconsin:	
Woodcock	Oct. 5–Oct. 23 & Nov. 26–Dec. 11 & Dec. 24–Jan. 19.	Rails, snipe, moorhens, and gallinules ¹ .	Sept. 1–Sept. 30.
Pennsylvania:		Woodcock	Sept. 1–Sept. 16.
Mourning doves	Oct. 10–Oct. 28 & Nov. 28–Dec. 18.	Ducks, mergansers, and coots ¹ .	
Virginia:		North Zone	Sept. 1–Sept. 30.
Doves	Dec. 11–Dec. 25 & Jan. 8–Jan. 29.	South Zone	Sept. 15–Sept. 30.
Rails	Dec. 24–Jan. 29.		
Woodcock	Nov. 27–Dec. 20 & Jan. 8–Jan. 29.		
Mississippi Flyway			
Illinois:		Colorado:	
Mourning doves	Oct. 31–Dec. 16.	Ducks, mergansers and coots ¹ .	Sept. 1–Sept. 2 & Sept. 12–Sept. 30.
Rails	Nov. 19–Dec. 25.	Montana: ²	
Woodcock	Sept. 1–Sept. 30 & Dec. 5–Dec. 16.	Ducks, mergansers, and coots ¹ .	Sept. 10–Sept. 30.
Indiana:		New Mexico:	
Mourning doves	Oct. 17–Nov. 3 & Jan. 1–Jan. 29.	Doves	Oct. 1–Nov. 6 & Nov. 30 & Dec. 31–Jan. 8.
Woodcock	Sept. 1–Sept. 23 & Nov. 28–Dec. 16.	Band-tailed pigeons:	
Ducks, mergansers, and coots ¹ .		North Zone	Sept. 21–Dec. 16.
North Zone	Sept. 25–Sept. 30.	South Zone	Oct. 21–Jan. 15.
Iowa:		Sandhill cranes:	
Ducks, mergansers, and coots ¹ .		Regular Sea-son Area.	Jan. 16–Jan. 29.
North Zone	Sept. 20–Sept. 30.	North Dakota:	
		Ducks, mergansers, coots, and snipe ¹ .	Sept. 1–Sept. 30.
		Oklahoma:	
		Ducks, mergansers, and coots ¹ .	
		High Plains	Sept. 19–Sept. 30.

	Extended falconry dates		Extended falconry dates		Extended falconry dates
South Dakota: Ducks, mergansers, and coots ¹ .	Sept. 4–Sept. 30.	Colorado: Ducks, mergansers, and coots ¹ .	Sept. 17–Sept. 30.	Band-tailed pigeons	Sept. 1–Sept. 14 & Sept. 24–Dec. 16.
Texas: Mourning and white-winged doves.	Nov. 14–Dec. 20.	Idaho: Mourning Doves	Oct. 1–Nov. 30 & Feb. 23–Mar. 10.	Utah: Mourning doves and band-tailed pigeons.	Oct. 1–Dec. 16.
Rails and gallinules	Nov. 14–Dec. 20.	Ducks, mergansers, and coots ¹ .	Sept. 1–Oct. 2.	Washington: Mourning doves	Oct. 1–Dec. 31.
Wyoming: Rails	Sept. 1–Sept. 9.	Geese: Zones 1–4	Sept. 1–Sept. 7.	Wyoming: Rails and snipe	Sept. 1–Sept. 9.
Ducks, mergansers, and coots ¹ .	Sept. 1–Sept. 30.	Zone 5	Sept. 1–Sept. 14.	Ducks, mergansers, and coots ¹ .	Sept. 1–Sept. 30.
Pacific Flyway		New Mexico: Doves	Oct. 1–Nov. 6 & Nov. 30 & Dec. 31–Jan. 8.	¹ Additional days occurring after Sept. 30 will be published with the late-season selec- tions.	
Arizona: Doves	Sept. 12–Oct. 28.	Band-tailed pi- geons:		² In Montana and New Mexico, the bag limit is 2 and the possession limit is 6.	
Ducks and mergan- sers: ¹		North Zone	Sept. 21–Dec. 16.	³ In Oregon, no more than 1 pigeon daily in bag or possession.	
North Zone	Sept. 1–Oct. 6.	South Zone	Oct. 21–Jan. 15.	[FR Doc. 94-21510 Filed 8-31-94; 8:45 am]	
		Oregon: ³		BILLING CODE 4310-55-M	
		Mourning doves	Oct. 1–Dec. 16.		

Environmental Protection Agency

Thursday
September 1, 1994

Part V

**Environmental
Protection Agency**

40 CFR Part 172

Microbial Pesticides; Experimental Use
Permits and Notifications; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 172

[OPP-50668B; FRL-4752-7]

RIN 2070-AB77

Microbial Pesticides; Experimental Use Permits and Notifications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This notice promulgates an amendment to the experimental use permit (EUP) regulations for pesticides that was proposed on January 22, 1993. These regulations clarify the circumstances under which an EUP is presumed not to be required and implement a screening procedure that requires notification to EPA before initiation of small-scale testing of certain microbial pesticides. This notification scheme implements provisions of the EPA policy statement published in the *Federal Register* of June 26, 1986, with modifications.

DATES: This final rule is effective October 31, 1994.

FOR FURTHER INFORMATION CONTACT: By mail: Evert K. Byington, Chief, Science Analysis and Coordination Staff, Environmental Fate and Effects Division (7507C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1016A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703-305-6307).

SUPPLEMENTARY INFORMATION: Section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136c, and 40 CFR part 172 provide for issuance by the Agency of experimental use permits (EUPs) for the testing of new pesticides or new uses of existing pesticides. Such permits are generally issued for large-scale testing of pesticides.

Large-scale tests under 40 CFR part 172 include any terrestrial application on a cumulative total of more than 10 acres of land or any aquatic application on more than 1 surface acre of water. EPA has generally presumed that testing on up to 10 acres of land or 1 surface acre of water ("small-scale test") would not require EUPs. However, the Agency believes that small-scale tests in the environment with some microbial pesticides may pose sufficiently different risk considerations from conventional chemical pesticides that a closer evaluation at the small-scale testing stage may be warranted.

Therefore, the Agency is amending 40 CFR part 172 to require notification before initiation of small-scale testing in the environment of certain microbial pesticides so that EPA may determine whether these tests should be conducted under an EUP. This rule codifies the notification provisions of the Agency's policy statement of June 26, 1986 (51 FR 23302), with modifications.

I. Authority and Background

A. Statutory and Regulatory Authority

These regulations are promulgated under sections 3(a), 5, 8, and 25 of FIFRA. Section 5 governs the issuance of EUPs; section 3(a), 7 U.S.C. 136a(a), allows the Agency to regulate unregistered pesticides that are not subject to an EUP in order to prevent unreasonable adverse effects on the environment; section 8, 7 U.S.C. 136f, gives the Agency authority to require recordkeeping; and section 25, 7 U.S.C. 136w, gives EPA the authority to issue regulations and to exempt pesticides from regulation under FIFRA.

Section 5 of FIFRA provides that any person wishing to test a pesticide may apply for an EUP. As stated in the preamble proposing the issuance of the original regulations under section 5 (39 FR 11306, March 27, 1974), "The purpose behind section 5 is to facilitate the generation of data necessary to support an application for registration under section 3 and yet provide sufficient regulatory control to prevent adverse environmental effects." An EUP issued pursuant to section 5 authorizes limited use of a pesticide on a limited number of acres, under specific and controlled conditions, to develop the necessary data.

EPA will issue an EUP only if issuance of such a permit will not cause unreasonable adverse effects on the environment. Similarly, EPA may revoke an existing EUP if it determines that the terms and conditions of the permit are inadequate to avoid unreasonable adverse effects, 7 U.S.C. 136c; 40 CFR 172.10. Section 2(bb) of FIFRA, 7 U.S.C. 136(bb), defines "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of use of [the] pesticide."

When the EUP regulations, 40 CFR part 172, were originally promulgated (40 FR 18782, April 30, 1975), the Agency recognized that the development of an effective pesticide, culminating in registration, is a multi-stage process that warrants a scaling in the level of oversight by EPA. EPA

therefore set forth procedures that would "... place experimental programs under reasonable constraints without imposing burdens unrelated to needed protection of human health and the environment" (39 FR 11307, March 27, 1974). The final regulations included a presumption that EUPs would not be required for most small-scale tests (40 CFR 172.3). However, the regulations also explicitly recognized that a wide variety of testing situations may arise and that a flexible regulatory approach is needed to deal with these situations.

B. Historical Development

The Agency recognizes that there has been a long history of safe use of microbial pesticides. With respect to small-scale testing of most microbial pesticides, the Agency believes that the likelihood that such tests will result in significant adverse impacts on human health or the environment is sufficiently low that Agency oversight is unnecessary. Thus, the Agency believes that, in most instances, small-scale tests with microbial pesticides should continue to be excluded from the requirement for an EUP.

However, since the issuance of the original EUP regulations, new and different microbial pesticides have been developed that warrant a closer review before being excluded from the EUP requirements at the small-scale testing stage. In amending the EUP regulations, the Agency's goal is to set forth a system that focuses on the characteristics and risks of the product, protects human health and the environment, establishes a screening mechanism that does not unduly impede potentially beneficial research, and is designed to accommodate rapid advances in biotechnology.

In 1984, EPA issued an interim policy statement entitled "Microbial Pesticides: Interim Policy on Small-Scale Field Testing" (49 FR 40659, October 17, 1984). This statement announced that the presumption in the 1975 EUP regulations (40 CFR 172.3) would not automatically apply to tests using genetically altered and nonindigenous microbial pesticide products and that the Agency should be notified before initiation of any such testing. Since 1984, the Agency has used this notification scheme to evaluate small-scale tests involving genetically altered and/or nonindigenous microbial pesticides for possible risk to human health or the environment and to determine whether EUPs would be required before the tests could be initiated.

Subsequent to publication of the Interim Policy, this same basic position

was published for comment in EPA's section of the Office of Science and Technology Policy (OSTP) "Proposal for a Coordinated Framework for Regulation of Biotechnology" (49 FR 50856, December 31, 1984). The final OSTP statement of policy was published on June 26, 1986 (51 FR 23302, June 26, 1986). In the 1986 Policy Statement, the Agency stated its intention to codify the major elements of the notification procedure in the EUP regulations (40 CFR part 172).

EPA published a proposal to amend its EUP regulations on January 22, 1993 (58 FR 5878). The proposal reflected changes in the 1986 Policy position made in response to public comments, the recommendations of the FIFRA Scientific Advisory Panel (SAP) and the EPA Biotechnology Science Advisory Committee (BSAC), and Federal biotechnology policy statements.

Specifically influencing the Agency's proposal were the "Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits" (55 FR 31118), and the policy announcement (57 FR 6753) entitled "Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment."

The Agency received 19 comments in response to the notice of proposed rulemaking published on January 22, 1993 (58 FR 5878). These comments were received from trade associations, business firms, public interest groups, scientific researchers, State and Federal agencies, and others. Unit IV of this preamble summarizes and responds to the significant issues raised in these comments.

II. Summary of Proposed Rule

The proposed rule set out a scheme for codifying the Agency procedure, under which EPA has been operating from 1984, of screening planned small-scale tests to evaluate the potential for adverse effects on human health or the environment and allowing EPA to determine whether an EUP would be required for the test. The proposed rule added a Subpart C, "Notification for Certain Genetically Modified Microbial Pesticides," to the existing EUP regulations (40 CFR part 172). The Agency proposed that its review of a notification would be completed within 90 days. At the conclusion of the review, the Agency could make one of the following determinations: Approve the test without requiring an EUP; approve the test without requiring an EUP as long as certain modifications in

the proposed test plan are incorporated; require additional information; require an EUP for the test; or disapprove the test because of the potential for unreasonable adverse effects.

The proposed rule requested comment on two options (Options 1 and 3) for defining which microbial pesticides would be subject to the notification requirement. A third option was also discussed (Option 2), but only for illustrative and comparative purposes. The Agency's goal in setting forth these options was to discuss alternative approaches to identifying those microbial pesticides having the greatest potential to pose risks, or those where sufficient information and knowledge are lacking about the potential risk when the microbial pesticide is introduced into the environment. In the proposal, EPA indicated its preference for Option 1.

Under Option 1, the Agency proposed that the Agency be notified before initiation of small-scale testing with microbial pesticides "whose pesticidal properties have been enhanced or imparted by the introduction of genetic material that has been deliberately modified." Key terms in Option 1 were defined as follows:

1. "Deliberately modified" means the directed addition, rearrangement, or removal of a nucleotide sequence(s) to or from genetic material.

2. "Introduction of genetic material" means the movement of a nucleotide sequence(s) into a microorganism, regardless of the technique used.

3. "Pesticidal property" means a characteristic exhibited by a microorganism that contributes to the intentional use of the microorganism to prevent, destroy, repel, or mitigate a pest or to act as a plant regulator, defoliant, or desiccant.

In Option 3, EPA proposed notification for "Indigenous microbial pesticides for which specific pesticidal activities have been created or increased by deliberate processes or techniques."

Under Option 3, notification would not be required for microbial pesticides whose pesticidal activities have been increased, but which are unlikely to pose a greater risk in the test site environment, in terms of increased host range, competitiveness, survivability, or genetic mobility, compared to the microorganism(s) from which they were derived, and notification would not be required for microorganisms whose phenotype has been changed only by the microorganism's introduction into a new environment, but which are unlikely to pose a greater risk in the test site environment resulting from an

increase in host range, competitiveness, survivability, or genetic mobility.

Key terms used in Option 3 were defined as follows:

1. "Pesticidal activities," for the purpose of this option, means hazard characteristics expressed by the microorganism, which is the active ingredient, that prevent, repel, destroy, or mitigate a pest or act as a plant growth regulator, defoliant, or desiccant through toxin production, infectivity, pathogenicity, or virulence. Pesticidal activities do not include non-cytotoxic modes of action such as those brought about by niche exclusion, substrate competition, or nutrient sequestration.

2. "Created" means the microorganism has been given a pesticidal activity that is not part of the normal genetic complement of the species in nature.

3. "Increased pesticidal activity" means an augmentation of a pesticidal activity that can be shown to be part of the normal genetic complement of the species in nature.

4. "Deliberate processes or techniques" means the intentional movement of the microorganism to a new environment or a change in the genetic information of the microorganism resulting from natural breeding, selection for spontaneous mutations, chemical or physical mutagenesis, transduction, transformation, conjugation, cell fusion, recombinant DNA or other genetic manipulations.

5. "Test site environment" means the immediate test site and the area surrounding the test site to which the microorganism or its genetic material may reasonably be expected to be dispersed.

6. "Genetic mobility" means the horizontal movement [i.e., from the genome of one species to the genome of another] of genetic material.

The Agency also requested comment on specific administrative aspects of implementation of the scope of coverage.

Under any option, the Agency proposed to no longer require notifications for any naturally occurring nonindigenous microbial pesticides. EPA based its decision on its experience since 1984 with the assessment of these types of microbial pesticide products at the small-scale testing stage and its belief that continued imposition of the notification requirement for these microbial pesticides would constitute unnecessary duplicative oversight of research and development with that of the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA/APHIS).

The proposed rule also provided, at § 172.45, that testing conducted in a facility with adequate containment and inactivation controls would not be subject to the notification requirement. Responsibility for selection and use of adequate containment and inactivation controls would lie with the researcher or institution conducting the test.

The proposed rule contained a discussion of the kinds of data and information to be submitted in a notification at § 172.48. Procedures for claiming data and information provided to the Agency in a notification as confidential business information (CBI) were proposed in § 172.46(d).

A mechanism for designating, in the future, generic exemptions from the requirement for notification prior to testing at the small-scale stage was proposed at § 172.52. Using this mechanism, certain subgroups of microbial pesticides, otherwise subject to notification would, on the basis of scientific knowledge and experience, be added to a list of exemptions from the notification requirement.

The Agency also proposed to revise § 172.3 to clarify its rationale for presuming that an EUP is not required prior to small-scale testing with most pesticides. The Agency would modify the language of the rule to clarify that the determination of whether an EUP is required is based on risk considerations, rather than on a definitional presumption about whether the substance is a pesticide. Whether a substance is a pesticide, and therefore under the jurisdiction of FIFRA, is governed by the definition in section 2(u) of FIFRA; whether a pesticide should be regulated under FIFRA is governed by risk/benefit considerations.

EPA proposed, at §§ 172.57 and 172.59, means to address situations where small-scale tests covered in Subpart C result in unanticipated and untoward effects. Section 172.57 was proposed to address situations where a person using a microbial pesticide in small-scale testing obtains information concerning the potential for unreasonable adverse effects. This section would require a person to submit such information to EPA within 30 days so that the Agency could evaluate the information and take any necessary action to minimize the potential for adverse effects. In situations where threat of harm to human health or the environment is immediate and serious, § 172.59(a) sets out the manner in which EPA would act immediately to prevent adverse impacts.

The provisions set forth in proposed Subpart C §§ 172.43 through 172.59 for the review of small-scale tests of certain

microbial pesticides would not affect the already established Agency procedures for the review of pesticides for EUPs or for registration purposes.

III. Summary of Final Rule

The Agency has determined that Option 1 of the proposed rule provides a scope of coverage which best addresses potential risks presented by certain categories of small-scale testing with microbial pesticides. It does so by focusing the notification requirement on tests involving microbial pesticides with the potential for presenting new and different hazards or exposures to humans or the environment on the basis of simple and directly addressable criteria that form the scope definition. This final rule significantly reduces the number of notifications that will be sent to EPA relative to existing EPA policy. Thus, Option 1 as it appears in the proposed rule will become part of Subpart C to be added to the existing EUP regulations in 40 CFR part 172.

In the proposed rule, EPA provided a rationale for, and requested comment on, the scientific merit of adding a categorical exemption to proposed Option 1 for microorganisms modified solely by rearrangement or deletion of nucleotide sequences within a single genome. Public comment supported this approach. Thus, at § 172.45(d) of the regulatory text, EPA specifically exempts a category of microbial pesticides otherwise captured by the scope of the requirements, by adding the following language.

"Microbial pesticides resulting from deletions or rearrangements within a single genome that are brought about by the introduction of genetic material."

Key terms are defined as follows:

1. "Single genome" means the sum total of chromosomal and extrachromosomal genetic material of an isolate and any descendants derived under axenic culture conditions from that isolate.

2. "Microbial pesticides resulting from rearrangements" means microbial pesticides resulting from translocations or inversions.

With regard to nonindigenous microbial pesticides, the Agency, through discussions with USDA/APHIS and its own investigations, has not been able to identify any category of nonindigenous microorganisms potentially used as a pesticide that are not covered by APHIS authorities. However, in response to public comment, Subpart C contains, in § 172.45(c), a provision that EPA require notifications, at the small-scale testing stage, for nonindigenous microbial pesticides that have not been acted

upon by USDA (i.e., either by issuing or denying a permit or determining that a permit is unnecessary; or a permit is not pending with USDA).

In the final rule, testing conducted in a facility with adequate containment and inactivation controls will not be subject to the notification requirements. Responsibility for selection and use of adequate containment and inactivation controls lies with the researcher or institution conducting the research and can be based on available guidance. In the proposed rule, the Agency asked for public comment on whether minimal recordkeeping to document the selection and use of containment and inactivation controls should be required. Public comment favored this proposal and at 40 CFR 172.45(e) contains language to this effect.

Section 172.46 describes the format of a notification and when and where to submit the notification. A provision for claiming data and information provided in a notification as CBI is included in § 172.46(d). Section 172.48 identifies the data and information to be included in a notification. Section 172.50 indicates the time (90 days) the Agency allows itself to review and respond to a notification.

Section 172.52 describes a process petitioners may use to request exemption of specific microbial pesticides or categories of microbial pesticides from the notification requirement.

Sections 172.57 and 172.59 are included to enable the Agency to address situations where small-scale tests covered by Subpart C result in unanticipated and untoward effects.

The Agency has revised 40 CFR 172.3 to clarify its rationale for presuming that an EUP is not required prior to small-scale testing with most pesticides. In response to public comment on the proposed rule, EPA has revised the proposed text of § 172.3 to clarify that the applicability of EUP requirements will be based upon risk/benefit considerations, and to include testing of new uses of registered pesticides.

IV. Response to Comments

EPA received a total of 19 comments on its proposal to amend its EUP regulations for microbial pesticides (58 FR 5878, January 22, 1993). A detailed analysis of the public comments was prepared by EPA and is available in the public record ("Analysis of Comments, 40 CFR part 172 Microbial Pesticides; Experimental Use Permits and Notification; Proposed Rule. 58 FR 5878." Docket Control Number OPP-50668A).

The following organizations or individuals provided comments on the proposed rule: S. Abramson; American Council on Science and Health (ACSH); American Farm Bureau Federation (AFBF); The American Phytopathological Society (APS); Council for Responsible Genetics (CRG); DuPont Agricultural Products (DuPont); Ecogen, Inc.; Environmental Defense Fund (EDF); M. Goettel; Industrial Biotechnology Association (IBA); D. Keppel; Massachusetts Audubon Society (MAS); Mycogen, Inc.; National Audubon Society (NAS); National Wildlife Federation (NWF); Novo Nordisk Bioindustrials (NNB); U.S. Department of Agriculture National Agriculture Pesticide Impact Assessment Program (USDA/NAPIAP); Wisconsin Department of Agriculture, Trade, and Consumer Protection (WDATCP); A. Wood.

A. Scope of Coverage

In its proposal, EPA requested comment on two approaches to scope of coverage. EPA's preferred option, Option 1, represents a "centralized" approach to regulation. That is, EPA defined in Option 1 the specific microbial pesticides subject to the notification requirement. To arrive at Option 1, EPA performed an initial assessment of the potential risk presented by certain categories of small-scale testing with microbial pesticides to determine which microbial pesticides need not be subject to the notification requirement. The Option 1 language was then drafted to describe those microbial pesticides which could not generically be exempted from the notification requirement. EPA would perform the review of the risks and benefits of the subject microbial pesticides on a case-specific basis. The language used to describe the microbial pesticides subject to notification consisted of three fairly straightforward and specific criteria that could be answered by either a "yes" or "no."

Option 3, on the other hand, is an option based on a "decentralized" approach. That is, based on general criteria supplied by EPA, the researcher conducts a comprehensive evaluation of the microbial pesticide and the proposed test and makes a determination of whether a test would be subject to EPA notification review. Those microbial pesticides the researcher determines would be subject to notification would be reviewed by EPA on a case-specific basis. The criteria used to determine whether the test would be subject to notification are greater in number and would not usually be answered by either a simple

"yes" or "no." Rather, researchers would use their judgement to determine whether EPA should be notified.

A total of 16 comments were received on the question of the relative merits of the two options. Fifteen commenters supported Option 1. One commenter (ACSH) supported Option 3 unequivocally. Of the 15 commenters supporting Option 1, seven (NWF, M. Goettel, NAS, Ecogen, IBA, NNB, and AFBF) supported the option unequivocally; eight (EDF, MAS, CRG, A. Wood, WDATCP, Mycogen, APS, and USDA/NAPIAP) supported the option but suggested modifications to the scope of coverage. Seven (Ecogen, NWF, CRG, EDF, WDATCP, MAS, and NAS) of the 15 commenters supporting Option 1 specifically voiced opposition to Option 3. All seven were opposed to a decentralized approach *per se*; two (MAS and CRG) of these seven identified major concerns with the language of the scope of coverage of Option 3. Among the 15 who supported Option 1, two (AFBF and APS) saw some advantages to a decentralized approach; and 1 of these 2 (APS) requested that EPA reconsider a decentralized approach in 3 years.

Commenters who supported Option 1 but suggested modifications to the language of the scope of coverage can be grouped into three categories based on the extensiveness of the suggested modifications. In the first group, five commenters (EDF, MAS, CRG, A. Wood, and WDATCP) suggested that the definition of "deliberately modified" be changed to include all genetic material that is introduced and not, as currently set forth in Option 1, only that genetic material that has experienced "directed addition, rearrangement, or removal of a nucleotide sequence(s) to or from genetic material." In the second group, one of the seven commenters (Mycogen) requested a broad scope of coverage. Specifically, this commenter suggested that the Agency adopt the centralized approach with the following scope language, "Indigenous microbial pesticides for which specific pesticidal activities have been created or increased by deliberate processes or techniques." In the third group, two commenters suggested a somewhat different direction. USDA/NAPIAP suggested that "biological control agents" be differentiated from "microbial pesticides" and that microbial biological control agents be exempted from the notification requirement. The EPA proposal did not make such a differentiation. The other commenter (APS) offered a suggestion that "[a] modification to Option 1 might be considered for potential exemption or to

allow initiation of experiments simultaneously with notification in the case of rearrangements or deletions within a single genome that result in phenotypes comparable to those observed in natural populations."

EPA Response: EPA agrees with the comments supporting Option 1 and has adopted Option 1 in the final rule. EPA believes that a centralized approach is the more efficient and protective approach to small-scale testing of microbial pesticides at this time.

EPA believes the scope of coverage of Option 1 creates a structure wherein the assessment of whether a test is subject to notification to EPA is made on the basis of simple and directly addressable criteria that form the scope definitions. Under this approach, all interested parties (e.g., industry, researchers, public interest groups, and EPA) would, in most instances, conclude from a reading of the definitions alone whether a test involving a specific microbial pesticide is subject to the notification requirement. In addition, this final rule significantly reduces the number of notifications that will be sent to EPA relative to existing EPA policy.

EPA believes Option 1 appropriately focuses attention on microbial pesticides with (1) new or different hazard traits; and, (2) the potential to present new or different exposures, e.g., organisms which heretofore might not have been exposed to a particular substance might now be exposed to that substance through the microbial pesticide. EPA judges pesticides in these categories to present relatively greater potential for risk than those microbial pesticides EPA would no longer subject to the notification requirement.

EPA has examined the eight comments suggesting modification of the Option 1 language; however, EPA does not believe any of the suggested modifications are warranted. EPA believes the word "directed" in the definition of "deliberately modified" as proposed in Option 1 addresses what appears to be the primary concerns of the majority of commenters. From their letters, three commenters (EDF, CRG, and WDATCP) appear to believe that some types of microbial pesticides EPA intends to be captured for notification under Option 1, would not be captured. EDF, for example, noted that an "unmodified scorpion gene would not require notification" under Option 1. WDATCP made a similar point using a wasp toxin gene as an example.

EPA believes that the Option 1 language in its proposal of January 22, 1993, would capture such microbial pesticides, because some type of

"directed" modification would have to be made in the development of these microbial pesticides. In the examples mentioned by EDF and WDATCP, appropriate regulatory sequences would have to be added directly to the nucleotide sequences encoding the structural gene for the toxin, and this complete genetic construct introduced into the recipient microorganism, in order to be expressed in the recipient microorganism. Inserted structural genes lacking appropriate regulatory sequences have an extremely low probability of being expressed. Without appropriate regulatory sequences, the only possibility for an introduced gene to be expressed is if it accidentally inserts in a position on the microorganism's chromosome adjacent to appropriate regulatory genes. However, an introduced gene is unlikely to insert by chance at a position adjacent to sequences necessary for expression by the recipient microorganism. EPA is not aware of any reports in the scientific literature documenting that this can occur, and no examples of such genetic modifications were provided in public comments on the proposed rule.

An additional technical problem would arise as a result of the extreme difficulty of identifying and isolating, without the use of marker genes, microorganisms appropriately expressing the desired introduced pesticidal traits. The use of marker genes entails "directed" modification. Without marker genes, the time required for researchers to test thousands, if not millions, of individual microbial isolates to identify the microorganism that has undergone the rare event of insertion of a pesticidal trait is not practical.

To summarize, it is technically extremely difficult to introduce an "unmodified" scorpion or wasp gene into a microorganism to create a novel microbial pesticide. Directed addition of nucleotide sequences would be necessary for either selection of the modified microorganism or proper expression of the gene encoding the pesticide.

EPA has not modified the rule to incorporate the suggestion (Mycogen) to broaden the scope to all genetically altered microbial pesticides by utilizing a scope of coverage for all "indigenous microbial pesticides for which specific pesticidal activities have been created or increased by deliberate processes or techniques." EPA's experience, in the past 10 years, in reviewing notifications for small-scale testing with genetically altered microbial pesticides has allowed the Agency to conclude that certain of

these microbial pesticides need not be subject to the notification process. EPA believes the scope of coverage in the final rule addresses the appropriate category of microbial pesticides, while excluding from notification microbial pesticides similar to those likely to occur in microbial populations in nature. Laboratory-generated microbial pesticides similar to those likely to occur in nature are not likely to present new hazard or exposure issues when tested at small-scale, with the possible exception of certain nonindigenous microbial pesticides as discussed below.

EPA has determined not to take the suggestion that "biological control agents" be differentiated from "microbial pesticides." Since EPA did not propose such a distinction in the proposed rule, the distinction cannot be incorporated into this final rule. Moreover, such a modification would require substantive changes in regulations and guidance that are not related to this rulemaking; changes that EPA does not believe are warranted. FIFRA applies to all pesticides, whether they be microbial pesticides or other types of biological control agents. EPA does not know of any risk-based reason to create two separate categories that should be treated differently. The commenter has not provided sufficient support for the suggestion that microorganisms that act by means of competitive displacement pose low risk. Little data either supporting or disproving this contention exist in the literature. Competitive displacement interactions among microorganisms can be mediated by microbial toxins, and such toxins can raise concerns for effects on nontarget organisms.

With regard to the comment suggesting that deletions or rearrangements within a single genome be handled either as exemptions or as post-card notifications, the Agency believes this suggestion could be handled under the exemption provision of § 172.52, and the Agency's determination is discussed under unit E, "Exemption Process," of this final rule.

B. Administrative Aspects of Implementation of Scope of Coverage

EPA requested comment on four administrative aspects of implementation of scope of coverage. These four administrative procedures could apply to both Options 1 and 3, but are more relevant to Option 3. The four procedures are: (1) Guidance from EPA on the considerations used in making a determination of whether a microorganism is covered by the scope; (2) documentation of the determination; (3) review of the determination by a

third party; and, (4) retention of the records of the determination.

Six respondents commented on this issue. Three comments (AFBF, WDATCP, and MAS) were received supporting the need for Agency guidance on considerations relevant to determining whether a microbial pesticide is subject to the notification requirement.

Three commenters (EDF, NAS, and NWF) stated that, if Option 3 were adopted, a third-party review procedure would not adequately protect human health and the environment. One comment (AFBF) was received suggesting that third-party review would strengthen a process where researchers make a determination of whether a microorganism is covered by the scope in terms of consistency, ensuring the correct determination, and addressing the concerns of the public. One comment (AFBF) was received supporting the retention of records.

Two commenters (MAS and AFBF) stated that if Option 3 were chosen by EPA, documentation of the considerations used in making a determination of whether a microorganism is covered by the scope should be required.

EPA Response: EPA will implement in the final rule the scope of coverage described in its proposed Option 1. EPA believes that researchers' laboratory notebooks routinely include the types of information considered in making a determination of whether a microorganism is covered by the notification requirement set forth in Option 1. Although researchers are not required to develop and maintain records specifically supporting a determination of whether a microorganism is covered by this notification requirement, researchers' laboratory notebooks or other documentation would be treated by EPA as records.

Because of the sufficiently straightforward nature of the language of Option 1, third-party review would add little to the determination, and this is not judged by EPA to be necessary for Option 1. In terms of guidance to submitters, the Agency believes that the selection of Option 1 obviates the need for extensive guidance. The criteria contained in Option 1 are fairly straightforward and the selection criteria set forth in the scope definition, as well as the rationale discussion in Unit III of the proposed rule, provide sufficient guidance. Developers of microbial pesticides may also consult with the Agency for guidance on notification requirements, including whether a particular microbial pesticide

is subject to the notification requirement.

C. Nonindigenous Microbial Pesticides

Since 1984, EPA has had in place policies that require notification to EPA for small-scale testing of all genetically altered and nonindigenous microbial pesticides. "Nonindigenous microorganism" was defined in the 1986 "Coordinated Framework for Regulation of Biotechnology" (51 FR 23302, June 26, 1986), which stated that a microorganism would be considered to be nonindigenous to "any one of the geographic areas listed below if it is isolated from outside that area: (1) The continental United States, including Alaska,* and the immediately adjoining countries (i.e., Canada and Mexico); (2) The Hawaiian Islands; (3) The Caribbean Islands including Puerto Rico and the U.S. Virgin Islands." EPA stated in the proposed rule that "nonindigenous" microbial pesticides should no longer be subject to the notification requirement because they are adequately regulated by another Federal agency. In the proposed rule, EPA requested comment on whether a category could be identified consisting of nonindigenous microbial pesticides that pose a potential for significant risk to human health or the environment, when used in testing at small-scale, that are not otherwise reviewed by another Federal agency. Three commenters (IBA, NNB, and Ecogen) supported EPA's proposal to exclude nonindigenous microbial pesticides from the scope of coverage. Four other commenters (MAS, EDF, A. Wood, and ACSH) opposed omitting nonindigenous microbial pesticides from the scope of coverage of this rule. Two among this second group of commenters (MAS and EDF) stated that the Agency should consider covering those nonindigenous microbial pesticides not regulated by other Federal agencies. These commenters asked the Agency to provide a more detailed analysis of how other Federal agencies' authorities would apply to nonindigenous microorganisms, and ensure safe use. The other two commenters opposed to omitting nonindigenous microbial pesticides from the scope of coverage (A. Wood and ACSH) believed that all microbial pesticides should be reviewed before initial field testing.

EPA Response: The Agency believes that the vast majority, if not all, of nonindigenous microorganisms (some of which are microbial pesticides) are addressed by the regulatory authorities of USDA/APHIS. Nonindigenous microorganisms that may have direct or indirect plant pest or adverse animal

health effects are regulated by USDA/APHIS. Under its authorities (Federal Plant Pest Act, U.S.C. 150aa et. seq., Plant Quarantine Act, 7 U.S.C. 151 et. seq.; Federal Noxious Weed Act, 7 U.S.C. 2801 et. seq.; and several animal quarantine statutes, 21 U.S.C. 111, 114, 134), and pursuant to its responsibilities under the National Environmental Policy Act (NEPA) 42 U.S.C. 4321 et seq., USDA/APHIS considers the human health and environmental impacts associated with nonindigenous microorganisms that have plant pest potential or are animal pests. USDA/APHIS has issued regulations at 7 CFR part 330 which regulate the importation and interstate movement of plant pests including provisions on the port of entry, inspection, emergency measures, and the information needed in applications for permits to move plant pests.

EPA believes that small-scale tests involving naturally occurring nonindigenous microbial pesticides, that have been acted upon by USDA (i.e., either by issuing or denying a permit or determining that a permit is unnecessary; or a permit is not pending with USDA), are adequately regulated and thus are unlikely to cause any significant impact on the environment. Another measure of oversight is provided by the U.S. Public Health Service, which regulates the importation and subsequent distribution of microorganisms that are of human health concern.

EPA's preferred option in the proposed rule was to exclude, based on its analysis of USDA/APHIS regulatory authorities, nonindigenous microbial pesticides from the notification requirement. However, EPA also stated that it would consider reviewing nonindigenous microbial pesticides that pose a potential for significant risk to human health or the environment when used in testing at small-scale and that are not otherwise reviewed by another Federal agency, provided that a category of such microorganisms can be identified. However, the Agency explained that it was not aware of the existence of such a category of nonindigenous microbial pesticides.

In this final rule EPA will require notification, at small-scale field testing, for nonindigenous microbial pesticides that have not been acted upon by USDA (i.e., either by issuing or denying a permit or determining that a permit is unnecessary; or a permit is not pending with USDA), even though at this time no microbial pesticides may be described by this category. EPA believes this approach will ensure that all nonindigenous microbial pesticides,

tested at small-scale, will be reviewed by a Federal agency. EPA believes this cautious approach addresses the concerns raised in public comments and the comments of the SAP (see proposed rule at 58 FR 5878), both of which suggested a similar approach.

The Agency will, under its EUP and registration authority, continue to regulate nonindigenous microbial pesticides prior to any use at more than 10 acres of land or 1 surface acre of water.

D. Testing in Contained Facilities

In the proposed rule, EPA proposed that testing within a contained facility, such as a laboratory or greenhouse, where appropriate containment controls and procedures are employed, would not require notification. The individual or institution conducting the contained research would be given the discretion to select and use procedures and controls appropriate to achieve the "performance standard" of adequate containment. EPA requested comment on whether minimal recordkeeping to document the selection and use of containment and inactivation controls should be required.

Six respondents commented on this issue. None of the six commenters (IBA, NNB, APS, Ecogen, AFBF, and EDF) supported the concept that notification to EPA for contained research is necessary. Two commenters (IBA and NNB) thought the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules provided suitable guidance and standards for selecting and using procedures and equipment to obtain appropriate containment. One commenter (AFBF) suggested guidance should be based on USDA, NIH, or American Society for Microbiology guidelines.

Two commenters (AFBF and APS) stated that no additional and specific recordkeeping is necessary beyond what occurs in standard laboratory practice; e.g., laboratory notebooks. One commenter (EDF) strongly supported requiring minimal recordkeeping to document the selection and use of the containment and inactivation controls. In addition, this commenter believed that EPA's proposed performance standard for containment is vague and not protective.

EPA Response: EPA continues to believe that notification for contained research with microbial pesticides is not necessary. EPA agrees that adequate guidance on selecting appropriate microbiological procedures for achieving adequate containment is available from sources such as the

Public Health Service, Centers for Disease Control guidance on the use of etiologic agents and the NIH Guidelines for Research Involving Recombinant DNA Molecules. Selection and use of specific containment and inactivation controls can be based on this available guidance, and EPA does not plan to issue additional guidance at this time. Researchers are reminded that they must keep records documenting selection and use of appropriate containment and inactivation controls. These may be kept in laboratory notebooks. If the NIH Guidelines are used as guidance, the researcher's notebook should indicate the level of containment suggested by the Guidelines and that this guidance was selected and used. In order to clarify that such records should be available for either inspection by EPA or submission to EPA upon the Agency's request, § 172.45(e)(4) of the regulatory text reads as follows: "Records shall be developed and maintained describing the selection and use of the containment and inactivation controls, including contingency plans for emergency clean-up and test termination, that will be used during the test. These records shall be available for inspection at the test facility. In addition, these records shall be submitted to EPA at EPA's request and within the timeframe specified in EPA's request." EPA believes that persons following the NIH Guidelines would keep adequate records as part of normal procedures for informing their Institutional Biosafety Committee of the contained research.

In the proposed rule, the Agency asked for comment on whether selection of containment and inactivation controls should be approved in writing by an authorized official of the organization. EPA received no specific comments on this provision either in support or opposition. EPA believes that most research organizations follow such a provision on approval by an authorized official as a matter of course. For example, those institutions complying with the NIH Guidelines would meet this provision through the Institutional Biosafety Committee provisions of the Guidelines. EPA therefore has included the provision on approval by an authorized official at § 172.45(e)(3) of the regulatory text.

In comments on the proposed rule, EDF stated that EPA's performance standard is too vague and not protective because EPA fails to define what is meant by "adequate" containment and inactivation controls. EPA believes that it is appropriate to give the individual or institution conducting the testing the discretion to select and use procedures

that would achieve adequate containment, based on available guidance, such as the guidance on containment procedures for microorganisms used in research laboratories found in the NIH Guidelines for Research Involving Recombinant DNA Molecules. EPA's approach accepts that the judgement of the individual or institution conducting the research must take into account the many different kinds of microorganisms used in research and the fact that appropriate containment conditions vary depending on the microorganism. EPA believes that experience with contained research with microbial pesticides demonstrates that this approach is adequate in protecting against unreasonable adverse effects to human health and the environment. Thus, EPA has determined that the recordkeeping requirements at §§ 172.45(e)(3) and 172.45(e)(4) of the regulatory text, along with the procedures for reporting unreasonable adverse effects at §§ 172.57 and 172.59, are appropriate for the level of risk presented by contained research with microbial pesticides.

E. Exemption Process

The Agency proposed in § 172.52 a process for exempting from the notification requirement certain subgroups of microbial pesticides otherwise captured by the scope of coverage laid out by Option 1. All five comments (AFBF, IBA, NNB, APS, and MAS) received on this issue supported the concept of a mechanism for exemption of microbial pesticides, otherwise captured by the scope of the rule, from the notification requirements. Two commenters (IBA and NNB) suggested as candidates for exemption *Bacillus thuringiensis* which have been genetically modified through the introduction of genetic material from other strains of *Bacillus thuringiensis* and/or genetic material for selectable marker genes. One commenter (MAS) suggested changes in the exemption process: a longer public comment period and "less vague" qualification criteria. One commenter (APS) suggested in their comments on scope of coverage a somewhat different exemption mechanism than discussed by the Agency in its proposal. The commenter proposed that "[a] modification to Option 1 might be considered for potential exemption or to allow initiation of experiments simultaneously with notification in the case of rearrangements or deletions within a single genome that result in phenotypes comparable to those observed in natural populations."

EPA Response: The Agency has included at § 172.52 a mechanism for exempting, as information warranting such action becomes available, certain subgroups of microbial pesticides from the notification requirement. EPA agrees with the comment (MAS) received concerning the time allowed for public comment on proposed exemptions. EPA will utilize a comment period of 45 days, instead of the proposed 30 days, in order to allow more time for public participation. EPA will still review these petitions within the 180-day timeframe stated in the regulatory text.

With regard to the comment on the criteria for exemption (MAS), EPA believes that, at this time, it is not possible to generically describe the criteria that will be used for specific exemptions from notification under § 172.52 of the final regulation. EPA believes that petitions for exemption have to be addressed on a case-specific basis. In instances where EPA believes that an exemption is appropriate, EPA will issue a notice of proposed rulemaking in the *Federal Register*, which will explain the basis for the Agency's proposed decision.

MAS also asked how the exemptions from notification under § 172.52 would differ from EPA's policy, stated in the proposed rule, of informing submitters on an individual basis when no further notification to EPA was required for specific microbial pesticides. EPA will encourage submitters to use the exemption from notification process to address such situations in the future. Use of the exemption from notification process under § 172.52 will allow the public the opportunity to comment on any exemption petition submitted to EPA.

In the proposed rule, EPA requested comment on the scientific merit of adding an exemption under § 172.45(d)(1) of the regulatory text for "... microorganisms modified solely by rearrangement (i.e., translocation or inversion) or deletion of nucleotide sequences within a single genome, including its extrachromosomal elements." This concept was supported by APS when they suggested a modification of the scope of coverage to exempt small-scale testing of microbial pesticides "... in the case of rearrangements or deletions within a single genome that result in phenotypes comparable to those observed in natural populations." An exemption describing this category of microbial pesticides is included at § 172.45(d)(1) of the regulatory text. EPA has gained experience in the review of notifications of such organisms and is persuaded that such microbial pesticides are similar to

those that would be likely to occur in microbial populations in nature, since it is known that deletions and rearrangements of genetic material within a single genome occur in microorganisms in nature. The microbial pesticides described by the exemption at § 172.45(d)(1)(i) would, thus, likely be subject to the same constraints as other naturally occurring microbial populations in the environment.

EPA agrees with the commenters (IBA and NNB) who proposed an exemption for microbial pesticides based on the organism *Bacillus thuringiensis* that such an exemption may be merited under § 172.52 of the regulatory text. After publication of this final rule in the *Federal Register*, EPA will begin work on developing an exemption for certain genetically modified *Bacillus thuringiensis* strains as proposed in public comments. EPA requests that individuals supporting this exemption provide to the Agency any information or data on why the specific microbial pesticide or class of microbial pesticides meet the criteria of § 172.3 for small-scale tests of pesticides that do not require an EUP.

F. Notification Process

Proposed § 172.48, included a discussion of the kinds of data and information to be submitted in a notification; e.g., the identity of the microbial pesticide, a characterization of its relevant biology and ecology, a description, if applicable, of how the microbial pesticide has been modified, and a description of the objectives, experimental design, and other relevant parameters of the proposed test. EPA proposed in § 172.46 that Agency review of a notification would be completed within 90 days. Proposed § 172.46 also contained information on where and how to submit a notification.

Six comments were received on the proposed notification process. Four of the six comments dealt with data requirements. Two of these four commenters (IBA and NNB) agreed with EPA's proposed regulatory text. The third (MAS) requested that EPA require the use of marker and suicide genes in microbial pesticides and also require information be submitted on the management of resistance to pesticides in populations of target organisms. The fourth commenter (WDATCP) offered suggestions on data requirements addressing survival and potential effects on non-target organisms. Two of the six comments (IBA and NNB) requested that EPA review notifications in 60 days rather than the 90 days proposed by the Agency. Two commenters (MAS and

WDATCP) addressed issues of coordination with State authorities responsible for oversight of microbial pesticides. One commenter (A. Wood) suggested that EPA develop a data base of human health and environmental data generated from field tests of microbial pesticides, including those under notification, in order to improve the data based for future regulatory decisions. One commenter (APS) suggested that EPA change the term "notification" to "screening procedure" or "microbial pesticides pre-test review procedure" because notification is a misnomer.

EPA Response: In this final rule EPA will implement its proposal of allowing 90 days as the outer limit for review of notifications. Ninety days is required to achieve coordination with State and local authorities and with USDA/APHIS where jurisdictional overlap occurs between EPA and USDA. Ninety days also permits the Agency sufficient time to fully evaluate whether any risk issues are associated with the test and to examine them in detail, including providing the opportunity for public participation in the review of notifications. EPA's goal is to complete reviews of notifications in a timely fashion and, whenever possible, notify submitters of the Agency's decision in less than 90 days.

In terms of the use of marker genes, EPA included, upon the request of the SAP in 1988, a statement in proposed § 172.48 encouraging the use of such genes. EPA is retaining this statement in the final rule. EPA believes use of such genes should be encouraged to facilitate the identification or monitoring of microbial pesticides in the environment. However, EPA will not make use of such genes a mandatory general requirement for all small-scale field tests. EPA has the flexibility to make a determination, on a case-specific basis, of whether the use of marker genes should be required for particular tests; for example, when the use of marker genes for monitoring of a microorganism is judged by EPA to be an appropriate means of risk management for a particular field test. Technical and efficacy considerations can be taken into account on a case-specific basis in determining the relative cost/benefit ratio of using marker genes. EPA believes the requirement that microbial pesticides contain suicide genes is premature because the efficacy of suicide genes in controlling microbial populations in the environment has not been demonstrated to date in the scientific literature.

The suggestion that EPA include a requirement for a pesticide resistance

management plan is beyond the scope of this rule, which addresses only notification for small-scale tests of certain microbial pesticides. The Agency is aware of this issue for all pesticides and is evaluating its approach to resistance management.

Comments on data requirements included the suggestion that survival of the microbial pesticide in the environment and evaluation of a broad range of potential non-target organisms for adverse effects is important (WDATCP). EPA agrees that information on the survival of a microbial pesticide should be evaluated in a notification and has retained this data requirement in the final rule at § 172.48. EPA will not, however, routinely require in a notification that a broad range of potential non-target organisms be addressed by the submitter. EPA can require testing of effects on potential non-target organisms in a specific notification if the characteristics of a particular microbial pesticide indicate that this is justified. Data requirements for EUPs and registration in § 158.740 describe tests to address non-target effects of microbial pesticides. These requirements utilize single-species testing, which the Agency has found to be the most effective way to address potential for non-target effects.

The suggestion (A. Wood) that EPA develop a data base of human health and environmental data generated from field tests of microbial pesticides is beyond the scope of this rule which addresses only notification for small-scale testing of certain microbial pesticides. However, applicants submit human health and environmental data as part of the notification, EUP, and registration processes, and the Agency's experience base grows through this process.

While, as suggested by APS, the term "screening procedure" or "microbial pesticides pre-test review procedure" may provide a more accurate description of the reporting process described in the proposed rule, the term "notification" has been used by EPA since the publication of the 1984 policy statement and is both accepted and understood by interested parties. To change the term now could lead to confusion. EPA, thus, will continue to use the term "notification" to describe this process. The notification process described in § 172.46(b) indicates how submissions should be marked to ensure that notifications are properly processed.

G. Substantiation of Claims for Confidential Information

The Agency requested comment on the proposed requirement (§ 172.46(d)) that any claim of confidentiality must be substantiated at the time the claim is made (i.e., "up-front substantiation"). Specifically, the Agency sought comment on how to achieve the best balance between the burden on industry to provide substantiation before public disclosure becomes an active issue (e.g., in preparation for SAP meetings) and the regulated community's desire to receive timely responses on notifications. This balance must take into consideration the needs of pesticide developers to protect information they believe to be critical to maintaining their competitiveness and the public's need for access to information related to potential environmental or human health effects early enough in the notification review process to provide informed comment before the Agency makes a decision.

Five respondents (Ecogen, IBA, NNB, EDF, and CRG) commented on EPA's proposed approach on substantiation of CBI claims. All five commenters supported EPA's proposal to require up-front substantiation; three of these commenters (Ecogen, IBA, and NNB) recommended that EPA implement an initial screening process to identify and address expeditiously any CBI issues.

EPA Response: EPA continues to believe that up-front substantiation of CBI is appropriate and necessary for expeditious decisions on notifications. EPA believes that, given the Agency's procedural requirements for making final CBI determinations, without up-front substantiation, the 90-day response time associated with the notification procedure at § 172.50 would be difficult or impossible to meet if it becomes necessary to resolve a CBI issue before a decision on the notification can be made. Up-front substantiation allows the Agency to make available to the public expurgated copies of each submission and a rationale for any exclusions, and, in necessary cases, to make final determinations of the validity of CBI claims. The Agency does not believe that a formal initial screening process needs to be implemented because a submitter always has the option of consulting with the Agency on these and other issues.

Two commenters (IBA and NNB) felt that EPA should issue guidance on the types of information that constitute a valid claim of CBI for microbial pesticides. EPA will consider developing such guidance in the future.

It may be more useful for the Agency to develop such guidance after gaining more experience in the review of microbial pesticides subject to this final rule.

H. Voluntary Submissions

Although not specifically proposed in the rule, the Agency requested comment on whether, in addition to the notification requirement, EPA should offer the opportunity to obtain review on a voluntary basis, of any microbial pesticide that a company or researchers believes could benefit by such a review, regardless of the scope of coverage for notification in the final rule. The two commenters (IBA and NNB) who offered comment on this issue supported a provision for voluntary submissions, although one commenter (NNB) expressed concern over the burden on Agency resources as a result of the increased number of submissions.

EPA Response: EPA agrees with the comment that the Agency's resources may be overly burdened by voluntary submissions if developers of microbial pesticides decide to submit notifications for microbial pesticides outside the scope of coverage. Such voluntary reviews could be equivalent to a notification in terms of Agency resources required to conduct a review. After consideration of the public comments on this issue, the Agency believes that it should focus its limited resources on review of notifications of microbial pesticides subject to this rule. However, submitters who are not clear about the reporting status of a microbial pesticide, in terms of the scope of coverage, are encouraged to contact the Agency for guidance on whether a notification is required.

I. Scope of Requirement

Two commenters (Abramson and DuPont) questioned how the proposed changes in § 172.3 affect the relationship between FIFRA sections 5 and 12(b)(5) and the definition of pesticide in section 2(u) and how it would affect testing of registered pesticides in a non-registered use. One commenter (DuPont) suggested modifications of the language of proposed § 172.3(c)(1)(i) and §§ 172.3(c)(1)(iii), 172.3(c)(2)(iv), and 172.3(c)(3). The commenter believed such modified language would more clearly state EPA's intent. This commenter also suggested the word "not" had inadvertently been omitted from proposed § 172.3(d). In addition, the commenter asserted that proposed § 172.3(e) was impractical, unnecessary, and unwarranted, and would give the Agency new powers.

EPA Response: As described in the proposed rule, EPA is modifying § 172.3, to clarify that the basis for the presumption concerning the need for an EUP for small-scale testing is based on risk/benefit considerations, rather than on a definitional determination of whether a substance is a pesticide.

DuPont was concerned that, in revising § 172.3, EPA was modifying the status under FIFRA of a substance being tested, and questioned whether EPA intended to classify all test substances as pesticides.

As EPA stated in the preamble to the proposal, the determination of whether a substance or mixture of substances is a pesticide is governed by the intent test of FIFRA section 2(u). Once a substance is determined to be a pesticide, the applicability of FIFRA section 5 EUP requirements must still be set out. In other words, EPA must explain under what circumstances an EUP will be required for testing conducted on a pesticide. This determination is separate and distinct from whether the substance is or is not a pesticide. The current language of § 172.3(a) mingles the two determinations, and implies that a pesticidal determination can be made on the same basis as the determination of EUP applicability. In fact, a pesticide determination must be based upon intent under the definition of pesticide in FIFRA, whereas EUP applicability will be based upon risk/benefit considerations only after pesticide status has been attained. The revised § 172.3 only addresses the latter of these two determinations.

EPA emphasizes, however, that it does not intend to change the status of any testing with respect to EUP applicability. Small-scale testing previously conducted on a "substance" not subject to the requirement of an EUP, in most instances, will continue to be permitted on a "pesticide" without the requirement for an EUP. As under the existing § 172.3, this final rule will contain a presumption that an EUP is not required for small-scale testing of pesticidal substances. A substance that does not meet the intent test of FIFRA section 2(u) and is therefore not a pesticide would not be covered by FIFRA section 5 under any circumstances. In addition, in this final rule, EPA does not intend to change the status of the exemption under section 12(b)(5) of FIFRA which allows the shipping of a pesticidal substance, under the conditions of that section, without being subject to penalty for failure to have a registration or an EUP. Both Abramson and DuPont commented that EPA had omitted reference in its proposal to the status of testing of new

uses of registered pesticides that is currently explicitly stated in § 172.3(c). EPA did not intend to preclude such testing. Such testing will continue to be eligible for the presumption that an EUP is not required for certain small-scale testing under the final rule. In response to both these comments, EPA has revised the text of § 172.3(a) to clarify the applicability of EUP requirements as being a risk/benefit determination, and to include testing of new uses of registered pesticides.

Proposed § 172.3(e) reserved to the Agency the right to require an EUP on a case-by-case basis, notwithstanding the presumptions in earlier paragraphs that EUPs would not be required. DuPont contended that proposed § 172.3(e) would be impractical, unnecessary, unenforceable, and unduly expand the Agency's authority. DuPont's principal concern was that EPA had not set out criteria for making this determination, and that the regulated community could therefore not discern when it was subject to the requirement of an EUP.

EPA disagrees that the Agency is extending its authority. Rather, it is expressly articulating the authority it has always had to rebut the presumptions, either for specific tests or categories of tests. Section 5 of FIFRA authorizes EPA to require EUPs for all tests, regardless of acreage. EPA has determined, however, that based on risk considerations, EUPs generally are not necessary for small-scale tests conducted using most pesticides. Since the applicability of EUP requirements depends on risk/benefit considerations, EPA believes it is entirely appropriate that the Agency retain this flexibility and be able to make case-by-case determinations of EUP applicability. If EPA has reason to believe that certain small-scale testing should be regulated under an EUP for risk/benefit reasons, it should ensure that appropriate controls are in place before the testing takes place.

However, in response to DuPont's concern that the regulated community could not determine when an EUP would be required, EPA has revised § 172.3(e) in the final rule to specify that, if EPA determines that an EUP is required, it will notify the affected parties of the need for an EUP. Prior to such notice from the Agency, parties may assume that the presumption that no EUP is required is applicable to their small-scale tests. EPA notes that the provisions of Subpart C are an example of the type of circumstances where EPA has determined that it is appropriate to rebut the presumption that no EUP is required. Where, as in this rulemaking,

EPA is rebutting the presumption generically for a category of pesticides or tests, it will use the rulemaking process as the means of notification. In other cases, EPA could choose to notify a producer individually of the need for an EUP. DuPont commented that the language of proposed § 172.3(c), which pertains to testing covering more than one target pest occurring at different times and places, was confusing, and suggested revised text to clarify the intent. EPA recognizes that the proposed language may be confusing and has clarified §§ 172.3(c)(1) and (c)(2) of the regulatory text. For example, in § 172.3(c)(1), it is generally EPA's intent that testing of a pesticide for one target pest would qualify for the presumption when conducted on no more than 10 acres cumulative, including all test locations. When testing for more than one target pest, the presumption again applies to testing on no more than 10 acres per pest, where the testing occurs either in different locations or at different times. Thus, testing for two target pests on the same site, one of which occurs in the spring and the other in the fall, can be conducted without an EUP as long as neither test exceeds 10 acres. Similarly, testing for two pests at the same time, one of which is a pest only in the Southeast United States, and the other in the Southwest, can be conducted without an EUP as long as neither test exceeds 10 acres. However, testing is limited to 10 acres total if more than one target pest is being tested at the same time and same locality.

EPA has also addressed the comment from DuPont that the use of the term "crop" in proposed § 172.3(c)(1)(iii) is confusing when referring to pesticide residues in or on the crop. The confusion could arise because the term "crop" does not properly apply to fish and animals, even though these may be the subject of tests involving pesticides. EPA has clarified this language in § 172.3(c)(1)(ii) in the regulatory text by not specifically referring to crops.

With regard to the comment from DuPont on § 172.3(d), EPA acknowledges that the word "not" was inadvertently omitted from proposed § 172.3(d), and the final regulatory text has been corrected.

J. Submission of Information Regarding Potential Unreasonable Adverse Effects

One comment (WDATCP) was received on the proposal at § 172.57 to require reporting of unreasonable adverse effects. This commenter believed that: (1) Researchers tend to under assess potential impacts; (2) microorganisms may continue to

disperse and increase in numbers; and (3) the phrase "potential unreasonable adverse effects" should be defined.

EPA Response: In this final rule, EPA has included § 172.57 as proposed. Section 172.57 applies to all microbial pesticides identified in § 172.45(c), including those subject to the notification requirements and those that are exempt from the notification requirements under § 172.45(d). While EPA has done generic assessment of potential risk in the development of this rule, and concluded that some, but not all, categories of microbial pesticides warrant notification, the Agency cannot foresee all adverse effects to human health or the environment which may arise in specific individual small-scale tests. Section 172.57 is meant to address unforeseeable adverse effects resulting from use of such pesticides. EPA believes that such effects are likely to be extremely rare; however, § 172.57 is a means of ensuring that potential risk is addressed and that the Agency's data base is as complete as possible for future tests. Unreasonable adverse effects must be reported if they are directly observed by the submitter or if the submitter has learned through another source that a microbial pesticide has the potential to result in an unreasonable adverse effect.

K. Related Issues Not Specifically Posed for Comment

Two other topics, not specifically posed for comment by EPA in its January 22, 1993 proposal were also raised by commenters. One commenter (D. Keppel) requested that a moratorium be placed on all releases of genetically modified organisms. Two other commenters (IBA and NNB) requested that EPA reorganize the Office of Pesticide Programs (OPP) so as to form a specific branch dealing with biological pesticides.

EPA Response: EPA believes that its approach to microbial pesticides (i.e., its proposed notification program for small-scale testing, its EUP program for large-scale testing and its registration program) provide adequate protection from unreasonable adverse effects to human health and the environment. The Agency believes there is no evidence from experience with many years of small-scale testing of genetically modified microbial pesticides that would support a request for a moratorium on such tests. EPA, thus, does not believe a moratorium on testing is warranted.

The issue of OPP internal organization is not an issue which is appropriately addressed through rulemaking and is not considered in this final regulation. OPP is, however,

examining mechanisms to introduce efficiencies into its program for biological pesticides.

V. Statutory Requirements

In accordance with FIFRA section 25(a), a draft of this final rule was submitted to the FIFRA SAP, the Secretary of Agriculture (USDA), and the House Committee on Agriculture and Senate Committee on Agriculture, Nutrition, and Forestry for comment.

A. FIFRA Scientific Advisory Panel

A Subpanel of the SAP provided written comments on the draft final rule. No major issues were identified in comments received from the SAP. One comment was received from a Subpanel member noting that the SAP, at its meeting on September 26, 1990 (see 58 FR 5878), raised the issue that certain deletions or rearrangements of genetic material within a single genome could impart or enhance characteristics of potential concern. This commenter questioned EPA's scientific justification for including such an exemption in the final rule, while noting that there is no major problem with such an exemption.

EPA Response: EPA has included in the regulatory text, at § 172.45(d)(i), an exemption for small-scale testing of microbial pesticides resulting from deletions or rearrangements within a single genome. As stated in Unit IV of this preamble, EPA has gained experience in the review of notifications of such organisms and is persuaded that such microbial pesticides are similar to those that would be likely to occur in microbial populations in nature since deletions and rearrangements of genetic material within a single genome are known to occur in microorganisms in nature. EPA has also taken into consideration a point raised in the SAP report from the meeting on September 26, 1990, which noted that the long-term survival and/or competitiveness of these kinds of microorganisms may be compromised by genetic modifications involving deletions or rearrangements within a single genome. In making a decision on this exemption, EPA considered both the concerns and mitigating factors raised by the SAP, along with public comment. EPA believes that, on balance, these microbial pesticides, when tested at small-scale, would be subject to natural constraints on their populations in the environment.

Under § 172.57 of the regulatory text, unreasonable adverse effects resulting from microbial pesticides must be reported to EPA. These reporting requirements also apply to the microbial

pesticides exempted at § 172.45(d)(i), if any adverse effects should occur.

B. U.S. Congress and U.S. Department of Agriculture

In accordance with FIFRA section 25, a draft of this final rule was submitted in February 1994 to the U.S. Congress and USDA. USDA commented that the final rule simplifies the regulation of small-scale testing of microbial pesticides, focuses on microbial pesticides posing the greatest risk, and reduces the number of notifications to EPA when compared to current policy.

USDA requested two changes in their comments, both of which EPA agreed to incorporate in the final rule. The first modification pertained to the text in the parentheses in § 172.45(c)(2), which read as follows: "Nonindigenous microbial pesticides that have not been favorably acted upon by the USDA (i.e., by the granting of a permit or the determination that a permit is necessary)." The USDA suggested that the phrase "not favorably acted upon" may imply that if USDA were to deny a permit because of a plant pest risk, EPA could authorize testing under 40 CFR part 172. To avoid confusion, USDA suggested the language read: "Nonindigenous microbial pesticides that have not been acted upon by USDA (i.e., either by issuing or denying a permit or determining that a permit is unnecessary; or a permit is not pending with USDA)." EPA accepted this comment and the regulatory text suggested by USDA appears in the final rule at § 172.45(c)(2).

Second, USDA pointed out that both the USDA and EPA should consider the effect of the current regulations on the testing and introduction of biological control agents, given the commitment at USDA to the development of more environmentally friendly biological control approaches in agriculture. EPA agrees that it is important to work with USDA on this issue given EPA's authority to regulate pesticides. EPA and USDA will continue discussions on biological control agents and microbial pesticides to ensure that there is appropriate regulation of these applications, while minimizing potentially duplicative reviews and accelerating availability of safer pest management technologies.

No comments were received from the U.S. Congress during the 60-day comment period.

VI. Public Record

EPA has established a public record for this rulemaking (docket control number OPP-50668A). The record includes all information considered by

EPA in developing this final rule. The record includes the following items:

1. All prior **Federal Register** Notices, and supporting public dockets, relating to the regulation of microbial pesticides under FIFRA. These include:
 - a. The 1984 Statement of Interim Policy on Small-Scale Testing of Nonindigenous and Genetically Altered Microbial Pesticides (49 FR 40659, October 17, 1984).
 - b. The December 1984 EPA **Federal Register** Notice on Biotechnology (49 FR 50856, December 31, 1984).
 - c. The 1986 Policy Statement (51 FR 23302, June 26, 1986).
 - d. "Biotechnology; Request for Comment on Regulatory Approach," (54 FR 7027, February 15, 1989).
 - e. The 1993 Proposed Rule for Microbial Pesticides; Experimental Use Permits and Notifications (58 FR 5878, January 22, 1993).
2. Public comments submitted in response to each of the above Notices and the EPA "Analysis of Comments, Proposed Rule, FIFRA Part 172: Microbial Pesticides; Experimental Use Permits and Notifications."
3. "Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms With Modified Hereditary Traits," Office of Science and Technology Policy (55 FR 31118, July 31, 1990).
4. "Exercise of Federal Oversight Within Scope of Statutory Authority; Planned Introductions of Biotechnology Products into the Environment," Office of Science and Technology Policy (57 FR 6753, February 27, 1992).
5. Reports of all SAP and BSAC meetings pertaining to this rule.
6. The Regulatory Impact Analysis for this rule.
7. Support documents and reports, including:
 - a. National Research Council. 1989. "Field Testing Genetically Modified Organisms: Framework for Decisions." National Academy Press, Washington, D.C.
 - b. Tiedje, J.M., R.K. Colwell, Y.L. Grossman, R.E. Hodson, R.E. Lenski, R.N. Mack, and P.J. Regal. 1989. "The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations." *Ecology* 70:298-315.
 - c. The President's Council on Competitiveness. 1991. Report on National Biotechnology Policy, February 1991.
 8. Records of all communications between EPA personnel and persons outside EPA pertaining to the development of this rule. (This does not include any inter- or intra-agency memoranda, unless specifically noted in the Index of this docket.)

VII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order (E.O.) 12866, the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) Having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a section of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities ("economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, EPA has determined that this rule is "significant" because it raises novel policy issues arising out of legal mandates. As such, this action was submitted to OMB for review, and any comments or changes made in response to OMB suggestions or recommendations have been documented in the public record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605 (b)), EPA certifies that this rule will not have a significant economic impact on a substantial number of small businesses. This conclusion is based on the fact that this rule is only the codification, with modification, of relevant operative provisions of the June 26, 1986 Policy Statement. As such, this rule will not create any additional impacts on affected small businesses or other small entities beyond those currently in effect. In fact, this rule will reduce the number and scope of microbial pesticides requiring EPA oversight from those covered under the current policy.

C. Paperwork Reduction Act

The information collection requirements in this final amendment have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR)

document has been prepared by EPA (ICR No. 0276.07; OMB control No. 2070-0040) and a copy may be obtained from Sandy Farmer, Information Policy Branch (MC-2136); U.S. Environmental Protection Agency; 401 M St., SW.; Washington, DC 20460 or by calling (202) 260-2740.

List of Subjects in 40 CFR Part 172

Environmental protection, Intergovernmental relations, Labeling, Pesticides and pests, Recordkeeping and reporting requirements, Research.

Dated: August 19, 1994.

Carol M. Browner,
Administrator.

Therefore, 40 CFR part 172 is amended as follows:

PART 172—[AMENDED]

1. The authority citation for part 172 is revised to read as follows:

Authority: 7 U.S.C. 136a, 136c, 136f, 136v, and 136w.

2. By revising § 172.3 to read as follows:

§ 172.3 Scope of requirement.

(a) An experimental use permit (EUP) is generally required for testing of any unregistered pesticide or any registered pesticide being tested for an unregistered use. However, as described in paragraph (b) of this section, certain of such tests are presumed not to involve unreasonable adverse effects and, therefore, do not require an EUP.

(b) Except as provided in subpart C of this part or as specifically determined by the Environmental Protection Agency (EPA), it may be presumed that EUPs are not required when:

(1) The experimental use of the pesticide is limited to:

- (i) Laboratory or greenhouse tests,
- (ii) Limited replicated field trials as described in paragraph (c) of this section to confirm such tests, or
- (iii) Other tests as described in paragraph (c) of this section whose purpose is only to assess the pesticide's potential efficacy, toxicity, or other properties.

(2) The producer, applicator, or any other person conducting the test does not expect to receive any benefit in pest control from the pesticide's use.

(c) For purposes of paragraphs (b)(1)(ii) and (b)(1)(iii) of this section, the following types of experimental tests are presumed not to need an EUP:

(1) A small-scale test involving use of a particular pesticide that is conducted on a cumulative total of no more than 10 acres of land per pest, except that:

(i) When testing for more than one target pest occurs at the same time and

in the same locality, the 10 acre limitation shall encompass all of the target pests.

(ii) Any food or feed crops involved in, or affected by, such tests (including, but not limited to, crops subsequently grown on such land which may reasonably be expected to contain residues of the tested pesticides) shall be destroyed or consumed only by experimental animals unless an appropriate tolerance or exemption from a tolerance has been established under the Federal Food, Drug, and Cosmetic Act (FFDCA) for residues of the pesticide.

(2) A small-scale test involving the use of a particular pesticide that is conducted on a cumulative total of no more than 1 surface acre of water per pest, except that:

(i) When the testing for more than one target pest occurs at the same time and in the same locality, the 1 acre limitation shall encompass all of the target pests.

(ii) Waters which are involved in or affected by such tests are not used for irrigation purposes, drinking water supplies, or body contact recreational activities.

(iii) Testing shall not be conducted in any waters which contain or affect fish, shellfish, plants, or animals taken for recreational or commercial purposes and used for food or feed, unless an appropriate tolerance or exemption from a tolerance has been established under the FFDCA for residues of the pesticide.

(3) Animal treatment tests involving the use of a particular pesticide that are conducted only on experimental animals which will not be used for food or feed, unless an appropriate tolerance or an exemption from a tolerance has been established for animal products and byproducts under the FFDCA for residues of the pesticide.

(d) The examples in paragraphs (c)(1), (c)(2), and (c)(3) of this section are not all-inclusive and do not preclude testing in larger areas or larger numbers of units if the intended use meets the criteria of paragraph (a) of this section. However, tests which do not come within the examples in paragraphs (c)(1), (c)(2), and (c)(3) of this section, absent a specific determination by EPA to the contrary, require an EUP. Subdivision I of the Pesticide Assessment Guidelines provides guidance on the procedures, data requirements, and general aspects pertaining to the issuance and use of EUPs. Persons intending to conduct tests who are uncertain whether the testing may be conducted without a permit may submit a request for determination to the Registration Division (7505C), Office of Pesticide

Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (703-305-5447). Such a request shall include the information listed in § 172.4(b)(1)(ii) and (b)(1)(iii) and in the case of an unregistered product, the information in § 172.4(b)(3)(i).

(e) Notwithstanding paragraphs (b) through (d) of this section, EPA may, on a case-by-case basis, require that certain testing of a particular pesticide or class of pesticides be carried out under an EUP, if it is determined that such EPA oversight is warranted. If EPA determines that an EUP is required, it will notify the developer of the pesticide of the need for an EUP and provide opportunity for comment or objections before imposing the requirement.

(f) No EUP is required for a substance or mixture of substances being put through tests for the sole purpose of gathering data required for approval of such substance or mixture under the FFDCA (21 U.S.C. 301 et seq.) as:

- (1) A "new drug" (21 U.S.C. sec. 321(p) and sec. 355).
- (2) A "new animal drug" (21 U.S.C. sec. 321(w) and sec. 360(b)), or
- (3) An "animal feed" (21 U.S.C. sec. 321 (x)) containing a "new animal drug" (21 U.S.C. sec. 360(b)).

(g) Paragraph (f) of this section shall not apply when a purpose of such test is to accumulate information necessary to register a pesticide under section 3 of the Act.

3. By adding a new subpart C to read as follows:

Subpart C—Notification for Certain Genetically Modified Microbial Pesticides

Sec.	Definitions.
172.43	Requirement for a Notification.
172.46	Submission of a Notification.
172.48	Data requirements for a Notification.
172.50	Response to a Notification.
172.52	Notification exemption process.
172.57	Submission of information regarding potential unreasonable adverse effects.
172.59	Enforcement.

Subpart C—Notification for Certain Genetically Modified Microbial Pesticides

§ 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.

"Microbial pesticides resulting from rearrangements" means a microbial pesticide resulting from translocations or inversions of genetic material.

"Microorganism" means a bacterium, fungus, alga, virus, or protozoan.

"Nonindigenous microbial pesticide" means a microbial pesticide brought into one of the following geographic areas from outside that area:

- (1) The continental United States, including Alaska, and the immediately adjoining countries (i.e., Canada and Mexico).
- (2) The Hawaiian Islands.
- (3) The Caribbean Islands including Puerto Rico and the U.S. Virgin Islands.

"Pesticidal property" means a characteristic exhibited by a microorganism that contributes to the intentional use of the microorganism to prevent, destroy, repel, or mitigate a pest or to act as a plant regulator, defoliant, or desiccant.

"Single genome" means the sum total of chromosomal and extrachromosomal genetic material of an isolate and any descendants derived under axenic culture conditions from that isolate.

"Small-scale test" means the experimental use of a microbial pesticide in a facility such as a laboratory or greenhouse, or use in limited replicated field trials or other tests as described in § 172.3(c).

"Test" or "testing" means any use of a microbial pesticide consistent with section 5 of the Act, including limited replicated field trials and associated activities.

"Translocations of genetic material" means a chromosomal configuration in which part of a chromosome becomes attached to a different chromosome, or inserts in a different location on the same chromosome.

§ 172.45 Requirement for a Notification.

(a) Who must submit a Notification. Notwithstanding § 172.3, any person

who plans to conduct small-scale testing of a type of microbial pesticide identified in paragraph (c) of this section must submit a Notification to EPA and obtain prior approval for either of the following tests:

(1) Small-scale tests that involve an intentional environmental introduction of that microbial pesticide.

(2) Small-scale tests performed in a facility without adequate containment and inactivation controls as provided in paragraph (e) of this section.

(b) *Alternative to Notification.* In lieu of a Notification, any person required to submit a Notification under paragraph (a) of this section may submit an application for an experimental use permit (EUP) to EPA for approval.

(c) *Small-scale testing that requires a Notification.* As provided in paragraph (a) of this section, and notwithstanding any other approval by any governmental entity, EPA review and approval are required prior to the initiation of any small-scale test involving either of the following microbial pesticides:

(1) Microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified.

(2) Nonindigenous microbial pesticides that have not been acted upon by the U.S. Department of Agriculture (i.e., either by issuing or denying a permit or determining that a permit is unnecessary; or a permit is not pending with the USDA).

(d) *Small-scale testing that does not require a Notification.* (1) Testing conducted with microbial pesticides identified in paragraph (c) of this section, but made exempt pursuant to § 172.52, does not require a Notification. The following microbial pesticides (or classes of pesticides) are exempt from the notification requirement in paragraph (a) of this section:

(i) Microbial pesticides resulting from deletions or rearrangements within a single genome that are brought about by the introduction of genetic material that has been deliberately modified.

(ii) [Reserved]

(2) Testing conducted in a facility with adequate containment and inactivation controls, as provided in paragraph (e) of this section, does not require a Notification.

(e) *Selection and use of containment and inactivation controls.* (1) Selection and use of containment and inactivation controls for a particular microbial pesticide shall take into account the following:

(i) Factors relevant to the microbial pesticide's ability to survive in the environment.

(ii) Potential routes of release in air, solids, and liquids; in or on waste materials and equipment; in or on people (including maintenance and custodial personnel); and in or on other organisms such as insects and rodents.

(iii) Procedures for transfer of materials between facilities.

(iv) Plans for routine or emergency clean-up and test termination.

(2) For purposes of paragraph (e)(1) of this section, EPA will presume that compliance with the containment provisions of the National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules" (51 FR 16958, May 7, 1986) constitutes selection and use of adequate containment and inactivation controls.

(3) The selection of containment and inactivation controls shall be approved by an authorized official of the organization that is conducting the test prior to commencement of the test.

(4) Records shall be developed and maintained describing the selection and use of the containment and inactivation controls, including contingency plans for emergency clean-up and test termination, that will be used during the test. These records shall be available for inspection at the test facility. In addition, these records shall be submitted to EPA at EPA's request and within the time frame specified in EPA's request.

(5) Subsequent to any EPA review of the containment/inactivation controls selected under paragraph (e)(1) of this section, changes to the controls necessary to prevent unreasonable adverse effects must be made upon EPA request. Failure to comply with EPA's request shall result in automatic revocation of the exemption from the requirement to submit a Notification.

§ 172.46 Submission of a Notification.

(a) *When to submit a Notification.* A Notification shall be submitted for approval at least 90 days prior to the initiation of the proposed test.

(b) *Where to submit a Notification.* A Notification shall be submitted to the Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, and clearly marked "ATTN: Biotechnology Notification Review."

(c) *How to format a Notification.* A Notification submitted under this section must comply with the following procedures, but is not required to comply with the format and other provisions governing submission of data in §§ 158.32 and 158.33 of this chapter. However, because data submitted with

the Notification may subsequently be used to support other regulatory actions (e.g., used in EUP or registration applications), it is recommended that such data comply with EPA requirements in §§ 158.32 and 158.33 of this chapter.

(1) Each Notification must be accompanied by a transmittal document that clearly identifies the EPA action supported as a Biotechnology Notification Review.

(2) Five copies of each Notification must be submitted to EPA.

(3) Any claims of confidentiality for information submitted in the Notification must be made as described in paragraph (d) of this section.

(d) *How to make confidential business information (CBI) claims in a Notification.* Although it is strongly

recommended that the submitter minimize the amount of data and other information claimed as CBI, a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a Notification (See part 2, Subpart B of this chapter). To assert such a claim, the submitter must comply with the following procedures:

(1) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time will be considered a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of the Act, with no further notice to the submitter.

(2) Of the five copies of the Notification required by paragraph (c) of this section, four copies must be complete with the information that is claimed confidential clearly marked in the manner described in § 2.203(b) of this chapter. All information claimed as confidential must be deleted from the fifth copy, but it must be otherwise complete. The first page of the fifth copy must be marked "Contains no information claimed as confidential." EPA may include the fifth copy in a public file without further notice. EPA will consider incomplete a Notification containing information claimed as CBI that is not submitted in accordance with this paragraph and will suspend the review period on the Notification until such procedures are followed.

(3) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter should refer to § 2.204(e)(4) of this chapter for points to address in the substantiation. If such comments are themselves claimed

confidential and are marked confidential when submitted to EPA, they will be treated as such in accordance with § 2.205(c) of this chapter. EPA will consider incomplete all Notifications containing information claimed as CBI that are not accompanied by substantiation, and will suspend the review period on such Notifications until the required substantiation is provided.

(4) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent and by means of the procedures set forth in section 10 of the Act, in this subpart, and in part 2 of this chapter.

§ 172.48 Data requirements for a Notification.

This section identifies the data and information to be included in each Notification. When specific information is not submitted, an explanation of why it is not practical or necessary to provide the information is to be provided.

(a) The identity of the microorganism which constitutes the microbial pesticide including:

(1) Summary of data supporting the taxonomic designation and its interpretation.

(2) Means and limit of detection using sensitive and specific methods (e.g., note the use of any markers that are used to distinguish the introduced population from native microorganisms). Introduction into the microbial pesticide of a unique genetic marker is encouraged.

(b) Description of the natural habitat of the parental strain of the microbial pesticide including information on:

(1) Physical and chemical features important to growth and survival of the parental strain.

(2) Biological features of the parental strain that would have an impact on the microbial pesticide (e.g., presence of phages that infect the microorganism).

(3) Competitors.

(c) Information on the host range of the microbial pesticide, if any, with an assessment of infectivity and pathogenicity to nontarget organisms.

(d) Information on survival and the ability of the microbial pesticide to increase in numbers (biomass) in the environment (e.g., in the environment into which the microbial pesticide will be introduced, and in substantially different environments that may be in the immediate vicinity). These data may be derived from the scientific literature or from tests conducted in a laboratory or other containment facility.

(e) The identity of possible transmission vectors (e.g., insects).

(f) Data on relative environmental competitiveness compared to the parental strain of the microbial pesticide.

(g) Description of the methods used to genetically modify the microbial pesticide.

(h) The identity and location of the gene segments that have been rearranged or inserted/deleted (host source, nature, and, for example, base sequence data, or restriction enzyme map of the genes).

(i) Information on the control region of the genes, and a description of the new traits or characteristics that are expressed.

(j) Data on potential for genetic transfer and exchange with other organisms and on genetic stability of any inserted sequences in the microbial pesticide.

(k) A description of the proposed testing program including:

(1) The purpose or objectives of the proposed testing.

(2) Designation of the pest organisms involved (common and scientific names).

(3) The States in which the proposed program will be conducted.

(4) The exact location of the test sites (including proximity to residences and human activities, surface water, etc.).

(5) The crops, fauna, flora, geographical description of sites, modes, dosage rates, frequency, and situation of application on or in which the pesticide is to be used.

(6) The total amount of pesticide product proposed for use in the testing.

(7) The method of application.

(8) A comparison of the natural habitat of the microbial pesticide with the proposed test site.

(9) The number of acres, structural sites, or animals/plants by State, to be treated or included in the area of experimental use.

(10) Procedures to be used to protect the test area from intrusion by unauthorized individuals.

(11) The proposed dates or periods during which the testing program is to be conducted, and the manner in which supervision of the program will be accomplished.

(12) Description of procedures for monitoring the microbial pesticide within and adjacent to the test site during the test.

(13) The method of sanitation or disposal of plants, animals, soils, farm tools, machinery etc., that will be exposed to the microbial pesticide during or after the test.

(14) Means of evaluating potential adverse effects and methods of controlling the microbial pesticide if detected beyond the test area.

(l) A statement of composition for the formulation to be tested, giving:

(1) The name and percentage by weight (or other suitable units) of each ingredient, active and inert.

(2) Production methods.

(3) Extraneous microorganisms present as contaminants.

(4) Amount and potency of any toxin present.

(5) Where applicable, the number of viable microorganisms per unit weight or volume of the product or other appropriate system for designating the quantity of active ingredient.

(m) Any additional factual information regarding the potential for unreasonable adverse effects on the environment.

§ 172.50 Response to a Notification.

(a) EPA will review and evaluate each Notification as expeditiously as possible and will make a determination no later than 90 days after receipt of the complete Notification; however, under no circumstances shall the proposed test proceed until the submitter has received notice from EPA of its approval of such test.

(b) For each Notification, EPA may make the following determinations:

(1) Require additional information from the submitter to assess the proposed test adequately.

(2) Approve the proposed test.

(3) Approve the proposed test provided that the submitter makes certain modifications to the test proposal.

(4) Require an EUP for the test.

(5) Disapprove the proposed test because of the potential for unreasonable adverse effects. Such disapproval by EPA shall be considered the equivalent of denial of an EUP and the remedies for such denial provided by § 172.10 are available to the submitter.

(c) If the proposed test is approved by EPA, then the submitter shall perform the test in the same manner described in the Notification, subject to any requirements imposed under paragraph (b)(3) of this section.

§ 172.52 Notification exemption process.

(a) *Initiation of the exemption process.* Pesticides may be added to the list of exemptions in § 172.45(d) by rule at EPA's initiative or in response to a petition submitted in accordance with paragraph (b) of this section.

(b) *Petitions for exemption from the requirement for a Notification.*—(1) *Who may submit a petition.* Any person may submit a petition requesting an exemption from the notification requirements of this subpart for a

specific microbial pesticide or class of microbial pesticides.

(2) *Where to submit a petition.* All petitions shall be submitted to the following location: Registration Division (7507C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(3) *Content of petition.* Each petition shall contain the following:

(i) Name and address of petitioner and name, address, and telephone number of a person who may be contacted for further information.

(ii) Description of the exemption requested, including the specific microbial pesticide or class of microbial pesticides to be tested under the petition for exemption.

(iii) Basis for the petitioner's contention that the specific microbial pesticide or class of microbial pesticides meet the criteria of § 172.3 for small-scale tests of pesticides that do not require an EUP.

(iv) Discussion of the extent to which the microbial pesticide or class of microbial pesticides covered by the petition differ from microbial pesticides that are already registered or subject to an EUP under the Act.

(4) *Administrative action on a petition.* EPA will review and evaluate petitions as expeditiously as possible and may request further information from the petitioner to assess the proposed exemption adequately. No later than 180 days after the submission of a petition, or 90 days after the last submission of additional information by the petitioner, whichever is later, EPA will take one of the following actions with respect to the petition:

(i) Grant the petition and publish a notice of proposed rulemaking in the Federal Register for a 45-day comment period proposing the exemption requested by the petitioner.

(ii) Grant the petition and publish a notice of proposed rulemaking in the Federal Register for a 45-day comment period proposing an exemption under such terms and conditions as EPA deems appropriate.

(iii) Deny the petition and provide the petitioner with a written explanation of EPA's decision.

(5) *Confidential business information (CBI) claims.* To assert a claim of confidentiality, the petitioner must comply with the applicable procedures in § 172.46(d).

(6) *Supplements, amendments, and withdrawals.* The petitioner may supplement, amend, or withdraw his or her petition in writing without EPA approval at any time prior to the granting or denial of the petition under paragraph (b)(4) of this section. The

withdrawal of a petition shall be without prejudice to the resubmission of the petition at a later date.

§ 172.57 Submission of information regarding potential unreasonable adverse effects.

Any person using a microbial pesticide in small-scale testing covered by this subpart who obtains information regarding potential unreasonable adverse effects on health or the environment must within 30 days of receipt of such information submit the information to EPA, unless the person has actual knowledge that EPA has been adequately informed of such information. The requirement to submit information applies both to those microbial pesticides subject to the

notification requirements under § 172.45(c) and those that are exempt under § 172.45(d).

§ 172.59 Enforcement.

(a) *Imminent threat of substantial harm to health or the environment.* The use of a microbial pesticide in small-scale testing covered by this subpart (whether subject to the notification requirements of § 172.45(c) or exempt under § 172.45(d)) in a manner that creates an imminent threat of substantial harm to health or the environment is prohibited, and is considered a violation of section 12(a)(2)(S) of the Act.

(b) *EPA response to violations.* Under section 14 of the Act, EPA may seek civil or criminal penalties for violations

of the Act. Failure to comply with the regulations in this part could result in civil or criminal penalties. Moreover, under sections 14 and 16(c) of the Act, EPA may at any time take appropriate action against violators to prevent or otherwise restrain use of a microbial pesticide in small-scale testing if it is determined that:

(1) Such use would create an imminent threat of substantial harm to health or the environment that is prohibited under paragraph (a) of this section; or

(2) The terms or conditions on which approval of the testing was granted under this Subpart C are violated.

[FR Doc. 94-21358 Filed 8-31-94; 8:45 am]

BILLING CODE 6560-50-F